

Appendix 16.1.2 Sample case report forms

History of changes	
Version	Summary of changes
1.0	Original version

1 Sample case report forms

The blank sample case report forms provided for the main study include updates from [Protocol Amendment V2.0](#), [Protocol Amendment V3.0](#) and [Protocol Amendment V4.0](#). For the blank sample case report forms for the Dosimetry Sub-Study conducted in Germany, this includes the updates referenced above and [Protocol Amendment V4.4 DE](#).

Subject Case Report Forms
07.007 25Aug2020 CM - Master

Signature Prompt: I have verified that all the subject data is correct.

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07.007 25Aug2020 CM: Master
Folder: Screening
Form: Eligibility Criteria
Generated On: 15 Sep 2020 16:43:48

Date of Informed Consent

Sponsor's Protocol version the subject was consented under

- 1.0
1.1
2.0
3.0
4.0
4.1
4.4
5.0
6.0
7.0
8.0
9.0
10.0
-

Does the subject meet all the eligibility criteria?

- Yes
No
-

If No, please select the criteria not met:

- Inclusion #1
Inclusion #2
Inclusion #3
Inclusion #4
Inclusion #5
Inclusion #6
Inclusion #7
Inclusion #8
Inclusion #9
Inclusion #10
Inclusion #11
-

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Eligibility Criteria
Generated On: 15 Sep 2020 16:43:48

Inclusion #12	<input type="checkbox"/>
Inclusion #13	<input type="checkbox"/>
Inclusion #14A	<input type="checkbox"/>
Inclusion #14B	<input type="checkbox"/>
Inclusion #14C	<input type="checkbox"/>
Inclusion #15	<input type="checkbox"/>
Inclusion #16	<input type="checkbox"/>
Inclusion #17	<input type="checkbox"/>
Inclusion #18	<input type="checkbox"/>
Inclusion #19	<input type="checkbox"/>
Exclusion #1	<input type="checkbox"/>
Exclusion #2	<input type="checkbox"/>
Exclusion #3	<input type="checkbox"/>
Exclusion #4	<input type="checkbox"/>
Exclusion #5	<input type="checkbox"/>
Exclusion #6	<input type="checkbox"/>
Exclusion #7	<input type="checkbox"/>
Exclusion #8	<input type="checkbox"/>
Exclusion #9	<input type="checkbox"/>
Exclusion #10	<input type="checkbox"/>
Exclusion #11	<input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Demographics
Generated On: 15 Sep 2020 16:43:48

Year of Birth

Age (Derived)

Fixed Unit: years

Gender

Female

Male

Ethnicity

Hispanic or Latino

Not Hispanic or Latino

Not Reported

Race(Check All that Apply)

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

White

07.007 25Aug2020 CM: Master
Folder: Screening
Form: 68Ga-PSMA-11 Administration
Generated On: 15 Sep 2020 16:43:48

Was ^{68}Ga -PSMA-11 administered?

Yes
No

Date of Administration

Start Time of ^{68}Ga -PSMA-11

^{68}Ga -PSMA-11 Dose - Decay Corrected

MBq
mCi

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Enrollment
Generated On: 15 Sep 2020 16:43:48

Was the Subject Randomized?

Yes
No

If No, Date of Screen Failure

Reason for Screen Failure

Eligibility Criteria Not Fulfilled
Withdrew Consent (Protocol)
Progression Disease
Adverse Event
Subject Lost to Follow-up
Investigator Decision
Death
Other

If reason for Screen Failure is Investigator Decision or Other, specify

Select Primary AE

If Yes, Date of Randomization

Randomization Number

Treatment Arm

177 Lu-PSMA-617 and Best Supportive/Best Standard of Care
Best Supportive/Best Standard of Care

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Enrollment
Generated On: 15 Sep 2020 16:43:48

Serum Lactate Dehydrogenase (LDH) Level	<=260 IU/L <input type="checkbox"/>	>260 IU/L <input type="checkbox"/>
Presence of Liver Metastases?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ECOG Score	0-1 <input type="checkbox"/>	2 <input type="checkbox"/>
Inclusion of NAAD in Best Supportive/Best Standard of Care	Yes <input type="checkbox"/>	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Enrollment (Germany)
Generated On: 15 Sep 2020 16:43:48

Was the Subject Enrolled? Yes No

If No, Date of Screen Failure _____

Reason for Screen Failure Eligibility Criteria Not Fulfilled
 Withdrew Consent (Protocol)
 Progression Disease
 Adverse Event
 Subject Lost to Follow-up
 Investigator Decision
 Death
 Other

If reason for Screen Failure is Investigator Decision or Other, specify _____

Select Primary AE _____

If Yes, Date of Enrollment _____

Enrollment Number _____

Treatment Arm 177 Lu-PSMA-617 and Best Supportive/Best Standard of Care
 Best Supportive/Best Standard of Care

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Enrollment (Germany)
Generated On: 15 Sep 2020 16:43:48

Serum Lactate Dehydrogenase (LDH) Level	<=260 IU/L <input type="checkbox"/>	>260 IU/L <input type="checkbox"/>
Presence of Liver Metastases?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
ECOG Score	0-1 <input type="checkbox"/>	2 <input type="checkbox"/>
Inclusion of NAAD in Best Supportive/Best Standard of Care	Yes <input type="checkbox"/>	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Cancer History
Generated On: 15 Sep 2020 16:43:48

Please Provide Prostate Cancer History

Date Of Initial Diagnosis

Cancer Type

Prostate

Initial Histopathological Classification

Adenocarcinoma
Neuroendocrine
Unknown
Other

If Other, specify

Initial Histopathological Grade

Grade 1
Grade 2
Grade 3
Grade 3-4
Grade 4
Grade 5
Unknown

Initial Gleason Score

Score 2
Score 3
Score 4
Score 5
Score 6
Score 7
Score 8
Score 9

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Cancer History
Generated On: 15 Sep 2020 16:43:48

Score 10
Unknown

Staging at Initial Diagnosis

I
IA
IB
II
IIA
IIB
III
IIIA
IIIB
IIIC
IV
IVA
IVB
Unknown

Year of Diagnosis Date (derived)

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Prior Cancer Treatment
Generated On: 15 Sep 2020 16:43:48

Please Provide Prostate Cancer Treatment History

Has the subject had prior radiotherapy?

Yes
No

Has the subject had prior cancer related surgery?

Yes
No

Has the subject had prior cancer related systemic therapy?

Yes
No

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Prior Radiotherapy
Generated On: 15 Sep 2020 16:43:48

Please record any prior prostate cancer related radiotherapy the subject received.

Site of Radiotherapy

Adrenals	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Axillary Nodes	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Bone	<input type="checkbox"/>
Bone Marrow	<input type="checkbox"/>
Brain	<input type="checkbox"/>
CNS	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Esophagus	<input type="checkbox"/>
Eye	<input type="checkbox"/>
Femur	<input type="checkbox"/>
Gastroesophageal Junction	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Hepatic Lobe	<input type="checkbox"/>
Hips	<input type="checkbox"/>
Iliac Crest	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Large Intestine	<input type="checkbox"/>
Larynx	<input type="checkbox"/>
Liver	<input type="checkbox"/>
Lower Extremity Bones	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Lymph Node	<input type="checkbox"/>
Neck Nodes	<input type="checkbox"/>
Omentum/Peritoneum	<input type="checkbox"/>
Oropharynx	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Prior Radiotherapy
Generated On: 15 Sep 2020 16:43:48

Para-Aortic Nodes in	<input type="checkbox"/>
Inguinal	<input type="checkbox"/>
Pelvic Bone	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Prostate Bed	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Supraclavicular Nodes	<input type="checkbox"/>
Stomach	<input type="checkbox"/>
Testes	<input type="checkbox"/>
Thyroid	<input type="checkbox"/>
Upper Extremity Bones	<input type="checkbox"/>
Vertebral: Spine	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If Other, specify _____

Cumulative Dose **Gy**

cGy
rad

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Prior Radiotherapy
Generated On: 15 Sep 2020 16:43:48

Check if, Cumulative Dose is Unknown _____

Total number of Fractions _____

Check if, Total number of Fractions is Unknown _____

Start Date _____

Stop Date _____

Reason Treatment Ended

Treatment Toxicity

Progressive Disease

Completed Regimen

Attainment of Maximum

Allowable Dose

Unknown

Year of Start Date (derived) _____

Year of End Date (derived) _____

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Prior Cancer Related Surgery
Generated On: 15 Sep 2020 16:43:48

Please record any prior prostate cancer related surgery the subject received

Type of Surgery _____

Date of Surgery _____

Reason for Surgery _____

Therapeutic

Diagnostic/Biopsy

Palliative

Other

If Reason is Other, specify _____

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Prior Cancer Systemic Therapy - Regimen

Generated On: 15 Sep 2020 16:43:48

List all drugs used in this regimen. If medication is ongoing, record on the Concomitant Medication form as well.

Regimen number	1 <input type="checkbox"/>
	2 <input type="checkbox"/>
	3 <input type="checkbox"/>
	4 <input type="checkbox"/>
	5 <input type="checkbox"/>
	6 <input type="checkbox"/>
	7 <input type="checkbox"/>
	8 <input type="checkbox"/>
	9 <input type="checkbox"/>
	10 <input type="checkbox"/>

Best Overall Response for this Regimen

- | | |
|---------------------|--------------------------|
| Complete Response | <input type="checkbox"/> |
| Partial Response | <input type="checkbox"/> |
| Stable Disease | <input type="checkbox"/> |
| Progressive Disease | <input type="checkbox"/> |
| Not Applicable | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |
-

Date of Best Response

Did the Subject have PSA Progression During/After Regimen?

- | | |
|----------------|--------------------------|
| Yes | <input type="checkbox"/> |
| No | <input type="checkbox"/> |
| Not Applicable | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |
-

If Yes, Specify the Lab Draw Date of Progressive Disease was Noted

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Prior Cancer Systemic Therapy - Regimen

Generated On: 15 Sep 2020 16:43:48

Did the Subject have Bone Progression During/After Regimen?

Yes

No

Not Applicable

Unknown

If Yes, Specify the Image Date of Progressive Disease was Noted _____

Did the Subject have Soft Tissue Progression During/After Regimen?

Yes

No

Not Applicable

Unknown

If Yes, Specify the Image Date of Progressive Disease was Noted _____

Type(s) of Progression

New lesions

Existing lesions

New and existing lesions

Not Applicable

Unknown

Reason for Therapy

Neo-Adjuvant

Adjuvant

Therapeutic

Prophylaxis

Maintenance

Other

Unknown

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Prior Cancer Systemic Therapy - Regimen

Generated On: 15 Sep 2020 16:43:48

If reason for therapy is Other, specify _____

List all drugs used in this regimen. If medication is ongoing to record on CM page as well.

Drug Name (generic name is preferred) _____

Number of cycles completed _____

Number of cycles completed Unknown or Not Applicable?

Not Applicable

Unknown

Start date _____

Ongoing?

Yes

No

Stop date _____

Specify reason medication was stopped

Completed Regimen

Treatment Toxicity

Achieved Optimal Response

Disease Progression

Patient Choice

Investigator Decision

Insurance Issues

Treatment Break

Lack of Clinical Benefit

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Prior Cancer Systemic Therapy - Regimen

Generated On: 15 Sep 2020 16:43:48

Change with Drug within
this Regimen
Unknown
Other

If Reason Medication was Stopped is Other, specify _____

Dose _____

Dose Unit

%
Drops
g
L
mcg
mEq
mg
mL
Puffs
Sachets
Suppository
Tablespoon
Tablets
Teaspoon
units
IU
ug
Capsule
Application
Pack
Patch

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Prior Cancer Systemic Therapy - Regimen

Generated On: 15 Sep 2020 16:43:48

Unknown
Other

If Dose Unit is Other, specify _____

Frequency

Continuous
As Needed
Once
Daily
Twice per day
Three Times per day
Four Times per day
Five Times per day
Every Other day
Every Week
Every Two Weeks
Every Three Weeks
Twice per Week
Three Times per Week
Four Times per Week
Every Month
Every Two Months
Every Three Months
Every Four Months
Every Six Months
Unknown
Other

If Frequency is Other, specify _____

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Prior Cancer Systemic Therapy - Regimen

Generated On: 15 Sep 2020 16:43:48

Yes

No

Did the subject have another systemic therapy regimen?
If yes, complete another Prior Cancer Systemic Therapy
- Regimen form

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Medical History (Yes/No)
Generated On: 15 Sep 2020 16:43:48

Does the subject have any active conditions or clinically significant medical history?

Yes
No

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Medical History
Generated On: 15 Sep 2020 16:43:48

Medical Condition or Event

Start date

Ongoing?

Yes
 No

If not ongoing, End Date

Severity

Grade 1 (Mild)
 Grade 2 (Moderate)
 Grade 3 (Severe)
 Grade 4
(Life-threatening/debilitatin
g)
 Not Applicable
 Unknown

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed?

Yes
No

If No, Specify

- Patient felt too ill
Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable
Other

If Other, specify

Questionnaire

EQ-5D-5L
FACT-P
BPI-SF

Questionnaire Completed?

Yes
No

If No, Specify

Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Laboratory Sample Collection - Screening

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Laboratory Sample Collection - Screening

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry

07.007 25Aug2020 CM: Master

Folder: Screening

Form: Laboratory Sample Collection - Screening

Generated On: 15 Sep 2020 16:43:48

-
- | | |
|--------------|-------------------------------------|
| Hematology | <input type="checkbox"/> |
| Serum/Plasma | <input type="checkbox"/> |
| Testosterone | <input type="checkbox"/> |
| PSA | <input checked="" type="checkbox"/> |
| Urinalysis | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
-

Was Laboratory Sample Collection performed?

- | | |
|-----|--------------------------|
| Yes | <input type="checkbox"/> |
| No | <input type="checkbox"/> |
-

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Historic PSA Collection
Generated On: 15 Sep 2020 16:43:48

PSA Collection

PSA Collection 1
PSA Collection 2

Is PSA Collection Available?

Yes
No

Collection Date

Result

Unit

U/mL
kU/L
ug/L
ng/mL
Other

Other, Specify

Lower Limit

Upper Limit

PSA Collection

PSA Collection 1
PSA Collection 2

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Historic PSA Collection
Generated On: 15 Sep 2020 16:43:48

Is PSA Collection Available? Yes No

Collection Date _____

Result _____

Unit U/mL kU/L ug/L ng/mL Other

Other, Specify _____

Lower Limit _____

Upper Limit _____

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed?

Yes
No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Screening
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Screening
Form: ECG
Generated On: 15 Sep 2020 16:43:48

Was an ECG performed? Yes No

Date of ECG _____

Heart Rate (xxx) _____ Fixed Unit: bpm

PR Interval (xxx.x) _____ Fixed Unit: msec

RR Interval (xxx.x) _____ Fixed Unit: msec

QRS Interval (xxx.x) _____ Fixed Unit: msec

QTc Interval (xxxxx) _____ Fixed Unit: msec

ECG Interpretation Normal
 Abnormal - Clinically Significant
 Abnormal - Not Clinically Significant
 Not Evaluable
 Not Done

If Abnormal - Clinically Significant, describe _____

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify

Patient felt too ill
Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable
Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed?

Yes
No

Date _____

Height (xxx) cm
in

Weight (xxx.x) kg
lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes
No

Date of ECOG Performance Status

ECOG Performance Status

0
1
2
3
4
5

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead

07.007 25Aug2020 CM: Master

Folder: Cycle 1 >> Cycle 1 Day 1

Form: Estimated glomerular filtration rate (eGFR)

Generated On: 15 Sep 2020 16:43:48

Serum creatinine collection date:

Serum creatinine:

Serum creatinine units:

mg/dL

µmol/L

Age at time of Serum creatinine collection:

GFR Calculation (derived):

Fixed Unit: (mL/min/1.73 m²)

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Was ¹⁷⁷Lu-PSMA-617 Administered?

Yes
No

If No, specify reason

AE
Other

Select AE:

If Other, Specify

Date of Administration

Start Time of Administration

Fixed Unit: (24 HR)

End Time of Administration

Fixed Unit: (24 HR)

Date of Patient Discharge

Time of Patient Discharge

Timespan of patient discharge

Fixed Unit: hrs

Method of Dose Administration

Syringe with or without Pump
Vial with Pump

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Gravity Method

Planned Dose
GBq
mCi
MBq

Was Dose Adjusted from Assigned/Previous
No Adjustment of Dose
Prior Reduction Maintained
Dose Reduced

Dose Reduced, Select AE: _____

Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

¹⁷⁷Lu-PSMA-617 Administration total volume injected (to one decimal place)

Fixed Unit: ml

Total Dose Administered

GBq
mCi
MBq

Was Administration Interrupted?

Yes
No

If Administration was Interrupted; complete a log line for each instance

Reason

AE
Administration Issue
Other

If Reason is Adverse Event, Select AE:

If Reason is Other, Specify

Stop Time of Administration (24 HR)

Time Administration was restarted (24 HR)

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Blood Pressure Prior to ECG
Generated On: 15 Sep 2020 16:43:48

ECG Timepoint

NOTE: BP to be done just prior to the ECG Reading 1 at each timepoint

- Pre-infusion
- 1-hour post-infusion
- 4-hours post-infusion
- 24-hours post-infusion
- Unscheduled

Was Blood Pressure done?

- Yes
- No

Date _____

Time _____

Systolic Blood Pressure

Fixed Unit: mmHg

Diastolic Blood Pressure

Fixed Unit: mmHg

ECG Timepoint

NOTE: BP to be done just prior to the ECG Reading 1 at each timepoint

- Pre-infusion
- 1-hour post-infusion
- 4-hours post-infusion
- 24-hours post-infusion
- Unscheduled

Was Blood Pressure done?

- Yes

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Blood Pressure Prior to ECG
Generated On: 15 Sep 2020 16:43:48

No

Date _____

Time _____

Systolic Blood Pressure _____ Fixed Unit: mmHg

Diastolic Blood Pressure _____ Fixed Unit: mmHg

ECG Timepoint Pre-infusion
 1-hour post-infusion
 4-hours post-infusion
 24-hours post-infusion
 Unscheduled

Was Blood Pressure done? Yes
 No

Date _____

Time _____

Systolic Blood Pressure _____ Fixed Unit: mmHg

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Blood Pressure Prior to ECG
Generated On: 15 Sep 2020 16:43:48

Diastolic Blood Pressure Fixed Unit: mmHg

ECG Timepoint Pre-infusion
1-hour post-infusion
4-hours post-infusion
24-hours post-infusion
Unscheduled

NOTE: BP to be done just prior to the ECG Reading 1 at each timepoint

Was Blood Pressure done? Yes
No

Date _____

Time _____

Systolic Blood Pressure Fixed Unit: mmHg

Diastolic Blood Pressure Fixed Unit: mmHg

ECG Timepoint Pre-infusion
1-hour post-infusion
4-hours post-infusion
24-hours post-infusion

NOTE: BP to be done just prior to the ECG Reading 1 at each timepoint

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Blood Pressure Prior to ECG
Generated On: 15 Sep 2020 16:43:48

Unscheduled

Was Blood Pressure done? Yes No

Date _____

Time _____

Systolic Blood Pressure _____ Fixed Unit: mmHg

Diastolic Blood Pressure _____ Fixed Unit: mmHg

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

Timepoint	PREDOSE ECG A <input checked="" type="checkbox"/>
	PREDOSE ECG B <input type="checkbox"/>
	PREDOSE ECG C <input type="checkbox"/>
1 HOUR POST DOSE ECG A	<input type="checkbox"/>
1 HOUR POST DOSE ECG B	<input type="checkbox"/>
1 HOUR POST DOSE ECG C	<input type="checkbox"/>
4 HOURS POST DOSE ECG A	<input type="checkbox"/>
4 HOURS POST DOSE ECG B	<input type="checkbox"/>
4 HOURS POST DOSE ECG C	<input type="checkbox"/>
24 HOURS POST DOSE ECG A	<input type="checkbox"/>
24 HOURS POST DOSE ECG B	<input type="checkbox"/>
24 HOURS POST DOSE ECG C	<input type="checkbox"/>

Not Done

Date of ECG

Time of ECG

ECG Interpretation

- Normal
- Abnormal - Clinically Significant
- Abnormal - Not Clinically Significant
- Not Evaluable
- Not Done

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

Abnormal-Clinically Significant, describe and record on
AE form

Timepoint

- PREDOSE ECG A
PREDOSE ECG B
PREDOSE ECG C
1 HOUR POST DOSE ECG A
1 HOUR POST DOSE ECG B
1 HOUR POST DOSE ECG C
4 HOURS POST DOSE ECG
A
4 HOURS POST DOSE ECG B
B
4 HOURS POST DOSE ECG C
C
24 HOURS POST DOSE ECG A
24 HOURS POST DOSE ECG B
24 HOURS POST DOSE ECG C

Not Done

Date of ECG

Time of ECG

ECG Interpretation

- Normal
Abnormal - Clinically
Significant

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

Abnormal - Not Clinically Significant
Not Evaluable
Not Done

Abnormal-Clinically Significant, describe and record on AE form _____

Timepoint

PREDOSE ECG A
PREDOSE ECG B
PREDOSE ECG C
1 HOUR POST DOSE ECG A
1 HOUR POST DOSE ECG B
1 HOUR POST DOSE ECG C
4 HOURS POST DOSE ECG A
4 HOURS POST DOSE ECG B
4 HOURS POST DOSE ECG C
24 HOURS POST DOSE ECG A
24 HOURS POST DOSE ECG B
24 HOURS POST DOSE ECG C

Not Done

Date of ECG

Time of ECG

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

ECG Interpretation

- | | |
|---------------------------------------|--------------------------|
| Normal | <input type="checkbox"/> |
| Abnormal - Clinically Significant | <input type="checkbox"/> |
| Abnormal - Not Clinically Significant | <input type="checkbox"/> |
| Not Evaluable | <input type="checkbox"/> |
| Not Done | <input type="checkbox"/> |

Abnormal-Clinically Significant, describe and record on AE form

Timepoint

- | | |
|--------------------------|-------------------------------------|
| PREDOSE ECG A | <input type="checkbox"/> |
| PREDOSE ECG B | <input type="checkbox"/> |
| PREDOSE ECG C | <input type="checkbox"/> |
| 1 HOUR POST DOSE ECG A | <input checked="" type="checkbox"/> |
| 1 HOUR POST DOSE ECG B | <input type="checkbox"/> |
| 1 HOUR POST DOSE ECG C | <input type="checkbox"/> |
| 4 HOURS POST DOSE ECG A | <input type="checkbox"/> |
| 4 HOURS POST DOSE ECG B | <input type="checkbox"/> |
| 4 HOURS POST DOSE ECG C | <input type="checkbox"/> |
| 24 HOURS POST DOSE ECG A | <input type="checkbox"/> |
| 24 HOURS POST DOSE ECG B | <input type="checkbox"/> |
| 24 HOURS POST DOSE ECG C | <input type="checkbox"/> |

Not Done

Date of ECG

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

Time of ECG

ECG Interpretation

- Normal
Abnormal - Clinically Significant
Abnormal - Not Clinically Significant
Not Evaluable
Not Done
-

Abnormal-Clinically Significant, describe and record on AE form

Timepoint

- PREDOSE ECG A
PREDOSE ECG B
PREDOSE ECG C
1 HOUR POST DOSE ECG A
1 HOUR POST DOSE ECG B
1 HOUR POST DOSE ECG C
4 HOURS POST DOSE ECG A
4 HOURS POST DOSE ECG B
4 HOURS POST DOSE ECG C
24 HOURS POST DOSE ECG A
24 HOURS POST DOSE ECG B
24 HOURS POST DOSE ECG C
-

Not Done

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

Date of ECG

Time of ECG

ECG Interpretation

Normal

Abnormal - Clinically Significant

Abnormal - Not Clinically Significant

Not Evaluable

Not Done

Abnormal-Clinically Significant, describe and record on AE form

Timepoint

PREDOSE ECG A

PREDOSE ECG B

PREDOSE ECG C

1 HOUR POST DOSE ECG A

1 HOUR POST DOSE ECG B

1 HOUR POST DOSE ECG C

4 HOURS POST DOSE ECG A

4 HOURS POST DOSE ECG B

4 HOURS POST DOSE ECG C

24 HOURS POST DOSE ECG A

24 HOURS POST DOSE ECG B

24 HOURS POST DOSE ECG C

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

Not Done

Date of ECG

Time of ECG

ECG Interpretation

Normal

Abnormal - Clinically Significant

Abnormal - Not Clinically Significant

Not Evaluable

Not Done

Abnormal-Clinically Significant, describe and record on AE form

Timepoint

PREDOSE ECG A

PREDOSE ECG B

PREDOSE ECG C

1 HOUR POST DOSE ECG A

1 HOUR POST DOSE ECG B

1 HOUR POST DOSE ECG C

4 HOURS POST DOSE ECG A

4 HOURS POST DOSE ECG B

4 HOURS POST DOSE ECG C

24 HOURS POST DOSE ECG A

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

24 HOURS POST DOSE
ECG B
24 HOURS POST DOSE
ECG C

Not Done

Date of ECG

Time of ECG

ECG Interpretation

Normal
Abnormal - Clinically Significant
Abnormal - Not Clinically Significant
Not Evaluable
Not Done

Abnormal-Clinically Significant, describe and record on AE form

Timepoint

PREDOSE ECG A
PREDOSE ECG B
PREDOSE ECG C
1 HOUR POST DOSE ECG A
1 HOUR POST DOSE ECG B
1 HOUR POST DOSE ECG C
4 HOURS POST DOSE ECG A

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

- 4 HOURS POST DOSE ECG B
4 HOURS POST DOSE ECG C
24 HOURS POST DOSE ECG A
24 HOURS POST DOSE ECG B
24 HOURS POST DOSE ECG C

Not Done _____

Date of ECG _____

Time of ECG _____

ECG Interpretation _____

Normal
Abnormal - Clinically Significant
Abnormal - Not Clinically Significant
Not Evaluable
Not Done

Abnormal-Clinically Significant, describe and record on AE form

Timepoint _____

PREDOSE ECG A
PREDOSE ECG B
PREDOSE ECG C

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

-
- 1 HOUR POST DOSE ECG A
1 HOUR POST DOSE ECG B
1 HOUR POST DOSE ECG C
4 HOURS POST DOSE ECG
A
4 HOURS POST DOSE ECG
B
4 HOURS POST DOSE ECG
C
24 HOURS POST DOSE
ECG A
24 HOURS POST DOSE
ECG B
24 HOURS POST DOSE
ECG C
-

Not Done

Date of ECG

Time of ECG

ECG Interpretation

- Normal
Abnormal - Clinically Significant
Abnormal - Not Clinically Significant
Not Evaluable
Not Done

Abnormal-Clinically Significant, describe and record on AE form

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

Timepoint	
	PREDOSE ECG A <input type="checkbox"/>
	PREDOSE ECG B <input type="checkbox"/>
	PREDOSE ECG C <input type="checkbox"/>
1 HOUR POST DOSE	ECG A <input type="checkbox"/>
1 HOUR POST DOSE	ECG B <input type="checkbox"/>
1 HOUR POST DOSE	ECG C <input type="checkbox"/>
4 HOURS POST DOSE	ECG A <input type="checkbox"/>
4 HOURS POST DOSE	ECG B <input type="checkbox"/>
4 HOURS POST DOSE	ECG C <input type="checkbox"/>
24 HOURS POST DOSE	ECG A <input checked="" type="checkbox"/>
24 HOURS POST DOSE	ECG B <input type="checkbox"/>
24 HOURS POST DOSE	ECG C <input type="checkbox"/>

Not Done

Date of ECG

Time of ECG

ECG Interpretation

Normal

Abnormal - Clinically Significant

Abnormal - Not Clinically Significant

Not Evaluable

Not Done

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

Abnormal-Clinically Significant, describe and record on
AE form

Timepoint

- PREDOSE ECG A
PREDOSE ECG B
PREDOSE ECG C
1 HOUR POST DOSE ECG A
1 HOUR POST DOSE ECG B
1 HOUR POST DOSE ECG C
4 HOURS POST DOSE ECG
A
4 HOURS POST DOSE ECG
B
4 HOURS POST DOSE ECG
C
24 HOURS POST DOSE
ECG A
24 HOURS POST DOSE
ECG B
24 HOURS POST DOSE
ECG C

Not Done

Date of ECG

Time of ECG

ECG Interpretation

- Normal
Abnormal - Clinically
Significant

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

Abnormal - Not Clinically Significant
Not Evaluable
Not Done

Abnormal-Clinically Significant, describe and record on AE form _____

Timepoint	PREDOSE ECG A <input type="checkbox"/>
	PREDOSE ECG B <input type="checkbox"/>
	PREDOSE ECG C <input type="checkbox"/>
	1 HOUR POST DOSE ECG A <input type="checkbox"/>
	1 HOUR POST DOSE ECG B <input type="checkbox"/>
	1 HOUR POST DOSE ECG C <input type="checkbox"/>
	4 HOURS POST DOSE ECG A <input type="checkbox"/>
	4 HOURS POST DOSE ECG B <input type="checkbox"/>
	4 HOURS POST DOSE ECG C <input type="checkbox"/>
	24 HOURS POST DOSE ECG A <input type="checkbox"/>
	24 HOURS POST DOSE ECG B <input type="checkbox"/>
	24 HOURS POST DOSE ECG C <input checked="" type="checkbox"/>

Not Done _____

Date of ECG _____

Time of ECG _____

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: ECG for QTc
Generated On: 15 Sep 2020 16:43:48

ECG Interpretation

- | | |
|---------------------------------------|--------------------------|
| Normal | <input type="checkbox"/> |
| Abnormal - Clinically Significant | <input type="checkbox"/> |
| Abnormal - Not Clinically Significant | <input type="checkbox"/> |
| Not Evaluable | <input type="checkbox"/> |
| Not Done | <input type="checkbox"/> |

Abnormal-Clinically Significant, describe and record on AE form

07.007 25Aug2020 CM: Master

Folder: Cycle 1 >> Cycle 1 Day 1

Form: Unscheduled ECG for QTc (Yes/No)

Generated On: 15 Sep 2020 16:43:48

Were there any Unscheduled ECG for QTc assessments done?

Yes
No

**07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Unscheduled ECG for QTc
Generated On: 15 Sep 2020 16:43:48**

Timepoint	PREDOSE ECG
	<input type="checkbox"/>
	1 HOUR POST DOSE ECG
	<input type="checkbox"/>
	4 HOURS POST DOSE ECG
	<input type="checkbox"/>
	24 HOURS POST DOSE ECG
	<input type="checkbox"/>
	UNSCCHEDULED
Date of ECG	<hr/>
Time of ECG	<hr/>
Heart Rate	Fixed Unit: bpm <hr/>
PR Interval	Fixed Unit: msec <hr/>
RR Interval	Fixed Unit: msec <hr/>
QRS Interval	Fixed Unit: msec <hr/>
QT interval	Fixed Unit: msec <hr/>
QTcF Interval	Fixed Unit: msec <hr/>

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 1
Form: Unscheduled ECG for QTc
Generated On: 15 Sep 2020 16:43:48

ECG Interpretation

- | | |
|---------------------------------------|--------------------------|
| Normal | <input type="checkbox"/> |
| Abnormal - Clinically Significant | <input type="checkbox"/> |
| Abnormal - Not Clinically Significant | <input type="checkbox"/> |
| Not Evaluable | <input type="checkbox"/> |
| Not Done | <input type="checkbox"/> |

Abnormal-Clinically Significant, describe and record on AE form

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 8
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Cycle 1 >> Cycle 1 Day 8

Form: Laboratory Sample Collection - Chemistry/Hematology

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 15
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Cycle 1 >> Cycle 1 Day 15

Form: Laboratory Sample Collection - Chemistry/Hematology

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 22
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 22
Form: Laboratory Sample Collection - Chemistry/Hematology
Generated On: 15 Sep 2020 16:43:48

Laboratory Test	<input checked="" type="checkbox"/> Chemistry
	<input type="checkbox"/> Hematology
	<input type="checkbox"/> Serum/Plasma
	<input type="checkbox"/> Testosterone
	<input type="checkbox"/> PSA
	<input type="checkbox"/> Urinalysis
	<input type="checkbox"/> Other

Was Laboratory Sample Collection performed?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No

Date of Lab Sample Collection	_____

Laboratory Test	<input type="checkbox"/> Chemistry
	<input checked="" type="checkbox"/> Hematology
	<input type="checkbox"/> Serum/Plasma
	<input type="checkbox"/> Testosterone
	<input type="checkbox"/> PSA
	<input type="checkbox"/> Urinalysis
	<input type="checkbox"/> Other

Was Laboratory Sample Collection performed?	<input type="checkbox"/> Yes
	<input type="checkbox"/> No

Date of Lab Sample Collection	_____

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 29
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Cycle 1 >> Cycle 1 Day 29

Form: Laboratory Sample Collection - Chemistry/Hematology

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 36
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 36
Form: Laboratory Sample Collection - Chemistry/Hematology
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

**07.007 25Aug2020 CM: Master
Folder: Cycle 1 >> Cycle 1 Day 36
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Not Done

Nominal time of sample collection

Pre-infusion (immediately before administration)

End of Infusion (just before the end of infusion)

20 min Post-infusion

60 min Post-infusion

2 h Post-infusion

4 h Post-infusion

24 h Post-infusion

48 h Post-infusion

72 h Post-infusion

Day 6 Post-infusion

Date of sample collection

Actual time of sample collection

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

cpm

cps

(not decay corrected)

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Aliquot Activity

Fixed Unit: kBq

Not Done

Nominal time of sample collection

- Pre-infusion (immediately before administration)
End of Infusion (just before the end of infusion)
20 min Post-infusion
60 min Post-infusion
2 h Post-infusion
4 h Post-infusion
24 h Post-infusion
48 h Post-infusion
72 h Post-infusion
Day 6 Post-infusion

Date of sample collection

Actual time of sample collection

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Activity Count

cpm

(not decay corrected)

cps

Aliquot Activity

Fixed Unit: kBq

Not Done

Nominal time of sample collection

Pre-infusion (immediately before administration)

End of Infusion (just before the end of infusion)

20 min Post-infusion

60 min Post-infusion

2 h Post-infusion

4 h Post-infusion

24 h Post-infusion

48 h Post-infusion

72 h Post-infusion

Day 6 Post-infusion

Date of sample collection

Actual time of sample collection

Date of activity measurement

Time of activity measurement

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

cpm

(not decay corrected)

cps

Aliquot Activity

Fixed Unit: kBq

Not Done

Nominal time of sample collection

Pre-infusion (immediately before administration)

End of Infusion (just before the end of infusion)

20 min Post-infusion

60 min Post-infusion

2 h Post-infusion

4 h Post-infusion

24 h Post-infusion

48 h Post-infusion

72 h Post-infusion

Day 6 Post-infusion

Date of sample collection

Actual time of sample collection

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

cpm

(not decay corrected)

cps

Aliquot Activity

Fixed Unit: kBq

Not Done

Nominal time of sample collection

Pre-infusion (immediately before administration)

End of Infusion (just before the end of infusion)

20 min Post-infusion

60 min Post-infusion

2 h Post-infusion

4 h Post-infusion

24 h Post-infusion

48 h Post-infusion

72 h Post-infusion

Day 6 Post-infusion

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Date of sample collection

Actual time of sample collection

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

cpm

(not decay corrected)

cps

Aliquot Activity

Fixed Unit: kBq

Not Done

Nominal time of sample collection

Pre-infusion (immediately before administration)

End of Infusion (just before the end of infusion)

20 min Post-infusion

60 min Post-infusion

2 h Post-infusion

4 h Post-infusion

24 h Post-infusion

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

48 h Post-infusion

72 h Post-infusion

Day 6 Post-infusion

Date of sample collection

Actual time of sample collection

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

cpm

(not decay corrected)

cps

Aliquot Activity

Fixed Unit: kBq

Not Done

Nominal time of sample collection

Pre-infusion (immediately before administration)

End of Infusion (just before the end of infusion)

20 min Post-infusion

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

- 60 min Post-infusion
2 h Post-infusion
4 h Post-infusion
24 h Post-infusion
48 h Post-infusion
72 h Post-infusion
Day 6 Post-infusion

Date of sample collection

Actual time of sample collection

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

(not decay corrected)

cpm

cps

Aliquot Activity

Fixed Unit: kBq

Not Done

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Nominal time of sample collection

- Pre-infusion (immediately before administration)
End of Infusion (just before the end of infusion)
20 min Post-infusion
60 min Post-infusion
2 h Post-infusion
4 h Post-infusion
24 h Post-infusion
48 h Post-infusion
72 h Post-infusion
Day 6 Post-infusion

Date of sample collection

Actual time of sample collection

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

(not decay corrected)

cpm
cps

Aliquot Activity

Fixed Unit: kBq

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Not Done

Nominal time of sample collection

- Pre-infusion (immediately before administration)
End of Infusion (just before the end of infusion)
20 min Post-infusion
60 min Post-infusion
2 h Post-infusion
4 h Post-infusion
24 h Post-infusion
48 h Post-infusion
72 h Post-infusion
Day 6 Post-infusion

Date of sample collection

Actual time of sample collection

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

cpm

(not decay corrected)

cps

Aliquot Activity

Fixed Unit: kBq

07.007 25Aug2020 CM (116)

90 of 490

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Blood Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Not Done

Nominal time of sample collection

- Pre-infusion (immediately before administration)
End of Infusion (just before the end of infusion)
20 min Post-infusion
60 min Post-infusion
2 h Post-infusion
4 h Post-infusion
24 h Post-infusion
48 h Post-infusion
72 h Post-infusion
Day 6 Post-infusion

Date of sample collection

Actual time of sample collection

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

cpm

(not decay corrected)

cps

Aliquot Activity

Fixed Unit: kBq

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: Unscheduled PK Blood Sample and Radioactivity (Yes/No)

Generated On: 15 Sep 2020 16:43:48

Were any samples collected for Unscheduled PK Blood Sample and Radioactivity?

Yes
No

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: Unscheduled PK Blood Sample and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Date of sample collection

Time of sample collection

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

cpm
cps

(not decay corrected)

Aliquot Activity

Fixed Unit: kBq

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Urine Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Not Done

Nominal interval of urine collection

0-2 h Post infusion (up to first imaging)

Date of urine collection

Start time of urine collection

End time of urine collection

Cumulative volume of the urine collection

Fixed Unit: ml

Urine collection weight

Fixed Unit: g

Date of activity measurement

Time of activity measurement

Volume of the sample aliquot counted

Fixed Unit: ml

Activity Count

(not decay corrected)

cpm

cps

07.007 25Aug2020 CM (116)

94 of 490

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: PK Urine Sampling and Radioactivity

Generated On: 15 Sep 2020 16:43:48

Aliquot activity

Fixed Unit: kBq

07.007 25Aug2020 CM: Master
Folder: Dosimetry/PK
Form: PK Urine Sampling - HPLC
Generated On: 15 Sep 2020 16:43:48

Not Done

Nominal interval of urine collection

24 h Post-infusion

48 h Post infusion

72 h Post infusion

Date of urine collection

Time of urine collection

Not Done

Nominal interval of urine collection

24 h Post-infusion

48 h Post infusion

72 h Post infusion

Date of urine collection

Time of urine collection

Not Done

Nominal interval of urine collection

24 h Post-infusion

48 h Post infusion

07.007 25Aug2020 CM: Master
Folder: Dosimetry/PK
Form: PK Urine Sampling - HPLC
Generated On: 15 Sep 2020 16:43:48

72 h Post infusion

Date of urine collection

Time of urine collection

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: Unscheduled PK Urine Sampling - HPLC (Yes/No)

Generated On: 15 Sep 2020 16:43:48

Were any samples collected for Unscheduled PK Urine Sampling - HPLC?

Yes
No

07.007 25Aug2020 CM: Master

Folder: Dosimetry/PK

Form: Unscheduled PK Urine Sample - HPLC

Generated On: 15 Sep 2020 16:43:48

Date of urine collection

Time of urine collection

07.007 25Aug2020 CM: Master
Folder: Dosimetry/PK
Form: Well Counter Calibration Factor
Generated On: 15 Sep 2020 16:43:48

Date of Well Counter Calibration

Time of Well Counter Calibration

Well Counter Calibration Factor

cpm/kBq

cps/kBq

**07.007 25Aug2020 CM: Master
Folder: Dosimetry/PK
Form: Whole Body Planar Imaging
Generated On: 15 Sep 2020 16:43:48**

Imaging Session	<input checked="" type="radio"/>	1-2 hours
	<input type="radio"/>	18-26 hours
	<input type="radio"/>	36-48 hours
	<input type="radio"/>	156-168 hours

Were whole body planar images done? Yes No

Reason Not Done

Date of Scan _____

Start Time of Scan _____

Imaging Session	<input type="radio"/> 1-2 hours
	<input checked="" type="radio"/> 18-26 hours
	<input type="radio"/> 36-48 hours
	<input type="radio"/> 156-168 hours

Were whole body planar images done? Yes No

Reason Not Done _____

Date of Scan _____

07.007 25Aug2020 CM: Master
Folder: Dosimetry/PK
Form: Whole Body Planar Imaging
Generated On: 15 Sep 2020 16:43:48

Start Time of Scan

Imaging Session

- 1-2 hours
18-26 hours
36-48 hours
156-168 hours

Were whole body planar images done?

- Yes
No

Reason Not Done

Date of Scan

Start Time of Scan

Imaging Session

- 1-2 hours
18-26 hours
36-48 hours
156-168 hours

Were whole body planar images done?

- Yes
No

Reason Not Done

07.007 25Aug2020 CM: Master
Folder: Dosimetry/PK
Form: Whole Body Planar Imaging
Generated On: 15 Sep 2020 16:43:48

Date of Scan

Start Time of Scan

07.007 25Aug2020 CM: Master
Folder: Dosimetry/PK
Form: SPECT/CT Imaging
Generated On: 15 Sep 2020 16:43:48

Imaging Session (time after the 177Lu-PSMA-617 Administration)

1-2 hours (SPECT)

1-2 hours (CT)

18-26 hours (SPECT)

36-48 hours (SPECT)

156-168 hours (SPECT)

Were SPECT/CT images done?

Yes

No

Reason Not Done

Date of Scan

Start Time of Scan

Imaging Session (time after the 177Lu-PSMA-617 Administration)

1-2 hours (SPECT)

1-2 hours (CT)

18-26 hours (SPECT)

36-48 hours (SPECT)

156-168 hours (SPECT)

Were SPECT/CT images done?

Yes

No

Reason Not Done

07.007 25Aug2020 CM: Master
Folder: Dosimetry/PK
Form: SPECT/CT Imaging
Generated On: 15 Sep 2020 16:43:48

Date of Scan

Start Time of Scan

Imaging Session (time after the 177Lu-PSMA-617
Administration)

1-2 hours (SPECT)

1-2 hours (CT)

18-26 hours (SPECT)

36-48 hours (SPECT)

156-168 hours (SPECT)

Were SPECT/CT images done?

Yes

No

Reason Not Done

Date of Scan

Start Time of Scan

Imaging Session (time after the 177Lu-PSMA-617
Administration)

1-2 hours (SPECT)

1-2 hours (CT)

18-26 hours (SPECT)

36-48 hours (SPECT)

156-168 hours (SPECT)

Were SPECT/CT images done?

Yes

07.007 25Aug2020 CM: Master
Folder: Dosimetry/PK
Form: SPECT/CT Imaging
Generated On: 15 Sep 2020 16:43:48

No

Reason Not Done _____

Date of Scan _____

Start Time of Scan _____

Imaging Session (time after the 177Lu-PSMA-617 Administration) _____

1-2 hours (SPECT)
1-2 hours (CT)
18-26 hours (SPECT)
36-48 hours (SPECT)
156-168 hours (SPECT)

Were SPECT/CT images done? Yes
No

Reason Not Done _____

Date of Scan _____

Start Time of Scan _____

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire EQ-5D-5L
 FACT-P
 BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P
 BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed?

Yes
No

Date

Height (xxx)

cm
in

Weight (xxx.x)

kg
lb

Respiratory Rate (xxx)

Fixed Unit: breaths/min

Systolic Blood Pressure (xxx)

Fixed Unit: mmHg

Diastolic Blood Pressure (xxx)

Fixed Unit: mmHg

Pulse (xxx)

Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

07.007 25Aug2020 CM: Master

Folder: Cycle 2 >> Cycle 2 Day 1

Form: Estimated glomerular filtration rate (eGFR)

Generated On: 15 Sep 2020 16:43:48

Serum creatinine collection date:

Serum creatinine:

Serum creatinine units:

mg/dL

µmol/L

Age at time of Serum creatinine collection:

GFR Calculation (derived):

Fixed Unit: (mL/min/1.73 m²)

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Was ¹⁷⁷Lu-PSMA-617 Administered?

Yes
No

If No, specify reason

AE
Other

Select AE:

If Other, Specify

Date of Administration

Start Time of Administration

Fixed Unit: (24 HR)

End Time of Administration

Fixed Unit: (24 HR)

Date of Patient Discharge

Time of Patient Discharge

Timespan of patient discharge

Fixed Unit: hrs

Method of Dose Administration

Syringe with or without Pump
Vial with Pump

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Gravity Method

Planned Dose
GBq
mCi
MBq

Was Dose Adjusted from Assigned/Previous
No Adjustment of Dose
Prior Reduction Maintained
Dose Reduced

Dose Reduced, Select AE: _____

Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

¹⁷⁷Lu-PSMA-617 Administration total volume injected (to one decimal place)

Fixed Unit: ml

Total Dose Administered

GBq
mCi
MBq

Was Administration Interrupted?

Yes
No

If Administration was Interrupted; complete a log line for each instance

Reason

AE
Administration Issue
Other

If Reason is Adverse Event, Select AE:

If Reason is Other, Specify

Stop Time of Administration (24 HR)

Time Administration was restarted (24 HR)

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: Whole Body Planar Imaging - German Subjects
Generated On: 15 Sep 2020 16:43:48

Imaging Session

1-2 hours

18-26 hours

36-48 hours

156-168 hours

Were whole body planar images done?

Yes

No

Reason Not Done

Date of Scan

Start Time of Scan

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: SPECT/CT Imaging - German Subjects
Generated On: 15 Sep 2020 16:43:48

Imaging Session (time after the 177Lu-PSMA-617 Administration)

1-2 hours (SPECT)	<input type="radio"/>
1-2 hours (CT)	<input type="radio"/>
18-26 hours (SPECT)	<input type="radio"/>
36-48 hours (SPECT)	<input checked="" type="radio"/>
156-168 hours (SPECT)	<input type="radio"/>

Were SPECT/CT images done?

Yes	<input type="radio"/>
No	<input type="radio"/>

Reason Not Done

Date of Scan

Start Time of SPECT

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: ECG/Blood Pressure
Generated On: 15 Sep 2020 16:43:48

Did the subject have a clinically significant abnormal measurement during the Cycle 1 Day 1 Pre-infusion ECG?

Yes

No

Was an ECG performed?

Yes

No

Was Blood Pressure measured prior to ECG?

Yes

No

Date of Blood Pressure measurement _____

Time of Blood Pressure measurement _____

Systolic Blood Pressure _____ Fixed Unit: mmHg

Diastolic Blood Pressure _____ Fixed Unit: mmHg

Date of ECG _____

Time of ECG _____

ECG Interpretation _____

Normal
Abnormal - Clinically Significant
Abnormal - Not Clinically Significant
Not Evaluable

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 1
Form: ECG/Blood Pressure
Generated On: 15 Sep 2020 16:43:48

Not Done

If Abnormal-Clinically Significant, describe and record on
adverse event form _____

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 15
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Cycle 2 >> Cycle 2 Day 15

Form: Laboratory Sample Collection - Chemistry/Hematology

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 29
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 29
Form: Laboratory Sample Collection - Chemistry/Hematology
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

**07.007 25Aug2020 CM: Master
Folder: Cycle 2 >> Cycle 2 Day 29
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed?

Yes
No

Date _____

Height (xxx) cm
in

Weight (xxx.x) kg
lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

07.007 25Aug2020 CM: Master

Folder: Cycle 3 >> Cycle 3 Day 1

Form: Estimated glomerular filtration rate (eGFR)

Generated On: 15 Sep 2020 16:43:48

Serum creatinine collection date:

Serum creatinine:

Serum creatinine units:

mg/dL

µmol/L

Age at time of Serum creatinine collection:

GFR Calculation (derived):

Fixed Unit: (mL/min/1.73 m²)

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Was ¹⁷⁷Lu-PSMA-617 Administered?

Yes
No

If No, specify reason

AE
Other

Select AE:

If Other, Specify

Date of Administration

Start Time of Administration

Fixed Unit: (24 HR)

End Time of Administration

Fixed Unit: (24 HR)

Date of Patient Discharge

Time of Patient Discharge

Timespan of patient discharge

Fixed Unit: hrs

Method of Dose Administration

Syringe with or without Pump
Vial with Pump

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Gravity Method

Planned Dose
GBq
mCi
MBq

Was Dose Adjusted from Assigned/Previous
No Adjustment of Dose
Prior Reduction Maintained
Dose Reduced

Dose Reduced, Select AE: _____

Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

¹⁷⁷Lu-PSMA-617 Administration total volume injected (to one decimal place)

Fixed Unit: ml

Total Dose Administered

GBq
mCi
MBq

Was Administration Interrupted?

Yes
No

If Administration was Interrupted; complete a log line for each instance

Reason

AE
Administration Issue
Other

If Reason is Adverse Event, Select AE:

If Reason is Other, Specify

Stop Time of Administration (24 HR)

Time Administration was restarted (24 HR)

07.007 25Aug2020 CM: Master

Folder: Cycle 3 >> Cycle 3 Day 1

Form: Whole Body Planar Imaging - German Subjects

Generated On: 15 Sep 2020 16:43:48

Imaging Session

- 1-2 hours
18-26 hours
36-48 hours
156-168 hours

Were whole body planar images done?

- Yes
No

Reason Not Done

Date of Scan

Start Time of Scan

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 1
Form: SPECT/CT Imaging - German Subjects
Generated On: 15 Sep 2020 16:43:48

Imaging Session (time after the 177Lu-PSMA-617 Administration)

1-2 hours (SPECT)	<input type="radio"/>
1-2 hours (CT)	<input type="radio"/>
18-26 hours (SPECT)	<input type="radio"/>
36-48 hours (SPECT)	<input checked="" type="radio"/>
156-168 hours (SPECT)	<input type="radio"/>

Were SPECT/CT images done?

Yes	<input type="radio"/>
No	<input type="radio"/>

Reason Not Done

Date of Scan

Start Time of SPECT

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 15
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Cycle 3 >> Cycle 3 Day 15

Form: Laboratory Sample Collection - Chemistry/Hematology

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 29
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Cycle 3 >> Cycle 3 Day 29

Form: Laboratory Sample Collection - Chemistry/Hematology

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

**07.007 25Aug2020 CM: Master
Folder: Cycle 3 >> Cycle 3 Day 29
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed?

Yes
No

Date

Height (xxx)

cm
in

Weight (xxx.x)

kg
lb

Respiratory Rate (xxx)

Fixed Unit: breaths/min

Systolic Blood Pressure (xxx)

Fixed Unit: mmHg

Diastolic Blood Pressure (xxx)

Fixed Unit: mmHg

Pulse (xxx)

Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

07.007 25Aug2020 CM: Master

Folder: Cycle 4 >> Cycle 4 Day 1

Form: Estimated glomerular filtration rate (eGFR)

Generated On: 15 Sep 2020 16:43:48

Serum creatinine collection date:

Serum creatinine:

Serum creatinine units:

mg/dL

µmol/L

Age at time of Serum creatinine collection:

GFR Calculation (derived):

Fixed Unit: (mL/min/1.73 m²)

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Was ¹⁷⁷Lu-PSMA-617 Administered?

Yes
No

If No, specify reason

AE
Other

Select AE:

If Other, Specify

Date of Administration

Start Time of Administration

Fixed Unit: (24 HR)

End Time of Administration

Fixed Unit: (24 HR)

Date of Patient Discharge

Time of Patient Discharge

Timespan of patient discharge

Fixed Unit: hrs

Method of Dose Administration

Syringe with or without Pump
Vial with Pump

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Gravity Method

Planned Dose
GBq
mCi
MBq

Was Dose Adjusted from Assigned/Previous
No Adjustment of Dose
Prior Reduction Maintained
Dose Reduced

Dose Reduced, Select AE: _____

Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

¹⁷⁷Lu-PSMA-617 Administration total volume injected (to one decimal place)

Fixed Unit: ml

Total Dose Administered

GBq
mCi
MBq

Was Administration Interrupted?

Yes
No

If Administration was Interrupted; complete a log line for each instance

Reason

AE
Administration Issue
Other

If Reason is Adverse Event, Select AE:

If Reason is Other, Specify

Stop Time of Administration (24 HR)

Time Administration was restarted (24 HR)

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: Whole Body Planar Imaging - German Subjects
Generated On: 15 Sep 2020 16:43:48

Imaging Session

1-2 hours

18-26 hours

36-48 hours

156-168 hours

Were whole body planar images done?

Yes

No

Reason Not Done

Date of Scan

Start Time of Scan

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 1
Form: SPECT/CT Imaging - German Subjects
Generated On: 15 Sep 2020 16:43:48

Imaging Session (time after the 177Lu-PSMA-617 Administration)

1-2 hours (SPECT)	<input type="radio"/>
1-2 hours (CT)	<input type="radio"/>
18-26 hours (SPECT)	<input type="radio"/>
36-48 hours (SPECT)	<input checked="" type="radio"/>
156-168 hours (SPECT)	<input type="radio"/>

Were SPECT/CT images done?

Yes	<input type="radio"/>
No	<input type="radio"/>

Reason Not Done

Date of Scan

Start Time of SPECT

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 15
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Cycle 4 >> Cycle 4 Day 15

Form: Laboratory Sample Collection - Chemistry/Hematology

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 29
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 29
Form: Laboratory Sample Collection - Chemistry/Hematology
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

**07.007 25Aug2020 CM: Master
Folder: Cycle 4 >> Cycle 4 Day 29
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire EQ-5D-5L
 FACT-P
 BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P
 BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed?

Yes
No

Date _____

Height (xxx) cm
in

Weight (xxx.x) kg
lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

07.007 25Aug2020 CM: Master

Folder: Cycle 5 >> Cycle 5 Day 1

Form: Estimated glomerular filtration rate (eGFR)

Generated On: 15 Sep 2020 16:43:48

Serum creatinine collection date:

Serum creatinine:

Serum creatinine units:

mg/dL

µmol/L

Age at time of Serum creatinine collection:

GFR Calculation (derived):

Fixed Unit: (mL/min/1.73 m²)

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Was ¹⁷⁷Lu-PSMA-617 Administered?

Yes
No

If No, specify reason

AE
Other

Select AE:

If Other, Specify

Date of Administration

Start Time of Administration

Fixed Unit: (24 HR)

End Time of Administration

Fixed Unit: (24 HR)

Date of Patient Discharge

Time of Patient Discharge

Timespan of patient discharge

Fixed Unit: hrs

Method of Dose Administration

Syringe with or without Pump
Vial with Pump

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Gravity Method

Planned Dose
GBq
mCi
MBq

Was Dose Adjusted from Assigned/Previous
No Adjustment of Dose
Prior Reduction Maintained
Dose Reduced

Dose Reduced, Select AE: _____

Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

¹⁷⁷Lu-PSMA-617 Administration total volume injected (to one decimal place)

Fixed Unit: ml

Total Dose Administered

GBq
mCi
MBq

Was Administration Interrupted?

Yes
No

If Administration was Interrupted; complete a log line for each instance

Reason

AE
Administration Issue
Other

If Reason is Adverse Event, Select AE:

If Reason is Other, Specify

Stop Time of Administration (24 HR)

Time Administration was restarted (24 HR)

07.007 25Aug2020 CM: Master

Folder: Cycle 5 >> Cycle 5 Day 1

Form: Whole Body Planar Imaging - German Subjects

Generated On: 15 Sep 2020 16:43:48

Imaging Session

- 1-2 hours
18-26 hours
36-48 hours
156-168 hours

Were whole body planar images done?

- Yes
No

Reason Not Done

Date of Scan

Start Time of Scan

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 1
Form: SPECT/CT Imaging - German Subjects
Generated On: 15 Sep 2020 16:43:48

Imaging Session (time after the 177Lu-PSMA-617 Administration)

1-2 hours (SPECT)	<input type="radio"/>
1-2 hours (CT)	<input type="radio"/>
18-26 hours (SPECT)	<input type="radio"/>
36-48 hours (SPECT)	<input checked="" type="radio"/>
156-168 hours (SPECT)	<input type="radio"/>

Were SPECT/CT images done?

Yes	<input type="radio"/>
No	<input type="radio"/>

Reason Not Done

Date of Scan

Start Time of SPECT

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 15
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Cycle 5 >> Cycle 5 Day 15

Form: Laboratory Sample Collection - Chemistry/Hematology

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 29
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 29
Form: Laboratory Sample Collection - Chemistry/Hematology
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

**07.007 25Aug2020 CM: Master
Folder: Cycle 5 >> Cycle 5 Day 29
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes
No

Date _____

Height (xxx) cm
in

Weight (xxx.x) kg
lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

07.007 25Aug2020 CM: Master

Folder: Cycle 6 >> Cycle 6 Day 1

Form: Estimated glomerular filtration rate (eGFR)

Generated On: 15 Sep 2020 16:43:48

Serum creatinine collection date:

Serum creatinine:

Serum creatinine units:

mg/dL

µmol/L

Age at time of Serum creatinine collection:

GFR Calculation (derived):

Fixed Unit: (mL/min/1.73 m²)

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Was ¹⁷⁷Lu-PSMA-617 Administered?

Yes
No

If No, specify reason

AE
Other

Select AE:

If Other, Specify

Date of Administration

Start Time of Administration

Fixed Unit: (24 HR)

End Time of Administration

Fixed Unit: (24 HR)

Date of Patient Discharge

Time of Patient Discharge

Timespan of patient discharge

Fixed Unit: hrs

Method of Dose Administration

Syringe with or without Pump
Vial with Pump

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

Gravity Method

Planned Dose
GBq
mCi
MBq

Was Dose Adjusted from Assigned/Previous
No Adjustment of Dose
Prior Reduction Maintained
Dose Reduced

Dose Reduced, Select AE: _____

Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Pre-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement
GBq
mCi
MBq

Time of Post-¹⁷⁷Lu-PSMA-617 Injection Syringe Activity Measurement Fixed Unit: (24 HR)

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: 177 Lu-PSMA-617 Administration
Generated On: 15 Sep 2020 16:43:48

¹⁷⁷Lu-PSMA-617 Administration total volume injected (to one decimal place)

Fixed Unit: ml

Total Dose Administered

GBq
mCi
MBq

Was Administration Interrupted?

Yes
No

If Administration was Interrupted; complete a log line for each instance

Reason

AE
Administration Issue
Other

If Reason is Adverse Event, Select AE:

If Reason is Other, Specify

Stop Time of Administration (24 HR)

Time Administration was restarted (24 HR)

07.007 25Aug2020 CM: Master

Folder: Cycle 6 >> Cycle 6 Day 1

Form: Whole Body Planar Imaging - German Subjects

Generated On: 15 Sep 2020 16:43:48

Imaging Session

- 1-2 hours
18-26 hours
36-48 hours
156-168 hours

Were whole body planar images done?

- Yes
No

Reason Not Done

Date of Scan

Start Time of Scan

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 1
Form: SPECT/CT Imaging - German Subjects
Generated On: 15 Sep 2020 16:43:48

Imaging Session (time after the 177Lu-PSMA-617 Administration)

1-2 hours (SPECT)	<input type="radio"/>
1-2 hours (CT)	<input type="radio"/>
18-26 hours (SPECT)	<input type="radio"/>
36-48 hours (SPECT)	<input checked="" type="radio"/>
156-168 hours (SPECT)	<input type="radio"/>

Were SPECT/CT images done?

Yes	<input type="radio"/>
No	<input type="radio"/>

Reason Not Done

Date of Scan

Start Time of SPECT

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 15
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Cycle 6 >> Cycle 6 Day 15

Form: Laboratory Sample Collection - Chemistry/Hematology

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 29
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Cycle 6 >> Cycle 6 Day 29

Form: Laboratory Sample Collection - Chemistry/Hematology

Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

**07.007 25Aug2020 CM: Master
Folder: Cycle 6 >> Cycle 6 Day 29
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 7 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 7 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 7 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master

Folder: Cycle 7 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed?

Yes
No

If No, Specify

- Patient felt too ill
- Clinician or Nurse felt the patient was too ill
- Patient felt it was inconvenient, takes too much time
- Patient felt it was a violation of privacy
- Patient didn't understand the actual language/illiterate
- Administrative failure to distribute the questionnaire to the patient
- Translation unavailable
- Other

If Other, specify

Questionnaire

- EQ-5D-5L
- FACT-P
- BPI-SF

Questionnaire Completed?

Yes
No

If No, Specify

Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 7 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 7 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 7 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 7 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 7 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 7 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 7 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 8 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 8 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 8 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master

Folder: Cycle 8 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 8 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 8 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 8 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 8 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 8 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 8 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

07.007 25Aug2020 CM: Master
Folder: Cycle 8 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 9 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 9 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 9 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 9 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 9 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 9 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 9 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 9 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 9 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 9 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status

ECOG Performance Status

0

1

2

3

4

5

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 9 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 10 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 10 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 10 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 10 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 10 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 10 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 10 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 10 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed?

Yes
No

Date _____

Height (xxx) cm
in

Weight (xxx.x) kg
lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 10 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 10 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 10 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 11 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 11 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 11 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 11 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 11 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the
patient was too ill
Patient felt it was
inconvenient, takes too
much time
Patient felt it was a
violation of privacy
Patient didn't understand
the actual
language/illiterate
Administrative failure to
distribute the questionnaire
to the patient
Translation unavailable
Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 11 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 11 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 11 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 11 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 11 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 11 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 12 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 12 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 12 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 12 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 12 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 12 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 12 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 12 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes
No

Date _____

Height (xxx) cm
in

Weight (xxx.x) kg
lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 12 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 12 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 12 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 13 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 13 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 13 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 13 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 13 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the
patient was too ill
Patient felt it was
inconvenient, takes too
much time
Patient felt it was a
violation of privacy
Patient didn't understand
the actual
language/illiterate
Administrative failure to
distribute the questionnaire
to the patient
Translation unavailable
Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 13 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 13 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 13 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 13 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 13 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 13 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 14 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 14 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 14 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 14 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 14 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the
patient was too ill
Patient felt it was
inconvenient, takes too
much time
Patient felt it was a
violation of privacy
Patient didn't understand
the actual
language/illiterate
Administrative failure to
distribute the questionnaire
to the patient
Translation unavailable
Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 14 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 14 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 14 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 14 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 14 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 14 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 15 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 15 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 15 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 15 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 15 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 15 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 15 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 15 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes
No

Date _____

Height (xxx) cm
in

Weight (xxx.x) kg
lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 15 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 15 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 15 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 16 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 16 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 16 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 16 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 16 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the
patient was too ill
Patient felt it was
inconvenient, takes too
much time
Patient felt it was a
violation of privacy
Patient didn't understand
the actual
language/illiterate
Administrative failure to
distribute the questionnaire
to the patient
Translation unavailable
Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 16 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 16 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 16 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 16 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 16 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 16 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?
Yes
No

Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?
Yes
No

Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?
Yes
No

Has the Subject shown good tolerance to the ¹⁷⁷Lu-PSMA-617 treatment?
Yes
No

Does the Subject agree to continue with additional treatment of ¹⁷⁷Lu-PSMA-617?
Yes
No

Is the Subject continuing with ¹⁷⁷Lu-PSMA-617 Administration?
Yes
No

07.007 25Aug2020 CM: Master
Folder: Cycle 17 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 17 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 17 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 17 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 17 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 17 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 17 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 17 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 17 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes

No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 17 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 17 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 18 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 18 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 18 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 18 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 18 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 18 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 18 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 18 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes
No

Date _____

Height (xxx) cm
 in

Weight (xxx.x) kg
 lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 18 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 18 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 18 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Cycle 19 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 19 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master

Folder: Cycle 19 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 19 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 19 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 19 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 19 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 19 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 19 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 19 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 19 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?
Yes
No

Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?
Yes
No

Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?
Yes
No

Has the Subject shown good tolerance to the ¹⁷⁷Lu-PSMA-617 treatment?
Yes
No

Does the Subject agree to continue with additional treatment of ¹⁷⁷Lu-PSMA-617?
Yes
No

Is the Subject continuing with ¹⁷⁷Lu-PSMA-617 Administration?
Yes
No

07.007 25Aug2020 CM: Master
Folder: Cycle 20 Day 1
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master
Folder: Cycle 20 Day 1
Form: Cycle Delayed
Generated On: 15 Sep 2020 16:43:48

Indicate if this Cycle was Delayed

- No Delay
Delayed - Scheduling Purposes
Delayed - Adverse Event

Please Select AE

07.007 25Aug2020 CM: Master
Folder: Cycle 20 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

07.007 25Aug2020 CM: Master
Folder: Cycle 20 Day 1
Form: Quality of Life Questionnaire Completion
Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill
 Clinician or Nurse felt the patient was too ill
 Patient felt it was inconvenient, takes too much time
 Patient felt it was a violation of privacy
 Patient didn't understand the actual language/illiterate
 Administrative failure to distribute the questionnaire to the patient
 Translation unavailable
 Other

If Other, specify _____

Questionnaire EQ-5D-5L FACT-P BPI-SF

Questionnaire Completed? Yes No

If No, Specify Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Cycle 20 Day 1

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: Cycle 20 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
- Hematology
- Serum/Plasma
- Testosterone
- PSA
- Urinalysis
- Other

Was Laboratory Sample Collection performed?

- Yes
- No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 20 Day 1
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Cycle 20 Day 1
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: Cycle 20 Day 1
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: Cycle 20 Day 1
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status _____

ECOG Performance Status

0	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>
4	<input type="checkbox"/>
5	<input type="checkbox"/>

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

**07.007 25Aug2020 CM: Master
Folder: Cycle 20 Day 1
Form: Continuing
Generated On: 15 Sep 2020 16:43:48**

Is the Subject continuing on to the next cycle?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject show evidence of response (i.e. radiological, PSA, clinical benefit)?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject have signs of residual disease on CT with contrast/MRI or bone scan?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Has the Subject shown good tolerance to the ¹⁷⁷ Lu-PSMA-617 treatment?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Does the Subject agree to continue with additional treatment of ¹⁷⁷ Lu-PSMA-617?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
<hr/>	
Is the Subject continuing with ¹⁷⁷ Lu-PSMA-617 Administration?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: End of Treatment
Form: Visit Date
Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: End of Treatment

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

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Folder: End of Treatment

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed?

Yes
No

If No, Specify

- Patient felt too ill
Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable
Other

If Other, specify

Questionnaire

EQ-5D-5L
FACT-P
BPI-SF

Questionnaire Completed?

Yes
No

If No, Specify

Patient felt too ill

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Folder: End of Treatment

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the patient was too ill
Patient felt it was inconvenient, takes too much time
Patient felt it was a violation of privacy
Patient didn't understand the actual language/illiterate
Administrative failure to distribute the questionnaire to the patient
Translation unavailable Other

If Other, specify _____

07.007 25Aug2020 CM: Master
Folder: End of Treatment
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: End of Treatment
Form: Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

Laboratory Test

- Chemistry
Hematology
Serum/Plasma
Testosterone
PSA
Urinalysis
Other

Was Laboratory Sample Collection performed?

- Yes
No

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: End of Treatment
Form: Vital Signs
Generated On: 15 Sep 2020 16:43:48

Were vital signs performed? Yes No

Date _____

Height (xxx) cm in

Weight (xxx.x) kg lb

Respiratory Rate (xxx) Fixed Unit: breaths/min

Systolic Blood Pressure (xxx) Fixed Unit: mmHg

Diastolic Blood Pressure (xxx) Fixed Unit: mmHg

Pulse (xxx) Fixed Unit: bpm

07.007 25Aug2020 CM: Master
Folder: End of Treatment
Form: Physical Examination
Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes
No

Date of Examination

07.007 25Aug2020 CM: Master
Folder: End of Treatment
Form: ECOG Performance Status
Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes

No

Date of ECOG Performance Status

ECOG Performance Status

0
1
2
3
4
5

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead
-

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Folder: End of Treatment

Form: End of Treatment - 177 Lu-PSMA-617 Administration

Generated On: 15 Sep 2020 16:43:48

Date of End of Treatment Decision

Primary Reason Treatment was Discontinued

- Completed Treatment
Progressive Disease
No Longer Clinically Benefiting
Adverse Event
Subject Non-Compliance
Subject Lost to Follow-up
Investigator Decision
Protocol Deviation
Withdrew Consent (Treatment)
Death
Study Closure
Patient requires care not allowed in the study
Other
-

Select Primary AE:

If Other or Investigator Decision, specify

If Withdrew Consent, specify:

- No reason given
Perceived lack of benefit
Decided to pursue off-study treatment
Treatment "fatigue" due to travel or protocol procedures
Cannot afford medical costs related to the study
-

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Folder: End of Treatment

Form: End of Treatment - 177 Lu-PSMA-617 Administration

Generated On: 15 Sep 2020 16:43:48

Cannot afford non-medical
costs related to the study
(travel, etc.)

Because receiving best
supportive care without
177Lu-PSMA-617

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Folder: End of Treatment

Form: End of Treatment - Best Supportive / Best Standard Care

Generated On: 15 Sep 2020 16:43:48

Date of End of Treatment Decision

Primary Reason Treatment was Discontinued for this
Study

- Progressive Disease
No Longer Clinically Benefitting Adverse Event
Subject Non-Compliance
Subject Lost to Follow-up
Investigator Decision
Protocol Deviation
Withdrew Consent (Treatment)
Death
Study Closure
Patient requires care not allowed in the study
Other

Select Primary AE:

If Other or Investigator Decision, specify

If Withdrew Consent, specify:

- No reason given
Perceived lack of benefit
Decided to pursue off-study treatment
Treatment "fatigue" due to travel or protocol procedures
Cannot afford medical costs related to the study
Cannot afford non-medical costs related to the study (travel, etc.)
-

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Folder: End of Treatment

Form: End of Treatment - Best Supportive / Best Standard Care

Generated On: 15 Sep 2020 16:43:48

Because receiving best
supportive care without
177Lu-PSMA-617

07.007 25Aug2020 CM: Master
Folder: End of Treatment
Form: Long Term Follow-up Continuing
Generated On: 15 Sep 2020 16:43:48

Did the subject agree to continue in the Long Term Follow-up period?

Yes
No

What type of Long Term Follow-up did the subject agree to?

Full Long Term Follow-up
(e.g. blood work, information about treatments and response to treatments, adverse events)

Long Term Follow-up
Survival only

Did the subject come off treatment due to radiographic disease progression?

Yes
No

Did the subject voluntarily agree to take part in radiological follow-up up?

Yes
No

Date of agreement for radiological follow-up

07.007 25Aug2020 CM: Master
Folder: End of Study
Form: End of Study
Generated On: 15 Sep 2020 16:43:48

Date subject ended study

Primary Reason the Subject Discontinued from the Study

- Progressive Disease
No Longer Clinically Benefitting Adverse Event
Subject Non-Compliance
Subject Lost to Follow-up
Investigator Decision
Protocol Deviation
Withdrew Consent (Protocol)
Death
Study Closure
Patient requires care not allowed in the study
Other
-

Select Primary AE:

Select Primary Long Term Follow-up - AE:

If Primary Reason the Subject Discontinued from the Study is Investigator Decision or Other, specify

If Withdrew Consent, specify:

- No reason given
Perceived lack of benefit
Decided to pursue off-study treatment
Treatment "fatigue" due to travel or protocol procedures
-

07.007 25Aug2020 CM: Master
Folder: End of Study
Form: End of Study
Generated On: 15 Sep 2020 16:43:48

-
- Cannot afford medical
costs related to the study
Cannot afford non-medical
costs related to the study
(travel, etc.)
Because receiving best
supportive care without
- 177Lu-PSMA-617
-

07.007 25Aug2020 CM: Master
Folder: Clinical Progression
Form: Clinical Progression (Yes/No)
Generated On: 15 Sep 2020 16:43:48

Did the investigator determine the Subject met the standard for unequivocal evidence of clinical progression anytime up to and including the End of Treatment visit?

Yes
No

07.007 25Aug2020 CM: Master
Folder: Long-Term Follow-Up
Form: Long Term Follow-up Contact
Generated On: 15 Sep 2020 16:43:48

Date of Contact

Type of Contact

- In-Clinic Visit
Phone Contact
Email
Letter
Review of medical records
Review of public sources
-

Subject Status:

NOTE: If subject died, was lost to follow-up or withdrew consent, complete the End of Study CRF

- Alive
Dead
Lost to Follow-up
Withdrew consent
-

Has the Subject received further radiotherapy for the study indication since the last contact/visit?

- Yes
No
Unknown
-

Has the Subject received further systemic/chemo treatment for the study indication since the last contact/visit?

- Yes
No
Unknown
-

Has the Subject had a disease assessment for this cancer since the last contact/visit?

- Yes
No
Unknown
-

Was Chemistry Sample Collected?

- Yes
No
-

07.007 25Aug2020 CM: Master
Folder: Long-Term Follow-Up
Form: Long Term Follow-up Contact
Generated On: 15 Sep 2020 16:43:48

Was Hematology Sample Collected?

Yes
No

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Folder: Long-Term Follow-Up

Form: Post Treatment Anti-Cancer Therapies

Generated On: 15 Sep 2020 16:43:48

Were there any post treatment anti-cancer therapies taken?

Yes
No

Drug name (generic name is preferred)

Start date

Ongoing?

Yes
No

If not Ongoing, End date

07.007 25Aug2020 CM: Master
Folder: Long-Term Follow-Up
Form: Post Treatment Laboratory Sample Collection
Generated On: 15 Sep 2020 16:43:48

Was Laboratory Sample Collection performed?

Yes
No

Laboratory Test

Chemistry
Hematology

Date of Lab Sample Collection

07.007 25Aug2020 CM: Master
Folder: Long-Term Follow-Up
Form: Post Treatment Disease Assessment
Generated On: 15 Sep 2020 16:43:48

Has the Subject had a disease assessment for this cancer?

Yes
No

Date of Assessment

Assessment Method

PSA
Bone Scan
CT/MRI/PET
Clinical
Other

Other, specify:

Overall Response

Complete Response
Partial Response
Stable Disease
Progressive Disease
Unknown

07.007 25Aug2020 CM: Master
Folder: Long-Term Follow-Up
Form: Post Treatment Radiotherapy
Generated On: 15 Sep 2020 16:43:48

Has the Subject received further Radiotherapy? Yes No

Site of Radiotherapy

Adrenals	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Axillary Nodes	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Bone	<input type="checkbox"/>
Bone Marrow	<input type="checkbox"/>
Brain	<input type="checkbox"/>
CNS	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Esophagus	<input type="checkbox"/>
Eye	<input type="checkbox"/>
Femur	<input type="checkbox"/>
Gastroesophageal Junction	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Hepatic Lobe	<input type="checkbox"/>
Hips	<input type="checkbox"/>
Iliac Crest	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Large Intestine	<input type="checkbox"/>
Larynx	<input type="checkbox"/>
Liver	<input type="checkbox"/>
Lower Extremity Bones	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Lymph Node	<input type="checkbox"/>
Neck Nodes	<input type="checkbox"/>
Omentum/Peritoneum	<input type="checkbox"/>
Oropharynx	<input type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Long-Term Follow-Up
Form: Post Treatment Radiotherapy
Generated On: 15 Sep 2020 16:43:48

Pancreas	<input type="checkbox"/>
Para-Aortic Nodes in Inguinal	<input type="checkbox"/>
Pelvic Bone	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Prostate Bed	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Supraclavicular Nodes	<input type="checkbox"/>
Stomach	<input type="checkbox"/>
Testes	<input type="checkbox"/>
Thyroid	<input type="checkbox"/>
Upper Extremity Bones	<input type="checkbox"/>
Vertebral: Spine	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>

If Other, specify _____

Start Date _____

07.007 25Aug2020 CM: Master
Folder: Long-Term Follow-Up
Form: Post Treatment Radiotherapy
Generated On: 15 Sep 2020 16:43:48

Ongoing?

Yes
No

Stop Date

07.007 25Aug2020 CM: Master
Folder: Long-Term Follow-Up
Form: Long Term Follow-up - Adverse Events
Generated On: 15 Sep 2020 16:43:48

Did the subject experience any adverse events during long term follow-up?

Yes
No

Adverse Event

CTCAE Grade

Grade 1
Grade 2
Grade 3
Grade 4
Grade 5

07.007 25Aug2020 CM: Master
Folder: Radiotherapy
Form: Radiotherapy (Yes/No)
Generated On: 15 Sep 2020 16:43:48

Was Radiotherapy performed?

Yes
No

07.007 25Aug2020 CM: Master
Folder: Radiotherapy
Form: Radiotherapy
Generated On: 15 Sep 2020 16:43:48

Site of Radiotherapy

Adrenals	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Axillary Nodes	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Bone	<input type="checkbox"/>
Bone Marrow	<input type="checkbox"/>
Brain	<input type="checkbox"/>
CNS	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Esophagus	<input type="checkbox"/>
Eye	<input type="checkbox"/>
Femur	<input type="checkbox"/>
Gastroesophageal Junction	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Hepatic Lobe	<input type="checkbox"/>
Hips	<input type="checkbox"/>
Iliac Crest	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Large Intestine	<input type="checkbox"/>
Larynx	<input type="checkbox"/>
Liver	<input type="checkbox"/>
Lower Extremity Bones	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Lymph Node	<input type="checkbox"/>
Neck Nodes	<input type="checkbox"/>
Omentum/Peritoneum	<input type="checkbox"/>
Oropharynx	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Para-Aortic Nodes in Inguinal	<input type="checkbox"/>
Pelvic Bone	<input checked="" type="checkbox"/>

07.007 25Aug2020 CM: Master
Folder: Radiotherapy
Form: Radiotherapy
Generated On: 15 Sep 2020 16:43:48

Pleura	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Prostate Bed	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Supraclavicular Nodes	<input type="checkbox"/>
Stomach	<input type="checkbox"/>
Testes	<input type="checkbox"/>
Thyroid	<input type="checkbox"/>
Upper Extremity Bones	<input type="checkbox"/>
Vertebral: Spine	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If Other, specify

Symptomatic Skeletal Event?

Yes
No

Best Supportive/Best Standard of Care?

Yes
No

07.007 25Aug2020 CM: Master
Folder: Radiotherapy
Form: Radiotherapy
Generated On: 15 Sep 2020 16:43:48

Cumulative Dose

Gy
cGy
rad

Total number of Fractions

Start Date

Ongoing?

Yes
No

Stop Date

07.007 25Aug2020 CM: Master

Folder: Non-Trial Hospitalization and Outpatient Visits

Form: Non-Trial Hospitalization or Outpatient Visits (Yes/No)

Generated On: 15 Sep 2020 16:43:48

Did the subject have any Non-Trial Hospitalization or
Outpatient Visits through the End of Treatment visit?

Yes
No

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Folder: Non-Trial Hospitalization and Outpatient Visits

Form: Non-Trial Hospitalization or Outpatient Visits

Generated On: 15 Sep 2020 16:43:48

Type of Visit

Hospitalization
Outpatient

Date of Admission

Ongoing?

Yes
No

Date of Discharge

Reason for Visit

Adverse Event
Surgery
Other

Please select AE:

Please select Concurrent Surgical/Therapeutic Procedures

Other, specify:

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

Generated On: 15 Sep 2020 16:43:48

Date of CT/MRI if no Target Lesions

Total Sum of Target Lesion Diameter(s)

Fixed Unit: mm

Lesion Number

1

Not applicable

Location of the Lesion

- Gastroesophageal Junction
- Stomach
- Esophagus
- Liver
- Omentum/Peritoneum
- Lung
- Bone
- CNS
- Lymph Node
- Adrenals
- Kidney
- Pleura
- Bone Marrow
- Breast
- Head and Neck
- Colon
- Fallopian Tube
- Ovary
- Pancreas

07.007 25Aug2020 CM: Master

Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

Generated On: 15 Sep 2020 16:43:48

Skin	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>

07.007 25Aug2020 CM: Master

Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

Generated On: 15 Sep 2020 16:43:48

-
- | | |
|------------------------------|--------------------------|
| Peripancreatic (Soft Tissue) | <input type="checkbox"/> |
| Pleural Cavity | <input type="checkbox"/> |
| Pleural Effusion | <input type="checkbox"/> |
| Prostate | <input type="checkbox"/> |
| Retroperitoneum | <input type="checkbox"/> |
| Ribs | <input type="checkbox"/> |
| Sacrum | <input type="checkbox"/> |
| Scapula | <input type="checkbox"/> |
| Skull | <input type="checkbox"/> |
| Small Bowel | <input type="checkbox"/> |
| Subcutis | <input type="checkbox"/> |
| Thyroid | <input type="checkbox"/> |
| T-Spine | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

If location is Lymph Node, specify location

- | | |
|----------------------|--------------------------|
| Abdominal Nodes | <input type="checkbox"/> |
| Aorto Caval Nodes | <input type="checkbox"/> |
| Axillary Nodes | <input type="checkbox"/> |
| Celiac Nodes | <input type="checkbox"/> |
| Cervical Nodes | <input type="checkbox"/> |
| Common Iliac Nodes | <input type="checkbox"/> |
| Epitrochlear Nodes | <input type="checkbox"/> |
| External Iliac Nodes | <input type="checkbox"/> |
| Femoral Nodes | <input type="checkbox"/> |
| Frontal Lobe | <input type="checkbox"/> |
| Hilar Nodes | <input type="checkbox"/> |
| Inguinal Nodes | <input type="checkbox"/> |
| Internal Iliac Nodes | <input type="checkbox"/> |
| Mandibular Nodes | <input type="checkbox"/> |
| Mediastinal Nodes | <input type="checkbox"/> |

07.007 25Aug2020 CM: Master

Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

Generated On: 15 Sep 2020 16:43:48

- Mesenteric Nodes
- Para-Aortic Nodes
- Paracardiac Nodes
- Paratracheal Nodes
- Parietal Lobe
- Pelvic Nodes
- Portal Nodes
- Pre-Sacral Nodes
- Retrocrural Nodes
- Retroperitoneal Nodes
- Sub-Carinal Nodes
- Supraclavicular Nodes
- Thoracic Nodes
- Other Nodes

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

Method of Assessment

- CT (spiral)
- CT (conventional)
- PET/CT
- MRI
- FDG-PET Scan
- Bone Scan
- Clinical Examination
- Chest X-Ray
- Other

If Other please specify: _____

07.007 25Aug2020 CM: Master

Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

Generated On: 15 Sep 2020 16:43:48

Diameter (mm)

Lesion Number

2

Not applicable

Location of the Lesion

- | | |
|---------------------------|--------------------------|
| Gastroesophageal Junction | <input type="checkbox"/> |
| Stomach | <input type="checkbox"/> |
| Esophagus | <input type="checkbox"/> |
| Liver | <input type="checkbox"/> |
| Omentum/Peritoneum | <input type="checkbox"/> |
| Lung | <input type="checkbox"/> |
| Bone | <input type="checkbox"/> |
| CNS | <input type="checkbox"/> |
| Lymph Node | <input type="checkbox"/> |
| Adrenals | <input type="checkbox"/> |
| Kidney | <input type="checkbox"/> |
| Pleura | <input type="checkbox"/> |
| Bone Marrow | <input type="checkbox"/> |
| Breast | <input type="checkbox"/> |
| Head and Neck | <input type="checkbox"/> |
| Colon | <input type="checkbox"/> |
| Fallopian Tube | <input type="checkbox"/> |
| Ovary | <input type="checkbox"/> |
| Pancreas | <input type="checkbox"/> |
| Skin | <input type="checkbox"/> |
| Small Intestine | <input type="checkbox"/> |
| Rectum | <input type="checkbox"/> |
| Spinal | <input type="checkbox"/> |

07.007 25Aug2020 CM: Master

Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

Generated On: 15 Sep 2020 16:43:48

Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>
Peripancreatic (Soft Tissue)	<input type="checkbox"/>
Pleural Cavity	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>

07.007 25Aug2020 CM: Master

Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

Generated On: 15 Sep 2020 16:43:48

Retroperitoneum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Bowel	<input type="checkbox"/>
Subcutis	<input type="checkbox"/>
Thyroid	<input type="checkbox"/>
T-Spine	<input type="checkbox"/>
Other	<input type="checkbox"/>

If location is Lymph Node, specify location

Abdominal Nodes	<input type="checkbox"/>
Aorto Caval Nodes	<input type="checkbox"/>
Axillary Nodes	<input type="checkbox"/>
Celiac Nodes	<input type="checkbox"/>
Cervical Nodes	<input type="checkbox"/>
Common Iliac Nodes	<input type="checkbox"/>
Epitrochlear Nodes	<input type="checkbox"/>
External Iliac Nodes	<input type="checkbox"/>
Femoral Nodes	<input type="checkbox"/>
Frontal Lobe	<input type="checkbox"/>
Hilar Nodes	<input type="checkbox"/>
Inguinal Nodes	<input type="checkbox"/>
Internal Iliac Nodes	<input type="checkbox"/>
Mandibular Nodes	<input type="checkbox"/>
Mediastinal Nodes	<input type="checkbox"/>
Mesenteric Nodes	<input type="checkbox"/>
Para-Aortic Nodes	<input type="checkbox"/>
Paracardiac Nodes	<input type="checkbox"/>
Paratracheal Nodes	<input type="checkbox"/>

07.007 25Aug2020 CM: Master

Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

Generated On: 15 Sep 2020 16:43:48

- Parietal Lobe
Pelvic Nodes
Portal Nodes
Pre-Sacral Nodes
Retrocrural Nodes
Retroperitoneal Nodes
Sub-Carinal Nodes
Supraclavicular Nodes
Thoracic Nodes
Other Nodes

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

Method of Assessment

- CT (spiral)
CT (conventional)
PET/CT
MRI
FDG-PET Scan
Bone Scan
Clinical Examination
Chest X-Ray
Other

If Other please specify: _____

Diameter (mm) _____

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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Lesion Number 3

Not applicable

Location of the Lesion	Gastroesophageal Junction	<input type="checkbox"/>
	Stomach	<input type="checkbox"/>
	Esophagus	<input type="checkbox"/>
	Liver	<input type="checkbox"/>
	Omentum/Peritoneum	<input type="checkbox"/>
	Lung	<input type="checkbox"/>
	Bone	<input type="checkbox"/>
	CNS	<input type="checkbox"/>
	Lymph Node	<input type="checkbox"/>
	Adrenals	<input type="checkbox"/>
	Kidney	<input type="checkbox"/>
	Pleura	<input type="checkbox"/>
	Bone Marrow	<input type="checkbox"/>
	Breast	<input type="checkbox"/>
	Head and Neck	<input type="checkbox"/>
	Colon	<input type="checkbox"/>
	Fallopian Tube	<input type="checkbox"/>
	Ovary	<input type="checkbox"/>
	Pancreas	<input type="checkbox"/>
	Skin	<input type="checkbox"/>
	Small Intestine	<input type="checkbox"/>
	Rectum	<input type="checkbox"/>
	Spinal	<input type="checkbox"/>
	Spleen	<input type="checkbox"/>
	Abdomen	<input type="checkbox"/>
	Abdominal Wall	<input type="checkbox"/>

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>
Peripancreatic (Soft Tissue)	<input type="checkbox"/>
Pleural Cavity	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Retroperitoneum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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Scapula	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Bowel	<input type="checkbox"/>
Subcutis	<input type="checkbox"/>
Thyroid	<input type="checkbox"/>
T-Spine	<input type="checkbox"/>
Other	<input type="checkbox"/>

If location is Lymph Node, specify location

Abdominal Nodes	<input type="checkbox"/>
Aorta Caval Nodes	<input type="checkbox"/>
Axillary Nodes	<input type="checkbox"/>
Celiac Nodes	<input type="checkbox"/>
Cervical Nodes	<input type="checkbox"/>
Common Iliac Nodes	<input type="checkbox"/>
Epitrochlear Nodes	<input type="checkbox"/>
External Iliac Nodes	<input type="checkbox"/>
Femoral Nodes	<input type="checkbox"/>
Frontal Lobe	<input type="checkbox"/>
Hilar Nodes	<input type="checkbox"/>
Inguinal Nodes	<input type="checkbox"/>
Internal Iliac Nodes	<input type="checkbox"/>
Mandibular Nodes	<input type="checkbox"/>
Mediastinal Nodes	<input type="checkbox"/>
Mesenteric Nodes	<input type="checkbox"/>
Para-Aortic Nodes	<input type="checkbox"/>
Paracardiac Nodes	<input type="checkbox"/>
Paratracheal Nodes	<input type="checkbox"/>
Parietal Lobe	<input type="checkbox"/>
Pelvic Nodes	<input type="checkbox"/>
Portal Nodes	<input type="checkbox"/>

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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-
- | | |
|-----------------------|--------------------------|
| Pre-Sacral Nodes | <input type="checkbox"/> |
| Retrocrural Nodes | <input type="checkbox"/> |
| Retroperitoneal Nodes | <input type="checkbox"/> |
| Sub-Carinal Nodes | <input type="checkbox"/> |
| Supraclavicular Nodes | <input type="checkbox"/> |
| Thoracic Nodes | <input type="checkbox"/> |
| Other Nodes | <input type="checkbox"/> |
-

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

Method of Assessment

- | | |
|----------------------|--------------------------|
| CT (spiral) | <input type="checkbox"/> |
| CT (conventional) | <input type="checkbox"/> |
| PET/CT | <input type="checkbox"/> |
| MRI | <input type="checkbox"/> |
| FDG-PET Scan | <input type="checkbox"/> |
| Bone Scan | <input type="checkbox"/> |
| Clinical Examination | <input type="checkbox"/> |
| Chest X-Ray | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
-

If Other please specify: _____

Diameter (mm) _____

Lesion Number _____

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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Not applicable

Location of the Lesion

Gastroesophageal Junction	<input type="checkbox"/>
Stomach	<input type="checkbox"/>
Esophagus	<input type="checkbox"/>
Liver	<input type="checkbox"/>
Omentum/Peritoneum	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Bone	<input type="checkbox"/>
CNS	<input type="checkbox"/>
Lymph Node	<input type="checkbox"/>
Adrenals	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Bone Marrow	<input type="checkbox"/>
Breast	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Fallopian Tube	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>
Peripancreatic (Soft Tissue)	<input type="checkbox"/>
Pleural Cavity	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Retroperitoneum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Bowel	<input type="checkbox"/>

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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Subcutis
Thyroid
T-Spine
Other

If location is Lymph Node, specify location

Abdominal Nodes
Aorto Caval Nodes
Axillary Nodes
Celiac Nodes
Cervical Nodes
Common Iliac Nodes
Epitrochlear Nodes
External Iliac Nodes
Femoral Nodes
Frontal Lobe
Hilar Nodes
Inguinal Nodes
Internal Iliac Nodes
Mandibular Nodes
Mediastinal Nodes
Mesenteric Nodes
Para-Aortic Nodes
Paracardiac Nodes
Paratracheal Nodes
Parietal Lobe
Pelvic Nodes
Portal Nodes
Pre-Sacral Nodes
Retrocrural Nodes
Retroperitoneal Nodes

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Sub-Carinal Nodes

Supraclavicular Nodes

Thoracic Nodes

Other Nodes

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

Method of Assessment

CT (spiral)

CT (conventional)

PET/CT

MRI

FDG-PET Scan

Bone Scan

Clinical Examination

Chest X-Ray

Other

If Other please specify:

Diameter (mm)

Lesion Number

5

Not applicable

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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Location of the Lesion

Gastroesophageal Junction	<input type="checkbox"/>
Stomach	<input type="checkbox"/>
Esophagus	<input type="checkbox"/>
Liver	<input type="checkbox"/>
Omentum/Peritoneum	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Bone	<input type="checkbox"/>
CNS	<input type="checkbox"/>
Lymph Node	<input type="checkbox"/>
Adrenals	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Bone Marrow	<input type="checkbox"/>
Breast	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Fallopian Tube	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>
Peripancreatic (Soft Tissue)	<input type="checkbox"/>
Pleural Cavity	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Retroperitoneum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Bowel	<input type="checkbox"/>
Subcutis	<input type="checkbox"/>
Thyroid	<input type="checkbox"/>

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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T-Spine
Other

If location is Lymph Node, specify location

Abdominal Nodes
Aorto Caval Nodes
Axillary Nodes
Celiac Nodes
Cervical Nodes
Common Iliac Nodes
Epitrochlear Nodes
External Iliac Nodes
Femoral Nodes
Frontal Lobe
Hilar Nodes
Inguinal Nodes
Internal Iliac Nodes
Mandibular Nodes
Mediastinal Nodes
Mesenteric Nodes
Para-Aortic Nodes
Paracardiac Nodes
Paratracheal Nodes
Parietal Lobe
Pelvic Nodes
Portal Nodes
Pre-Sacral Nodes
Retrocrural Nodes
Retroperitoneal Nodes
Sub-Carinal Nodes
Supraclavicular Nodes

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Target Lesions

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Thoracic Nodes
Other Nodes

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

Method of Assessment

CT (spiral)
CT (conventional)
PET/CT
MRI
FDG-PET Scan
Bone Scan
Clinical Examination
Chest X-Ray
Other

If Other please specify: _____

Diameter (mm) _____

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Non-Target Lesions

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Were any Non-Target Lesions identified?
(If Yes, complete remaining fields below. Enter one log
line for each non-target lesion.)

Yes

No

Location of the Lesion

- Gastroesophageal Junction
- Stomach
- Esophagus
- Liver
- Omentum/Peritoneum
- Lung
- Bone
- CNS
- Lymph Node
- Adrenals
- Kidney
- Pleura
- Bone Marrow
- Breast
- Head and Neck
- Colon
- Fallopian Tube
- Ovary
- Pancreas
- Skin
- Small Intestine
- Rectum
- Spinal
- Spleen
- Abdomen
- Abdominal Wall
- Acetabulum

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Non-Target Lesions

Generated On: 15 Sep 2020 16:43:48

Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>
Peripancreatic (Soft Tissue)	<input type="checkbox"/>
Pleural Cavity	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Retroperitoneum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Scapula	<input type="checkbox"/>

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Non-Target Lesions

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-
- | | |
|-------------|--------------------------|
| Skull | <input type="checkbox"/> |
| Small Bowel | <input type="checkbox"/> |
| Subcutis | <input type="checkbox"/> |
| Thyroid | <input type="checkbox"/> |
| T-Spine | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

If location is Lymph Node, specify location

- | | |
|----------------------|--------------------------|
| Abdominal Nodes | <input type="checkbox"/> |
| Aorto Caval Nodes | <input type="checkbox"/> |
| Axillary Nodes | <input type="checkbox"/> |
| Celiac Nodes | <input type="checkbox"/> |
| Cervical Nodes | <input type="checkbox"/> |
| Common Iliac Nodes | <input type="checkbox"/> |
| Epitrochlear Nodes | <input type="checkbox"/> |
| External Iliac Nodes | <input type="checkbox"/> |
| Femoral Nodes | <input type="checkbox"/> |
| Frontal Lobe | <input type="checkbox"/> |
| Hilar Nodes | <input type="checkbox"/> |
| Inguinal Nodes | <input type="checkbox"/> |
| Internal Iliac Nodes | <input type="checkbox"/> |
| Mandibular Nodes | <input type="checkbox"/> |
| Mediastinal Nodes | <input type="checkbox"/> |
| Mesenteric Nodes | <input type="checkbox"/> |
| Para-Aortic Nodes | <input type="checkbox"/> |
| Paracardiac Nodes | <input type="checkbox"/> |
| Paratracheal Nodes | <input type="checkbox"/> |
| Parietal Lobe | <input type="checkbox"/> |
| Pelvic Nodes | <input type="checkbox"/> |
| Portal Nodes | <input type="checkbox"/> |
| Pre-Sacral Nodes | <input type="checkbox"/> |

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Non-Target Lesions

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-
- | | |
|-----------------------|--------------------------|
| Retrocrural Nodes | <input type="checkbox"/> |
| Retroperitoneal Nodes | <input type="checkbox"/> |
| Sub-Carinal Nodes | <input type="checkbox"/> |
| Supraclavicular Nodes | <input type="checkbox"/> |
| Thoracic Nodes | <input type="checkbox"/> |
| Other Nodes | <input type="checkbox"/> |

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

Method of Assessment

- | | |
|----------------------|--------------------------|
| CT (spiral) | <input type="checkbox"/> |
| CT (conventional) | <input type="checkbox"/> |
| PET/CT | <input type="checkbox"/> |
| MRI | <input type="checkbox"/> |
| FDG-PET Scan | <input type="checkbox"/> |
| Bone Scan | <input type="checkbox"/> |
| Clinical Examination | <input type="checkbox"/> |
| Chest X-Ray | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
-

If Other please specify: _____

Lesion Assessment

- | | |
|-------------------------|--------------------------|
| Present | <input type="checkbox"/> |
| Absent | <input type="checkbox"/> |
| Unequivocal Progression | <input type="checkbox"/> |
| Not evaluable | <input type="checkbox"/> |
-

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Folder: Tumor Assessments >> Screening Tumor Asmt

Form: Subsequent Tumor Assessment (Yes/No)

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Was another tumor assessment performed?

Yes

No

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Folder: Tumor Assessments >> Tumor Asmt -
Form: Target Lesions (2)
Generated On: 15 Sep 2020 16:43:48

Total Sum of Target Lesion Diameter(s) _____ Fixed Unit: mm

Lesion Number _____ 1

Not applicable _____

Location of the Lesion _____

Gastroesophageal Junction	<input type="checkbox"/>
Stomach	<input type="checkbox"/>
Esophagus	<input type="checkbox"/>
Liver	<input type="checkbox"/>
Omentum/Peritoneum	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Bone	<input type="checkbox"/>
CNS	<input type="checkbox"/>
Lymph Node	<input type="checkbox"/>
Adrenals	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Bone Marrow	<input type="checkbox"/>
Breast	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Fallopian Tube	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Rectum	<input type="checkbox"/>

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Folder: Tumor Assessments >> Tumor Asmt -
Form: Target Lesions (2)
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Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>
Peripancreatic (Soft Tissue)	<input type="checkbox"/>
Pleural Cavity	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>

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Folder: Tumor Assessments >> Tumor Asmt -
Form: Target Lesions (2)
Generated On: 15 Sep 2020 16:43:48

Prostate	<input type="checkbox"/>
Retroperitoneum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Bowel	<input type="checkbox"/>
Subcutis	<input type="checkbox"/>
Thyroid	<input type="checkbox"/>
T-Spine	<input type="checkbox"/>
Other	<input type="checkbox"/>

If location is Lymph Node, specify location

Abdominal Nodes	<input type="checkbox"/>
Aorto Caval Nodes	<input type="checkbox"/>
Axillary Nodes	<input type="checkbox"/>
Celiac Nodes	<input type="checkbox"/>
Cervical Nodes	<input type="checkbox"/>
Common Iliac Nodes	<input type="checkbox"/>
Épitrochlear Nodes	<input type="checkbox"/>
External Iliac Nodes	<input type="checkbox"/>
Femoral Nodes	<input type="checkbox"/>
Frontal Lobe	<input type="checkbox"/>
Hilar Nodes	<input type="checkbox"/>
Inguinal Nodes	<input type="checkbox"/>
Internal Iliac Nodes	<input type="checkbox"/>
Mandibular Nodes	<input type="checkbox"/>
Mediastinal Nodes	<input type="checkbox"/>
Mesenteric Nodes	<input type="checkbox"/>
Para-Aortic Nodes	<input type="checkbox"/>
Paracardiac Nodes	<input type="checkbox"/>

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Folder: Tumor Assessments >> Tumor Asmt -

Form: Target Lesions (2)

Generated On: 15 Sep 2020 16:43:48

- | | |
|-----------------------|--------------------------|
| Paratracheal Nodes | <input type="checkbox"/> |
| Parietal Lobe | <input type="checkbox"/> |
| Pelvic Nodes | <input type="checkbox"/> |
| Portal Nodes | <input type="checkbox"/> |
| Pre-Sacral Nodes | <input type="checkbox"/> |
| Retrocrural Nodes | <input type="checkbox"/> |
| Retroperitoneal Nodes | <input type="checkbox"/> |
| Sub-Carinal Nodes | <input type="checkbox"/> |
| Supraclavicular Nodes | <input type="checkbox"/> |
| Thoracic Nodes | <input type="checkbox"/> |
| Other Nodes | <input type="checkbox"/> |

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

Method of Assessment _____

- | | |
|----------------------|--------------------------|
| CT (spiral) | <input type="checkbox"/> |
| CT (conventional) | <input type="checkbox"/> |
| PET/CT | <input type="checkbox"/> |
| MRI | <input type="checkbox"/> |
| FDG-PET Scan | <input type="checkbox"/> |
| Bone Scan | <input type="checkbox"/> |
| Clinical Examination | <input type="checkbox"/> |
| Chest X-Ray | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

If Other please specify: _____

Diameter (mm) _____

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Folder: Tumor Assessments >> Tumor Asmt -
Form: Target Lesions (2)
Generated On: 15 Sep 2020 16:43:48

Diameter units mm

If measurement is not available, specify reason

Diameter Too Small to Measure
 Diameter Not Measured
 Undetectable

Lesion Number 2

Not applicable

Location of the Lesion

Gastroesophageal Junction
 Stomach
 Esophagus
 Liver
 Omentum/Peritoneum
 Lung
 Bone
 CNS
 Lymph Node
 Adrenals
 Kidney
 Pleura
 Bone Marrow
 Breast
 Head and Neck
 Colon
 Fallopian Tube
 Ovary

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Folder: Tumor Assessments >> Tumor Asmt -
Form: Target Lesions (2)
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Pancreas	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>

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Folder: Tumor Assessments >> Tumor Asmt -
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-
- Pericardial Effusion
Peripancreatic (Soft Tissue)
Pleural Cavity
Pleural Effusion
Prostate
Retroperitoneum
Ribs
Sacrum
Scapula
Skull
Small Bowel
Subcutis
Thyroid
T-Spine
Other
-

If location is Lymph Node, specify location

- Abdominal Nodes
Aorta Caval Nodes
Axillary Nodes
Celiac Nodes
Cervical Nodes
Common Iliac Nodes
Epitrochlear Nodes
External Iliac Nodes
Femoral Nodes
Frontal Lobe
Hilar Nodes
Inguinal Nodes
Internal Iliac Nodes
Mandibular Nodes
-

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-
- | | |
|-----------------------|--------------------------|
| Mediastinal Nodes | <input type="checkbox"/> |
| Mesenteric Nodes | <input type="checkbox"/> |
| Para-Aortic Nodes | <input type="checkbox"/> |
| Paracardiac Nodes | <input type="checkbox"/> |
| Paratracheal Nodes | <input type="checkbox"/> |
| Parietal Lobe | <input type="checkbox"/> |
| Pelvic Nodes | <input type="checkbox"/> |
| Portal Nodes | <input type="checkbox"/> |
| Pre-Sacral Nodes | <input type="checkbox"/> |
| Retrocrural Nodes | <input type="checkbox"/> |
| Retroperitoneal Nodes | <input type="checkbox"/> |
| Sub-Carinal Nodes | <input type="checkbox"/> |
| Supraclavicular Nodes | <input type="checkbox"/> |
| Thoracic Nodes | <input type="checkbox"/> |
| Other Nodes | <input type="checkbox"/> |
-

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

Method of Assessment _____

- | | |
|----------------------|--------------------------|
| CT (spiral) | <input type="checkbox"/> |
| CT (conventional) | <input type="checkbox"/> |
| PET/CT | <input type="checkbox"/> |
| MRI | <input type="checkbox"/> |
| FDG-PET Scan | <input type="checkbox"/> |
| Bone Scan | <input type="checkbox"/> |
| Clinical Examination | <input type="checkbox"/> |
| Chest X-Ray | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
-

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Folder: Tumor Assessments >> Tumor Asmt -

Form: Target Lesions (2)

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If Other please specify:

Diameter (mm)

Diameter units

mm

If measurement is not available, specify reason

Diameter Too Small to Measure

Diameter Not Measured

Undetectable

Lesion Number

3

Not applicable

Location of the Lesion

- Gastroesophageal Junction
- Stomach
- Esophagus
- Liver
- Omentum/Peritoneum
- Lung
- Bone
- CNS
- Lymph Node
- Adrenals
- Kidney
- Pleura
- Bone Marrow

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Folder: Tumor Assessments >> Tumor Asmt -

Form: Target Lesions (2)

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Breast	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Fallopian Tube	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>

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L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>
Peripancreatic (Soft Tissue)	<input type="checkbox"/>
Pleural Cavity	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Retroperitoneum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Bowel	<input type="checkbox"/>
Subcutis	<input type="checkbox"/>
Thyroid	<input type="checkbox"/>
T-Spine	<input type="checkbox"/>
Other	<input type="checkbox"/>

If location is Lymph Node, specify location

Abdominal Nodes	<input type="checkbox"/>
Aorta Caval Nodes	<input type="checkbox"/>
Axillary Nodes	<input type="checkbox"/>
Celiac Nodes	<input type="checkbox"/>
Cervical Nodes	<input type="checkbox"/>
Common Iliac Nodes	<input type="checkbox"/>
Epitrochlear Nodes	<input type="checkbox"/>
External Iliac Nodes	<input type="checkbox"/>
Femoral Nodes	<input type="checkbox"/>

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Folder: Tumor Assessments >> Tumor Asmt -

Form: Target Lesions (2)

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- | | |
|-----------------------|--------------------------|
| Frontal Lobe | <input type="checkbox"/> |
| Hilar Nodes | <input type="checkbox"/> |
| Inguinal Nodes | <input type="checkbox"/> |
| Internal Iliac Nodes | <input type="checkbox"/> |
| Mandibular Nodes | <input type="checkbox"/> |
| Mediastinal Nodes | <input type="checkbox"/> |
| Mesenteric Nodes | <input type="checkbox"/> |
| Para-Aortic Nodes | <input type="checkbox"/> |
| Paracardiac Nodes | <input type="checkbox"/> |
| Paratracheal Nodes | <input type="checkbox"/> |
| Parietal Lobe | <input type="checkbox"/> |
| Pelvic Nodes | <input type="checkbox"/> |
| Portal Nodes | <input type="checkbox"/> |
| Pre-Sacral Nodes | <input type="checkbox"/> |
| Retrocrural Nodes | <input type="checkbox"/> |
| Retroperitoneal Nodes | <input type="checkbox"/> |
| Sub-Carinal Nodes | <input type="checkbox"/> |
| Supraclavicular Nodes | <input type="checkbox"/> |
| Thoracic Nodes | <input type="checkbox"/> |
| Other Nodes | <input type="checkbox"/> |

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

Method of Assessment

- | | |
|-------------------|--------------------------|
| CT (spiral) | <input type="checkbox"/> |
| CT (conventional) | <input type="checkbox"/> |
| PET/CT | <input type="checkbox"/> |
| MRI | <input type="checkbox"/> |
| FDG-PET Scan | <input type="checkbox"/> |

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-
- Bone Scan
Clinical Examination
Chest X-Ray
Other
-

If Other please specify: _____

Diameter (mm) _____

Diameter units _____ mm

If measurement is not available, specify reason

- Diameter Too Small to
Measure
Diameter Not Measured
Undetectable
-

Lesion Number _____ 4

Not applicable

Location of the Lesion

Gastroesophageal Junction
Stomach
Esophagus
Liver
Omentum/Peritoneum
Lung
Bone
CNS

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Folder: Tumor Assessments >> Tumor Asmt -
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Lymph Node	<input type="checkbox"/>
Adrenals	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Bone Marrow	<input type="checkbox"/>
Breast	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Fallopian Tube	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>

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-
- Femur Neck
Femur Subtrochanter
Gallbladder
Humerus
Lateral Ventricle
L-Spine
Mediastinum
Mesenteric (Soft Tissue)
Muscle
Pelvic (Soft Tissue)
Pericardial Effusion
Peripancreatic (Soft Tissue)
Pleural Cavity
Pleural Effusion
Prostate
Retroperitoneum
Ribs
Sacrum
Scapula
Skull
Small Bowel
Subcutis
Thyroid
T-Spine
Other

If location is Lymph Node, specify location

- Abdominal Nodes
Aorta Caval Nodes
Axillary Nodes
Celiac Nodes

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Folder: Tumor Assessments >> Tumor Asmt -
Form: Target Lesions (2)
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Cervical Nodes	<input type="checkbox"/>
Common Iliac Nodes	<input type="checkbox"/>
Epitrochlear Nodes	<input type="checkbox"/>
External Iliac Nodes	<input type="checkbox"/>
Femoral Nodes	<input type="checkbox"/>
Frontal Lobe	<input type="checkbox"/>
Hilar Nodes	<input type="checkbox"/>
Inguinal Nodes	<input type="checkbox"/>
Internal Iliac Nodes	<input type="checkbox"/>
Mandibular Nodes	<input type="checkbox"/>
Mediastinal Nodes	<input type="checkbox"/>
Mesenteric Nodes	<input type="checkbox"/>
Para-Aortic Nodes	<input type="checkbox"/>
Paracardiac Nodes	<input type="checkbox"/>
Paratracheal Nodes	<input type="checkbox"/>
Parietal Lobe	<input type="checkbox"/>
Pelvic Nodes	<input type="checkbox"/>
Portal Nodes	<input type="checkbox"/>
Pre-Sacral Nodes	<input type="checkbox"/>
Retrocrural Nodes	<input type="checkbox"/>
Retroperitoneal Nodes	<input type="checkbox"/>
Sub-Carinal Nodes	<input type="checkbox"/>
Supraclavicular Nodes	<input type="checkbox"/>
Thoracic Nodes	<input type="checkbox"/>
Other Nodes	<input type="checkbox"/>

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

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Folder: Tumor Assessments >> Tumor Asmt -
Form: Target Lesions (2)
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Method of Assessment

- CT (spiral)
- CT (conventional)
- PET/CT
- MRI
- FDG-PET Scan
- Bone Scan
- Clinical Examination
- Chest X-Ray
- Other

If Other please specify:

Diameter (mm)

Diameter units

mm

If measurement is not available, specify reason

- Diameter Too Small to Measure
- Diameter Not Measured
- Undetectable

Lesion Number

5

Not applicable

Location of the Lesion

- Gastroesophageal Junction
- Stomach
- Esophagus

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Liver	<input type="checkbox"/>
Omentum/Peritoneum	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Bone	<input type="checkbox"/>
CNS	<input type="checkbox"/>
Lymph Node	<input type="checkbox"/>
Adrenals	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Bone Marrow	<input type="checkbox"/>
Breast	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Fallopian Tube	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>

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Form: Target Lesions (2)

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Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>
Peripancreatic (Soft Tissue)	<input type="checkbox"/>
Pleural Cavity	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Retroperitoneum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Bowel	<input type="checkbox"/>
Subcutis	<input type="checkbox"/>
Thyroid	<input type="checkbox"/>
T-Spine	<input type="checkbox"/>
Other	<input type="checkbox"/>

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Folder: Tumor Assessments >> Tumor Asmt -
Form: Target Lesions (2)
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If location is Lymph Node, specify location

- Abdominal Nodes
- Aorto Caval Nodes
- Axillary Nodes
- Celiac Nodes
- Cervical Nodes
- Common Iliac Nodes
- Epitrochlear Nodes
- External Iliac Nodes
- Femoral Nodes
- Frontal Lobe
- Hilar Nodes
- Inguinal Nodes
- Internal Iliac Nodes
- Mandibular Nodes
- Mediastinal Nodes
- Mesenteric Nodes
- Para-Aortic Nodes
- Paracardiac Nodes
- Paratracheal Nodes
- Parietal Lobe
- Pelvic Nodes
- Portal Nodes
- Pre-Sacral Nodes
- Retrocrural Nodes
- Retroperitoneal Nodes
- Sub-Carinal Nodes
- Supraclavicular Nodes
- Thoracic Nodes
- Other Nodes

If location is Other, or Lymph Node - Other, specify _____

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Folder: Tumor Assessments >> Tumor Asmt -

Form: Target Lesions (2)

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Date of Scan

Method of Assessment

- | | |
|----------------------|--------------------------|
| CT (spiral) | <input type="checkbox"/> |
| CT (conventional) | <input type="checkbox"/> |
| PET/CT | <input type="checkbox"/> |
| MRI | <input type="checkbox"/> |
| FDG-PET Scan | <input type="checkbox"/> |
| Bone Scan | <input type="checkbox"/> |
| Clinical Examination | <input type="checkbox"/> |
| Chest X-Ray | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
-

If Other please specify:

Diameter (mm)

Diameter units

mm

If measurement is not available, specify reason

- | | |
|-------------------------------|--------------------------|
| Diameter Too Small to Measure | <input type="checkbox"/> |
| Diameter Not Measured | <input type="checkbox"/> |
| Undetectable | <input type="checkbox"/> |
-

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Folder: Tumor Assessments >> Tumor Asmt -

Form: Non-Target Lesions (2)

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Location of the Lesion

Gastroesophageal Junction	<input type="checkbox"/>
Stomach	<input type="checkbox"/>
Esophagus	<input type="checkbox"/>
Liver	<input type="checkbox"/>
Omentum/Peritoneum	<input type="checkbox"/>
Lung	<input type="checkbox"/>
Bone	<input type="checkbox"/>
CNS	<input type="checkbox"/>
Lymph Node	<input type="checkbox"/>
Adrenals	<input type="checkbox"/>
Kidney	<input type="checkbox"/>
Pleura	<input type="checkbox"/>
Bone Marrow	<input type="checkbox"/>
Breast	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Fallopian Tube	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>

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Folder: Tumor Assessments >> Tumor Asmt -
Form: Non-Target Lesions (2)
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Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>
Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>
Peripancreatic (Soft Tissue)	<input type="checkbox"/>
Pleural Cavity	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Retroperitoneum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Bowel	<input type="checkbox"/>

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Folder: Tumor Assessments >> Tumor Asmt -
Form: Non-Target Lesions (2)
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Subcutis
Thyroid
T-Spine
Other

If location is Lymph Node, specify location

Abdominal Nodes
Aorto Caval Nodes
Axillary Nodes
Celiac Nodes
Cervical Nodes
Common Iliac Nodes
Epitrochlear Nodes
External Iliac Nodes
Femoral Nodes
Frontal Lobe
Hilar Nodes
Inguinal Nodes
Internal Iliac Nodes
Mandibular Nodes
Mediastinal Nodes
Mesenteric Nodes
Para-Aortic Nodes
Paracardiac Nodes
Paratracheal Nodes
Parietal Lobe
Pelvic Nodes
Portal Nodes
Pre-Sacral Nodes
Retrocrural Nodes
Retroperitoneal Nodes

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Folder: Tumor Assessments >> Tumor Asmt -

Form: Non-Target Lesions (2)

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Sub-Carinal Nodes

Supraclavicular Nodes

Thoracic Nodes

Other Nodes

If location is Other, or Lymph Node - Other, specify _____

Date of Scan _____

Method of Assessment

CT (spiral)

CT (conventional)

PET/CT

MRI

FDG-PET Scan

Bone Scan

Clinical Examination

Chest X-Ray

Other

If Other please specify:

Lesion Assessment

Complete Response

Non-CR/Non-PD

Progressive Disease

Not Evaluable

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Folder: Tumor Assessments >> Tumor Asmt -

Form: New Lesions

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Date of Scan

Method of Assessment

- CT (spiral)
CT (conventional)
PET/CT
MRI
FDG-PET Scan
Bone Scan
Clinical Examination
Chest X-Ray
Other
-

If Other please specify:

New Lesion Type

- Measurable
Not Measurable
-

Location of the Lesion

- Gastroesophageal Junction
Stomach
Esophagus
Liver
Omentum/Peritoneum
Lung
Bone
CNS
Lymph Node
Adrenals
Kidney
Pleura
-

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Folder: Tumor Assessments >> Tumor Asmt -
Form: New Lesions
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Bone Marrow	<input type="checkbox"/>
Breast	<input type="checkbox"/>
Head and Neck	<input type="checkbox"/>
Colon	<input type="checkbox"/>
Fallopian Tube	<input type="checkbox"/>
Ovary	<input type="checkbox"/>
Pancreas	<input type="checkbox"/>
Skin	<input type="checkbox"/>
Small Intestine	<input type="checkbox"/>
Rectum	<input type="checkbox"/>
Spinal	<input type="checkbox"/>
Spleen	<input type="checkbox"/>
Abdomen	<input type="checkbox"/>
Abdominal Wall	<input type="checkbox"/>
Acetabulum	<input type="checkbox"/>
Ascites	<input type="checkbox"/>
Biliary Tract/Gallbladder	<input type="checkbox"/>
Bladder	<input type="checkbox"/>
Cerebellum	<input type="checkbox"/>
Chest Wall	<input type="checkbox"/>
Clavicle	<input type="checkbox"/>
CNS (Brain)	<input type="checkbox"/>
Coccyx	<input type="checkbox"/>
C-Spine	<input type="checkbox"/>
Diaphragm	<input type="checkbox"/>
Femur Distal	<input type="checkbox"/>
Femur Midshaft	<input type="checkbox"/>
Femur Neck	<input type="checkbox"/>
Femur Subtrochanter	<input type="checkbox"/>
Gallbladder	<input type="checkbox"/>
Humerus	<input type="checkbox"/>

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Lateral Ventricle	<input type="checkbox"/>
L-Spine	<input type="checkbox"/>
Mediastinum	<input type="checkbox"/>
Mesenteric (Soft Tissue)	<input type="checkbox"/>
Muscle	<input type="checkbox"/>
Pelvic (Soft Tissue)	<input type="checkbox"/>
Pericardial Effusion	<input type="checkbox"/>
Peripancreatic (Soft Tissue)	<input type="checkbox"/>
Pleural Cavity	<input type="checkbox"/>
Pleural Effusion	<input type="checkbox"/>
Prostate	<input type="checkbox"/>
Retroperitoneum	<input type="checkbox"/>
Ribs	<input type="checkbox"/>
Sacrum	<input type="checkbox"/>
Scapula	<input type="checkbox"/>
Skull	<input type="checkbox"/>
Small Bowel	<input type="checkbox"/>
Subcutis	<input type="checkbox"/>
Thyroid	<input type="checkbox"/>
T-Spine	<input type="checkbox"/>
Other	<input type="checkbox"/>

If location is Lymph Node, specify location

Abdominal Nodes	<input type="checkbox"/>
Aorta Caval Nodes	<input type="checkbox"/>
Axillary Nodes	<input type="checkbox"/>
Celiac Nodes	<input type="checkbox"/>
Cervical Nodes	<input type="checkbox"/>
Common Iliac Nodes	<input type="checkbox"/>
Epitrochlear Nodes	<input type="checkbox"/>
External Iliac Nodes	<input type="checkbox"/>

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Folder: Tumor Assessments >> Tumor Asmt -

Form: New Lesions

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- Femoral Nodes
- Frontal Lobe
- Hilar Nodes
- Inguinal Nodes
- Internal Iliac Nodes
- Mandibular Nodes
- Mediastinal Nodes
- Mesenteric Nodes
- Para-Aortic Nodes
- Paracardiac Nodes
- Paratracheal Nodes
- Parietal Lobe
- Pelvic Nodes
- Portal Nodes
- Pre-Sacral Nodes
- Retrocrural Nodes
- Retroperitoneal Nodes
- Sub-Carinal Nodes
- SuprACLavicular Nodes
- Thoracic Nodes
- Other Nodes

If location is Other, or Lymph Node - Other, specify _____

New Lesion Status

- Equivocal (Not Progressive Disease)
- Unequivocal (Progressive Disease)
- Not evaluable

07.007 25Aug2020 CM: Master

Folder: Tumor Assessments >> Tumor Asmt -

Form: Overall RECIST Response Assessment

Generated On: 15 Sep 2020 16:43:48

Reason for Assessment

Scheduled

Unscheduled

If Unscheduled, Select Reason

Decline in ECOG
performance status
consistent with disease
progression

Physical examination or
systems review findings
consistent with disease
progression

Other

Other, specify _____

Date of CT/MRI _____

Target Lesions Response per RECIST

Complete Response

Partial Response

Stable Disease

Progressive Disease

Not Evaluable

Not Applicable

Non-target lesions response per RECIST

Complete Response

Non-CR/Non-PD

Progressive Disease

Not Evaluable

Not Applicable

Are there any New RECIST Lesions?

07.007 25Aug2020 CM: Master

Folder: Tumor Assessments >> Tumor Asmt -

Form: Overall RECIST Response Assessment

Generated On: 15 Sep 2020 16:43:48

Yes, Unequivocal
Progressive Disease
Yes, Equivocal Not
Progressive Disease
No

Overall RECIST Response

Complete Response
Partial Response
Stable Disease
Progressive Disease
Not Evaluable

Date of Overall RECIST Response

07.007 25Aug2020 CM: Master

**Folder: Tumor Assessments >> Tumor Asmt -
Form: Subsequent Tumor Assessment (Yes/No)
Generated On: 15 Sep 2020 16:43:48**

Was another tumor assessment performed?

Yes
No

07.007 25Aug2020 CM: Master

Folder: Bone Scan >> Bone Scan - Screening

Form: Bone Scan - Screening

Generated On: 15 Sep 2020 16:43:48

Bone Scan Date _____

Is There Radiolabeled Tracer (e.g., 99m Tc) Uptake in Metastatic Disease?

Yes

No

Image Not Evaluable

If Yes, Indicate Total Number of Lesions Related to metastatic disease at Screening:

1

2-4

5-9

10-20

>20

Comments Regarding the Image (if needed) _____

07.007 25Aug2020 CM: Master

Folder: Bone Scan >> Bone Scan - Screening

Form: Subsequent Bone Scan (Yes/No)

Generated On: 15 Sep 2020 16:43:48

Was another bone scan performed?

Yes

No

07.007 25Aug2020 CM: Master

Folder: Bone Scan >> Bone Scan - Week 8

Form: Bone Scan - Week 8

Generated On: 15 Sep 2020 16:43:48

Reason for Assessment

Scheduled

Unscheduled

If Unscheduled, Select Reason

Decline in ECOG
performance status
consistent with disease
progression

Physical examination or
systems review findings
consistent with disease
progression

Other

Other, specify _____

Bone Scan Date _____

Is there radiolabeled tracer (e.g., ^{99m}Tc) uptake in
metastatic disease?

Yes

No

Image Not Evaluable

If Yes, Indicate Total Number of New Lesions Compared
to Screening Bone Scan

0

1

2

3

4

5

>5

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Folder: Bone Scan >> Bone Scan - Week 8

Form: Bone Scan - Week 8

Generated On: 15 Sep 2020 16:43:48

Check Region(s) of NEW Disease Post-Screening

(Check all that apply)

Skull _____

Thorax _____

Spine _____

Pelvis _____

Extremities _____

Are there 2 or more NEW lesions on this Bone Scan
compared to the Screening Bone Scan?

Yes

No

Clinical Impression

Improved

Stable

Progression

Comments Regarding the Image (if needed)

07.007 25Aug2020 CM: Master

Folder: Bone Scan >> Bone Scan - Week 8

Form: Subsequent Bone Scan (Yes/No)

Generated On: 15 Sep 2020 16:43:48

Was another bone scan performed?

Yes

No

07.007 25Aug2020 CM: Master
Folder: Bone Scan >> Bone Scan -
Form: Bone Scan
Generated On: 15 Sep 2020 16:43:48

If Unscheduled, Select Reason	<input type="checkbox"/> Decline in ECOG performance status consistent with disease progression
	<input type="checkbox"/> Physical examination or systems review findings consistent with disease progression
	<input type="checkbox"/> Other

Other, specify _____

Bone Scan Date _____

Is there radiolabeled tracer (e.g., ^{99m}Tc) uptake in metastatic disease? Yes
No
Image Not Evaluable

If Yes, Indicate Total Cumulative Number of New Lesions
Since Week 8 Bone Scan

0
1
2
3
4
5
>5

07.007 25Aug2020 CM: Master
Folder: Bone Scan >> Bone Scan -
Form: Bone Scan
Generated On: 15 Sep 2020 16:43:48

Check Region(s) of NEW Disease Post-Week 8
(Check all that apply)

Skull _____

Thorax _____

Spine _____

Pelvis _____

Extremities _____

Has there been 2 or more NEW lesions as compared to
the Week 8 Bone Scan?

Yes

No

Were there at least 2 new lesions on 8 week scan with at
least 2 additional new lesions on the 16 week scan (2+2
rule) OR for scans after the 8 week scan, were there at
least 2 new lesions relative to the 8 weeks scan that
remained persistent (confirmed) on the subsequent
scan.

Yes

No

If YES, patient has met conditions for radiographic
progression by bone scan.

If NO, the patient does not have radiographic
progression by bone scan.

Clinical Impression

Improved

Stable

Progression

07.007 25Aug2020 CM: Master
Folder: Bone Scan >> Bone Scan -
Form: Bone Scan
Generated On: 15 Sep 2020 16:43:48

Comments Regarding the Image (if needed) _____

07.007 25Aug2020 CM: Master
Folder: Bone Scan >> Bone Scan -
Form: Subsequent Bone Scan (Yes/No)
Generated On: 15 Sep 2020 16:43:48

Was another bone scan performed?

Yes
No

07.007 25Aug2020 CM: Master
Folder: Adverse Event
Form: Adverse Events (Yes/No)
Generated On: 15 Sep 2020 16:43:48

Did the subject experience any adverse events during the study?

Yes
No

07.007 25Aug2020 CM: Master
Folder: Adverse Event
Form: Adverse Events
Generated On: 15 Sep 2020 16:43:48

Adverse Event

Symptomatic Skeletal Event?

Yes
No

Start Date

Start Time

Fixed Unit: (24 HR)

Ongoing?

Yes
No

If not Ongoing, End Date

Outcome

Recovered/Resolved
Recovering/Resolving
Not Recovered/Not Resolved
Recovered/Resolved with Sequelae
Fatal
Unknown

CTCAE Grade

Grade 1
Grade 2
Grade 3
Grade 4
Grade 5

07.007 25Aug2020 CM: Master
Folder: Adverse Event
Form: Adverse Events
Generated On: 15 Sep 2020 16:43:48

Is the adverse event serious?

Yes
No

AE Is Serious Due To (check all that apply)

Death

Life Threatening

Initial or Prolonged Hospitalization

Persistent or Significant Disability or Incapacity

Congenital Anomaly or Birth Defect

Other Medically Important Event (not covered by other serious criteria)

Relationship to Any Study Drug

Definitely Not Related
Probably Not Related
Possibly Related
Probably Related
Definitely Related

Action Taken with PSMA-617(check all that apply)

Dose Not Changed

Dose Reduced

Dose Interrupted

07.007 25Aug2020 CM: Master
Folder: Adverse Event
Form: Adverse Events
Generated On: 15 Sep 2020 16:43:48

Dose Withdrawn

Not Applicable

Action Taken with Best Supportive/Best Standard of Care (check all that apply)

Dose Not Changed

Dose Reduced

Dose Interrupted

Dose Withdrawn

Not Applicable

07.007 25Aug2020 CM: Master

Folder: Concomitant Medication/ Therapy

Form: Concomitant Medication/Therapy (Yes/No)

Generated On: 15 Sep 2020 16:43:48

Did the subject take any concomitant medications/therapies, including best supportive/best standard of care, during the study?

Yes

No

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Folder: Concomitant Medication/ Therapy

Form: Concomitant Medication/Therapy

Generated On: 15 Sep 2020 16:43:48

Reported Name of Drug, Medication or Therapy _____

Best Supportive/Best Standard of Care?

Yes

No

Dose _____

Dose Unit

%

Drops

g

L

mcg

mEq

mg

mL

Puffs

Sachets

Suppository

Tablespoon

Tablets

Teaspoon

units

IU

ug

Capsule

Application

Pack

Patch

Unknown

Other

07.007 25Aug2020 CM: Master
Folder: Concomitant Medication/ Therapy
Form: Concomitant Medication/Therapy
Generated On: 15 Sep 2020 16:43:48

If Dose Unit is Other, specify _____

Frequency

- Continuous
As Needed
Once
Daily
Twice per day
Three Times per day
Four Times per day
Five Times per day
Every Other day
Every Week
Every Two Weeks
Every Three Weeks
Twice per Week
Three Times per Week
Four Times per Week
Every Month
Every Two Months
Every Three Months
Every Four Months
Every Six Months
Unknown
Other
-

If Frequency is Other, specify _____

Route of Administration

- Oral
Subcutaneous
Topical
-

07.007 25Aug2020 CM: Master
Folder: Concomitant Medication/ Therapy
Form: Concomitant Medication/Therapy
Generated On: 15 Sep 2020 16:43:48

- | | |
|--------------------------|--------------------------|
| Transdermal | <input type="checkbox"/> |
| Intraocular | <input type="checkbox"/> |
| Intramuscular | <input type="checkbox"/> |
| Intralesional | <input type="checkbox"/> |
| Intraperitoneal | <input type="checkbox"/> |
| Intravenous | <input type="checkbox"/> |
| Ophthalmic | <input type="checkbox"/> |
| Nasal | <input type="checkbox"/> |
| Respiratory (Inhalation) | <input type="checkbox"/> |
| Rectal | <input type="checkbox"/> |
| Sublingual | <input type="checkbox"/> |
| Swish and Spit | <input type="checkbox"/> |
| Swish and Swallow | <input type="checkbox"/> |
| Unknown | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

If Route of Administration is Other, specify _____

Start Date _____

Ongoing? Yes No

If not Ongoing, End Date _____

Indication _____

Relationship Adverse Event
Medical History

07.007 25Aug2020 CM: Master
Folder: Concomitant Medication/ Therapy
Form: Concomitant Medication/Therapy
Generated On: 15 Sep 2020 16:43:48

Prophylaxis
Study Disease
Other

Please select AE:

Please select MH:

Other, specify:

07.007 25Aug2020 CM: Master

Folder: Concurrent Surgical / Therapeutic Procedures

Form: Concurrent Surgical / Therapeutic Procedures (Yes/No)

Generated On: 15 Sep 2020 16:43:48

Did the subject receive any Surgical/Therapeutic
Procedures within 90 days of Cycle 1 Day 1 through the
End of Treatment Visit?

Yes

No

07.007 25Aug2020 CM: Master

Folder: Concurrent Surgical / Therapeutic Procedures

Form: Concurrent Surgical / Therapeutic Procedures

Generated On: 15 Sep 2020 16:43:48

Procedure/therapy name

Best Supportive/Best Standard of Care?

Yes

No

Symptomatic Skeletal Event?

Yes

No

Start date

Ongoing

Yes

No

Stop date

Cytology/Pathology

Negative for Tumor

Positive for Tumor

Suspicious for Tumor

Inadequate Sample

Not Applicable

Unknown

Other

Other, specify:

Indication

Relationship

Adverse Event

07.007 25Aug2020 CM: Master

Folder: Concurrent Surgical / Therapeutic Procedures

Form: Concurrent Surgical / Therapeutic Procedures

Generated On: 15 Sep 2020 16:43:48

-
- | | |
|-------------------|--------------------------|
| Medical History | <input type="checkbox"/> |
| Diagnostic/Biopsy | <input type="checkbox"/> |
| Study Disease | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
-

Please select AE: _____

Please select MH: _____

Other, specify: _____

07.007 25Aug2020 CM: Master

Folder: Unscheduled Visits >> Unscheduled Visit

Form: Visit Date

Generated On: 15 Sep 2020 16:43:48

Visit Date

07.007 25Aug2020 CM: Master

Folder: Unscheduled Visits >> Unscheduled Visit

Form: Unscheduled Visit

Generated On: 15 Sep 2020 16:43:48

Check all that apply

ECG

ECOG Performance Status

Physical Exam

Vital Signs

Laboratory Sample Collection

07.007 25Aug2020 CM: Master

Folder: Unscheduled Visits >> Unscheduled Visit

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

07.007 25Aug2020 CM: Master

Folder: Unscheduled Visits >> Unscheduled Visit

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

Clinician or Nurse felt the patient was too ill

Patient felt it was inconvenient, takes too much time

Patient felt it was a violation of privacy

Patient didn't understand the actual language/illiterate

Administrative failure to distribute the questionnaire to the patient

Translation unavailable

Other

If Other, specify

Questionnaire

EQ-5D-5L

FACT-P

BPI-SF

Questionnaire Completed?

Yes

No

If No, Specify

Patient felt too ill

07.007 25Aug2020 CM: Master

Folder: Unscheduled Visits >> Unscheduled Visit

Form: Quality of Life Questionnaire Completion

Generated On: 15 Sep 2020 16:43:48

- Clinician or Nurse felt the
patient was too ill
Patient felt it was
inconvenient, takes too
much time
Patient felt it was a
violation of privacy
Patient didn't understand
the actual
language/illiterate
Administrative failure to
distribute the questionnaire
to the patient
Translation unavailable
Other

If Other, specify _____

07.007 25Aug2020 CM: Master

Folder: Unscheduled Visits >> Unscheduled Visit

Form: Laboratory Sample Collection (Unscheduled)

Generated On: 15 Sep 2020 16:43:48

Date of Lab Sample Collection

Laboratory Test

- | | |
|--------------|--------------------------|
| Chemistry | <input type="checkbox"/> |
| Hematology | <input type="checkbox"/> |
| Serum/Plasma | <input type="checkbox"/> |
| Testosterone | <input type="checkbox"/> |
| PSA | <input type="checkbox"/> |
| Urinalysis | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |
-

If Other, specify

07.007 25Aug2020 CM: Master

Folder: Unscheduled Visits >> Unscheduled Visit

Form: Vital Signs (Unscheduled)

Generated On: 15 Sep 2020 16:43:48

Date _____

Weight
(xxx.x) _____

kg
lb

Respiratory Rate - breaths/min
(xxx) _____

Systolic Blood Pressure - mmHg
(xxx) _____

Diastolic Blood Pressure - mmHg
(xxx) _____

Pulse - bpm
(xxx) _____

07.007 25Aug2020 CM: Master

Folder: Unscheduled Visits >> Unscheduled Visit

Form: Physical Examination

Generated On: 15 Sep 2020 16:43:48

Was Physical Examination performed?

Yes

No

Date of Examination

07.007 25Aug2020 CM: Master

Folder: Unscheduled Visits >> Unscheduled Visit

Form: ECG

Generated On: 15 Sep 2020 16:43:48

Was an ECG performed?

Yes

No

Date of ECG

Heart Rate (xxx)

Fixed Unit: bpm

PR Interval (xxx.x)

Fixed Unit: msec

RR Interval (xxx.x)

Fixed Unit: msec

QRS Interval (xxx.x)

Fixed Unit: msec

QTc Interval (xxxxx)

Fixed Unit: msec

ECG Interpretation

Normal

Abnormal - Clinically

Significant

Abnormal - Not Clinically

Significant

Not Evaluable

Not Done

If Abnormal - Clinically Significant, describe

07.007 25Aug2020 CM: Master

Folder: Unscheduled Visits >> Unscheduled Visit

Form: ECOG Performance Status

Generated On: 15 Sep 2020 16:43:48

Was ECOG Performance Status performed?

Yes
No

Date of ECOG Performance Status

ECOG Performance Status

0
1
2
3
4
5

GRADE

- 0 Fully active, able to carry on all pre-disease performance without restriction
- 1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
- 2 Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- 3 Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
- 4 Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
- 5 Dead

07.007 25Aug2020 CM: Master

Folder: Transferred Subject Identification

Form: Transferred Subject Identification

Generated On: 15 Sep 2020 16:43:48

Previous site number _____

Subject's screening number at the original site (S##) _____

Site number of the site the subject was transferred to _____

What is the first cycle visit subject completed at new site?

- Cycle 1 Day 1
- Cycle 1 Day 8
- Cycle 1 Day 15
- Cycle 1 Day 22
- Cycle 1 Day 29
- Cycle 1 Day 36
- Cycle 2 Day 1
- Cycle 2 Day 15
- Cycle 2 Day 29
- Cycle 3 Day 1
- Cycle 3 Day 15
- Cycle 3 Day 29
- Cycle 4 Day 1
- Cycle 4 Day 15
- Cycle 4 Day 29
- Cycle 5 Day 1
- Cycle 5 Day 15
- Cycle 5 Day 29
- Cycle 6 Day 1
- Cycle 6 Day 15
- Cycle 6 Day 29
- Cycle 7 Day 1
- Cycle 8 Day 1
- Cycle 9 Day 1

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Folder: Transferred Subject Identification

Form: Transferred Subject Identification

Generated On: 15 Sep 2020 16:43:48

Cycle 10 Day 1

End of Treatment

Long-Term Follow-Up

07.007 25Aug2020 CM: Master
Form: Subject
Generated On: 15 Sep 2020 16:43:48

Site ID _____

Screening Number
please enter the 2-digit number after the "S" _____

PSMA-617-01 eCRF Completion Guidelines _____

Screening ID _____