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### Screening Visit

**Patient Name:** ________________  ________________  
(first)  (last)

**Pt. Study ID#:** __________

**Date of Visit (dd/Mmm/yyyy):** _____/_____/_____

**Informed Consent Signed:** Date _____/_____/______  
(Time: ____:____ □ am □ pm)

#### SECTION 1. PHYSICAL EXAM

<table>
<thead>
<tr>
<th>Height</th>
<th>Weight</th>
<th>Blood Pressure</th>
<th>Heart Rate</th>
<th>Respiration</th>
<th>Temperature</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>System</th>
<th>Normal</th>
<th>Abnormal</th>
<th>If abnormal, briefly describe:</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEENT</td>
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<td>Chest</td>
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<td>Cardiovascular</td>
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<td>Musculoskeletal</td>
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<tr>
<td>Neurological</td>
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</tbody>
</table>

#### SECTION 2. CONCOMITANT MEDICATIONS (list all medications taken within xxx days of visit)

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dose</th>
<th>Regimen</th>
<th>Indication</th>
<th>Date Started</th>
<th>Date Disc.</th>
<th>Continuing, Medication (y/n)</th>
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#### SECTION 3. SOMATOSTATIN THERAPY

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dose</th>
<th>Route</th>
<th>Regimen</th>
<th>Date of Last Dose</th>
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</thead>
<tbody>
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</table>
SECTION 4. Serum Pregnancy Test Required? □ yes; complete below □ no

Date of Test (dd/Mmm/yyyy): _____/_____/_____

Results: □ negative □ positive: STOP – patient is not eligible

SECTION 5. Using x-ray Contrast? □ yes; first obtain serum creatinine level □ no

Date of Test (dd/Mmm/yyyy): _____/_____/_____

Results:______________ Acceptable: □ yes □ no: STOP – patient is not eligible

SECTION 6. Octreoscan Available □ yes; complete below □ no

Date of Octreoscan (dd/Mmm/yyyy): _____/_____/_____

SECTION 7. Subject Meets All Inclusion Criteria

□ yes: schedule Ga-68 DOTAXXXX scan

□ no: STOP – patient is not eligible

Person Completing this Form: ___________________________ on _____/_____/_____

Printed Name ___________________________ Date (dd/Mmm/yyyy)

Signature of Person Completing this Form: ___________________________
Image Visit – Baseline

Patient Name: ___________________________ ________________________
(first) (last)
Pt. Study ID#: _____________

Date of Visit (dd/Mmm/yyyy): ____/_____/_____

SECTION 1. PHYSICAL EXAM

<table>
<thead>
<tr>
<th>Time</th>
<th>Blood Pressure</th>
<th>Heart Rate</th>
<th>Respiration</th>
<th>Temperature</th>
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</table>

Any changes in medical history since the Screening Visit?

☐ yes; note changes in template below
☐ no

System | Briefly describe change:
-------|--------------------------------------------------
HEENT
Chest
Cardiovascular
Abdomen
Integument
Musculoskeletal
Neurological

Person Completing this Section: ___________________________ on _____/_____/_____
Printed Name
Date (dd/Mmm/yyyy)

Signature of Person Completing this Section: ___________________________

SEND THIS FORM TO THE PET CENTER WITH THE SUBJECT.

THE REMAINDER OF THIS FORM IS TO BE COMPLETED IN THE PET CENTER:

SECTION 2. URINE PREGNANCY TEST REQUIRED

☐ yes; complete below
☐ no

Date performed: ____/_____/_____   Time: _____:_____
(dd/Mmm/yyyy)   am  pm

Results:
☐ negative
☐ positive; STOP: PATIENT IS NOT ELIGIBLE
The Use of DOTA-XXX .... Study

SECTION 3.  IV Inserted  □ yes; complete below  □ no
Location: □ right arm  □ left arm  □ other ________________

SECTION 4.  Sedative Used  □ yes; complete below  □ no
Responsible person with the subject: □ yes (relationship to subject) ________________
□ No; DO NOT ADMINISTER SEDATIVE

SECTION 5.  Ga-68 DOTA-XXX PET/CT Scan Acquisition

<table>
<thead>
<tr>
<th>Drug Administered</th>
<th>Dose (mg)</th>
<th>Route</th>
<th>Time</th>
</tr>
</thead>
</table>

Ga-68 DOTA-XXX Dosing

Initial Dose (mCi)  Injection Time  :  □ am □ pm
Residual Dose (mCi)  Time Measured  :  □ am □ pm

PET Scan

Start Time  :  □ am □ pm
End Time  :  □ am □ pm

SECTION 6.  Vital Signs at Completion of Scan

<table>
<thead>
<tr>
<th>Time</th>
<th>Blood Pressure</th>
<th>Heart Rate</th>
<th>Respiration</th>
<th>Temperature</th>
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<td>□ pm</td>
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</table>

SECTION 7.  Adverse Events  □ none
□ yes; Complete the Adverse Event Form and follow protocol and IRB guidelines for reporting any Serious Adverse Event.

SECTION 8.  Post-Scan Follow-up Phone Call (24 hours after the study scan)

Phone number to call: ________________________  Subject phone number? □ yes  □ no
If no, Name ________________________ and Relationship of person ________________________ at the number

Person Completing this Section: ________________________ on ______/_____/______
Printed Name ____________________________ Date (dd/Mmm/yyyy)

Signature of Person Completing this Section: ________________________________
### ADVERSE EVENT FORM - BASELINE

**Ga-68 DOTA-XXX [abbreviated study name]**  
[study site ID#]

**Date of Baseline Study Scan**  
(dd/MM/yyyy)

**Study Patient ID #**

Were there any adverse events reported during the 24 hours after Ga-68 DOTA-XXX injection?  
- YES - complete the information below  
- NO - proceed to the end of form and sign

<table>
<thead>
<tr>
<th>AE #</th>
<th>Description of AE</th>
<th>Date of Onset</th>
<th>Date of Resolution</th>
<th>Serious* (1=yes / 2=no)</th>
<th>Grade</th>
<th>Action</th>
<th>Treatment</th>
<th>Outcome</th>
<th>Attribution</th>
<th>Imaging</th>
<th>Investigator</th>
<th>Initials</th>
</tr>
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</table>

*NOTE: Serious Adverse Events must be reported to ------------------------ at ----------------- within 24 hours of knowledge of event

<table>
<thead>
<tr>
<th>Scoring Legend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade</td>
</tr>
<tr>
<td>1=Mild</td>
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<tr>
<td>2=Moderate</td>
</tr>
<tr>
<td>3=Severe/medically significant</td>
</tr>
<tr>
<td>4=Life-threatening</td>
</tr>
<tr>
<td>5=Death</td>
</tr>
</tbody>
</table>

Are there additional adverse events to report?  
- YES - complete additional AE Form pages as necessary  
- NO - sign and date form

Person Completing Form _________________________________  |  Signature _________________________________

Date From Completed: ____/______/______ (dd/MM/yyyy)  |  Investigator's Signature _________________________________
Image Interpretation – Baseline

Patient Name: (first) ____________________________ (last) ____________________________  Pt. ID# __________

Date of Interpretation (dd/Mmm/yyyy): ______/_____/_____

1. Date of Ga-68 DOTA-XXX PET/CT scan (dd/Mmm/yyyy): ______/_____/_____

2. Were images able to be interpreted?  □ Yes  □ No: check all that apply; STOP - sign and date form
   □ Patient body weight unknown
   □ Injection time unknown
   □ Scan start time unknown
   □ Injected dose unknown
   □ Scanner not calibrated appropriately
   □ Uptake outside protocol time window
   □ Artifacts on CT (overlying all possible target lesions)
   □ Excessive patient movement
   □ Unacceptable/poor overall image quality
   □ Other; specify ____________________________________________

3. Lesion Identification and Reporting
   3a. Biodistribution of Ga-68 DOTA-XXX was as expected for the agent □ Yes  □ No
   3b. Targeted tumor located within the field of view □ Yes  □ No
   3c. Scan identified location(s) of an unknown primary □ Yes  □ No
   3d. Record information on no more than 5 of the hottest lesions, with no more than 2 lesions per organ

<table>
<thead>
<tr>
<th>Lesion #</th>
<th>✓ if seen OR mark “n/a”</th>
<th>Lesion Location</th>
<th>Lesion Size</th>
<th>SUVmax</th>
<th>SUVpeak optional*</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

*if available on analysis workstation

4. Were areas of tumor involvement prospectively visible on conventional imaging?
   □ Yes; check all tests that apply (do we need to know this?)
   □ Other imaging
   □ Clinical tests
   □ Laboratory data
   □ No
Did results of the Ga-68 DOTA-XXX scan have an impact on care?

- [ ] Yes; check all that apply:
  - [ ] Change in stage
  - [ ] Change in prognosis
  - [ ] Change in treatment

- [ ] No

**IMAGE REVIEW ATTESTATION**

**Primary Reviewer**

- [ ] Blinded Read: Yes
- [ ] No
- [ ] Not applicable

Printed Name ____________________________ Date of Review ____ /_______/_____

**Secondary Reviewer**

- [ ] Not applicable

Printed Name ____________________________ Date of Review ____ /_______/_____

Agree with Primary Reader:  [ ] Yes  [ ] No

**Person Completing this Form:** ____________________________ on ____/_______/_____

Printed Name ____________________________ Date (dd/Mmm/yyyy)

**Signature of Person Completing this Form:** ____________________________

**Investigators Signature:** ____________________________
24-Hour Follow-Up Call
Post-Ga-68 DOTA-XXX Injection

Patient Name (first): ______________________ (last) ______________________ Pt. ID#: __________

Date of Injection: _____/_____/_______ Time of Injection: _____:_____ □ am □ pm

Date of Call: _____/_____/_______ Time of Call: _____:_____ □ am □ pm

Person Providing Information on the Subject: ____________________________________________
(example: self [if subject], spouse, parent, etc)

Any new symptoms since the study PET scan was performed □ Yes □ No

If yes, briefly describe: ______________________________________________________________

__________________________________________________________________________________

Record all adverse events reported by the subject or representative on the study Adverse Event Form. If any are thought to be Serious, follow protocol and IRB guidelines in reporting a Serious Adverse Event.

If unable to obtain follow-up information on the first attempt, list subsequent follow-up efforts:

<table>
<thead>
<tr>
<th>Date (dd/Mmm/yyyy)</th>
<th>Time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ am □ pm</td>
<td>□ no answer</td>
<td>□ no information available</td>
</tr>
<tr>
<td>□ am □ pm</td>
<td>□ no answer</td>
<td>□ no information available</td>
</tr>
<tr>
<td>□ am □ pm</td>
<td>□ no answer</td>
<td>□ no information available</td>
</tr>
</tbody>
</table>

Person Completing this Form: ____________________________________________ on _____/_____/_______

Printed Name: ____________________________________________ Date (dd/Mmm/yyyy)

Signature of Person Completing this Form: ____________________________________________

DOTA-XXX Follow-up Call
Clinical Trials Network
Image Visit – Follow-up

Patient Name: ___________________________ ________________________  Pt. Study ID#: __________
(first) (last)
Date of Visit (dd/Mmm/yyyy): _____/_____/_____

SECTION 1. PHYSICAL EXAM

<table>
<thead>
<tr>
<th>Time</th>
<th>Blood Pressure</th>
<th>Heart Rate</th>
<th>Respiration</th>
<th>Temperature</th>
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</tbody>
</table>

Any changes in medical history since the Screening Visit?

☐ yes: note changes in template below  ☐ no

System  Briefly describe change

HEENT
Chest
Cardiovascular
Abdomen
Integument
Musculoskeletal
Neurological

SECTION 2. Was X-ray Contrast Used?  ☐ yes; obtain serum creatinine level  ☐ no

Date of Test (dd/Mmm/yyyy): _____/_____/_____  
Results:______________ Acceptable:  ☐ yes  ☐ no; action taken _______________________

SECTION 3. Serious Adverse Event Reporting

Has any serious adverse events occurred since the follow-up phone call?  ☐ yes  ☐ no

If yes, briefly describe:____________________________________

NOTE: Complete the Adverse Event Form and follow protocol and IRB guidelines for reporting a Serious Adverse Event.

Person Completing this Form: _____________________________ on _____/_____/_____

Printed Name  Date (dd/Mmm/yyyy)

Signature of Person Completing this Form: ________________________________
ADVERSE EVENT FORM - FOLLOW-UP

Date of Follow-up Study Scan __/______/______ (dd/Mmm/yyyy) Study Patient ID # ___________________

Were there any adverse events reported during the 24 hours after the Ga-68 DOTA-XXX injection?

- YES - complete the information below
- NO - proceed to the end of form and sign

<table>
<thead>
<tr>
<th>AE #</th>
<th>Description of AE</th>
<th>Date of Onset</th>
<th>Date of Resolution</th>
<th>Serious* (1=yes / 2=no)</th>
<th>Grade</th>
<th>Action</th>
<th>Treatment</th>
<th>Outcome</th>
<th>Attribution</th>
<th>Imaging Investigator</th>
<th>Initials</th>
</tr>
</thead>
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</tbody>
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*NOTE: Serious Adverse Events must be reported to ----------------------- at ----------------- within 24 hours of knowledge of event

Are there additional adverse events to report?

- YES - complete additional AE Form pages as necessary
- NO - sign and date form

Person Completing Form _________________________________ Signature ________________________________

Date From Completed: __/______/______ (dd/Mmm/yyyy) Investigator’s Signature ________________________________

Scoring Legend

<table>
<thead>
<tr>
<th>Grade</th>
<th>Action:</th>
<th>Outcome:</th>
<th>Attribution:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1=Mild</td>
<td>1=None</td>
<td>1=Resolved</td>
<td>1=Unrelated</td>
</tr>
<tr>
<td>2=Moderate</td>
<td>2=Scan interrupted but completed</td>
<td>2=Ongoing</td>
<td>2=Unlikely</td>
</tr>
<tr>
<td>3=Severe/medically significant</td>
<td>3=Scan not completed</td>
<td>3=Hospitalized</td>
<td>3=Possible</td>
</tr>
<tr>
<td>4=Life-threatening</td>
<td>3=Scan not completed</td>
<td>4=Death</td>
<td>4=Probable</td>
</tr>
<tr>
<td>5=Death</td>
<td></td>
<td></td>
<td>5=Definite</td>
</tr>
</tbody>
</table>
Image Interpretation – Follow-Up

Patient Name: (first) ___________________ (last) ___________________  Pt. ID# __________

Date of Interpretation (dd/Mmm/yyyy): ____/_____/______

1. Date of Ga-68 DOTA-XXX PET/CT scan (dd/Mmm/yyyy): ____/_____/______

2. Were images able to be interpreted?  □ Yes  □ No: check all that apply; STOP - sign and date form
   □ Patient body weight unknown
   □ Injection time unknown
   □ Scan start time unknown
   □ Injected dose unknown
   □ Scanner not calibrated appropriately
   □ Uptake outside protocol time window
   □ Artifacts on CT (overlying all possible target lesions)
   □ Excessive patient movement
   □ Unacceptable/poor overall image quality
   □ Other; specify ________________________________________________

3. Lesion Identification and Reporting
   3a. Biodistribution of Ga-68 DOTA-XXX was as expected for the agent  □Yes  □ No
   3b. Targeted tumor located within the field of view  □ Yes  □ No
   3c. Scan identified location(s) of an unknown primary  □ Yes  □ No
   3d. Size of previously identified lesions altered (grew or shrunk) post-therapy  □ Yes  □ No
   3e. New lesions appearing since baseline scan  □ Yes  □ No
   3f. Record information on no more than 5 of the hottest lesions, with no more than 2 lesions per organ

<table>
<thead>
<tr>
<th>Lesion #</th>
<th>✓ if seen OR mark “n/a”</th>
<th>Lesion Location</th>
<th>Lesion Size</th>
<th>SUVmax</th>
<th>SUVpeak optional*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2</td>
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<td>4</td>
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<tr>
<td>5</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

* if available on analysis workstation

3g. If the hottest lesion is new (not listed as a lesion at Baseline), record the information below.

<table>
<thead>
<tr>
<th>Lesion #</th>
<th>Lesion Location</th>
<th>Lesion Size</th>
<th>SUVmax</th>
<th>SUVpeak optional*</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. Were areas of tumor involvement prospectively visible on conventional imaging?
   - Yes; check all tests that apply (do we need to know this?)
     - Other imaging
     - Clinical tests
     - Laboratory data
   - No

5. Did results of the Ga-68 DOTA-XXX scan have an impact on care?
   - Yes; check all that apply:
     - Change in stage
     - Change in prognosis
     - Change in treatment
   - No

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**IMAGE REVIEW ATTESTATION**

**Primary Reviewer**
- Blinded Read
  - Yes
  - No
  - Not applicable
- Printed Name ____________________________ Date of Review ____ /_______/_____

**Secondary Reviewer**
- Not applicable
- Blinded Read
  - Yes
  - No
- Printed Name ____________________________ Date of Review ____ /_______/_____
- Agree with Primary Reader:  □ Yes  □ No

---

**Person Completing this Form:** ____________________________ on ____/_______/_____
- Printed Name ____________________________ Date (dd/Mmm/yyyy)

**Signature of Person Completing this Form:** ____________________________

**Investigators Signature:** ____________________________
Investigational Ga-68 DOTA-XXX Record

Pt. Study ID#: ____________  Date of Scan (dd/Mmm/yyyy): _____/_____/______

Date of Drug Receipt: _____/_____/______  Time of Drug Receipt: _____: ____  □ am  □ pm

Drug Received by: ____________________________  Product Lot ID Number: ________________

Provider: □ In-house  □ External: (name)______________________ (location)_____________________

Attach Investigational Drug label in the box below.

Affix label here*

Person Completing this Form: ____________________________ on _____/_____/______

Printed Name    Date (dd/Mmm/yyyy)

Signature of Person Completing this Form: ____________________________