ACRIN 6665
Malignant GI Stromal Tumors: Treatment Monitoring with PET

CRF Set
ACRIN PET Imaging/Primary and Recurrent Operable Malignant GIST Technical Assessment Form

If this is a revised or corrected form, indicate by checking box.

Instructions: The TA form is to be completed by the Technologist at the ACRIN site for each time point specified in the protocol, i.e., question 1 on the form. The completed form is faxed to R. Badawi, Ph.D., Dana Farber Cancer Institute. The original paper form is mailed to the ACRIN Headquarters. PET images are to be transmitted as defined in Appendix VIII. Please see attached instructions (page 3) for image transfer and data submission address. All dates must be reported as mm-dd-yyyy. All time fields must be reported in military format, i.e., 1:00 pm = 13:00 hrs. Code all questions unless otherwise specified.

PET TIME-POINT INFORMATION

1. [1] Protocol Imaging time point (if Q1 is code 4, complete Q4 and sign and date form)
   1. Baseline PET (pre-Gleevec therapy)
   2. Week 1 PET (at 24 hrs to 7 days post-initiation of Gleevec therapy)
   3. Week 4 or week 8 PET (prior to surgery)
   4. PET imaging not done, specify time point and complete item 4
      (i.e., baseline, week 1, week 4 or week 8) [2]

2. Date of PET imaging [3] mm dd yyyy

3. Date of PET image transfer [4] mm dd yyyy

4. [5] Was PET imaging completed?
   1. No*
   2. Yes
   3. Unknown
   [6] *If No, provide reason:
      1. Scheduling problem
      2. Equipment failure
      3. Patient refusal
      4. Medical reason
      5. Injection site complications
      6. Claustrophobia
      7. Other, specify [7]
      99 Unknown

5. [8] Location of injection site
   1. Right antecubital
   2. Right wrist
   3. Left antecubital
   4. Left wrist
   5. Right foot
   6. Left foot
   7. Other, specify [9]
   99 Unknown

6. [10] Primary tumor site
   1. Stomach
   2. Small Intestine
   3. Colon
   4. Other, specify [11]

PET Data Acquisition and Pre-processing
(Patient’s weight/height are measured on the day of imaging, not verbally relayed by the patient)

7. [12] Patient voided immediately pre-imaging?
   1. No
   2. Yes

8. [13] Patient voided immediately post-imaging?
   1. No
   2. Yes

9. Duration of patient fasting pre-PET imaging [14] hours (recorded up to the time of FDG injection)

10. Blood glucose at start of PET imaging (record value measured before FDG injection) [15] mg/dl

11. Patient weight (measured on day of scan) [16] kg

12. Patient height (measured) [17] cm

13. [18] Any radiotracer infiltration at injection site noted?
   0. None
   1. Minor (estimated to be less than 20% of dose)
   2. Severe (estimated to be more than 20% of dose)

14. Dose assay [19] mCi

15. Time of dose assay (military time) [20]:

16. Time of injection (military time) [21]:

ACRIN 6665 TA 4/02 1 of 4
17. Number of bed positions scanned
17a. mm Overlap of bed positions
18. IF INTERLEAVED EMISSION-TRANSMISSION SCANS USED:
18a. Minutes duration of transmission scan per bed
18b. Minutes duration of emission scan per bed
19. IF NON-INTERLEAVED EMISSION-TRANSMISSION SCANS USED:
19a. Minutes duration of transmission scan
20. Emission scan
   start time (military time)
   finish time (military time)
21. Emission scan dead time correction applied
   1. No
   2. Yes
22. Transmission scan processing used
   1. Segmentation
   2. Emission-subtraction
   3. Segmentation and emission subtraction
   4. Other, specify
23. Emission acquisition mode
   1. 2D
   2. 3D
24. Reconstruction algorithm used
   (complete all that apply)
   1. FORE
   2. RAMLA: Number of iterations:
   3. OSEM: Number of iterations:
   4. 3DRP
   5. FBP
25. Filter used for reconstruction
25a. Filter dimensions
   1. 2D filter
   2. 3D filter
26. Scatter Correction applied?
   1. No*
   2. Bergstrom
   3. Model-based
   4. Energy-window
   5. Tail-fit
   6. Other specify
27. Random Correction applied?
   1. No*
   2. Delayed window subtraction
   3. Tail fit
   4. Other specify
28. Pixel size of reconstructed images
29. Slice thickness of reconstructed images
F-18-FDG Procurement

30. **F-18-FDG Source**
   1. Synthesized
   2. Purchased
      If synthesized*, complete Q31, if F-18-FDG is purchased**, complete 32.

31. *If F-18-FDG is synthesized, provide the following
31a. Method ___________
31b. **Pyrogen test result**
   1. Passed
   2. Failed
   98 Not done

31c. Radiochemical purity test result: ___________
   Not done

32. **If F-18-FDG is purchased, provide the name of the pharmacy licensed to provide F-18-FDG
   ___________

COMMENTS: ___________

PRINT NAME OF PERSON COMPLETING FORM ___________
DATE FORM COMPLETED ___________
Image transmission via internet:

1. If transmitted by FTP, the following conventions and procedures must be observed. The primary folder on the FTP site is named 6665. A sub-folder must be created under 6665 with the institution acronym or ACRIN institution number as the folder name. Under this subfolder, individual subfolders must be created for each case to be submitted, with the folder name being the ACRIN case number. Do not send compressed or encrypted files. All patient identifying information must be scrubbed from the file header and/or image. If identification or clinical information needs to be sent for purposes of image review, it should be sent in an e-mail to the designated review site. When images (PET, CT) are transmitted via FTP, an e-mail should be sent to ACRIN headquarters specifying the case number sent, the institution it was sent from, and the number of images submitted. This e-mail should be sent to alevering@phila.acr.org and copied to rwelsch@phila.acr.org.

FTP Images via internet to:
Host: ftp://xray.acrin.org or ftp://206.137.103.34
Userid: 6665
Password: gist

2. Data Form and CT Scan Reports Submission

A. Fax completed TA form to:
   R. Badawi, Ph.D.
   Dana-Farber Cancer Institute
   Fax: 617-632-3581

   The patient identifiers (initials) should not appear on the form. The ACRIN Case #, protocol #, Institution # and name should appear in the header.

B. Mail the completed TA form and CT Scan Reports to:

   ACRIN 6665 Data Management
   American College of Radiology
   1101 Market Street, Suite 1400
   Philadelphia, PA 19107

   The data form should have all identifiers marked: ACRIN Case #, Institution name, Institution # and patient initials.
ACRIN Study 6665
PLACE LABEL HERE

Institution
Institution No.
Participant Initials
Case No.

Instructions: Form is to be completed by the Core Lab Reader and sent to the ACR office. All dates must be reported as mm-dd-yyyy. All time fields must be reported in military format [i.e. 1:00pm = 13:00 hrs]. Code all questions unless otherwise specified.

PET IMAGING REVIEW INFORMATION

1. Dates of PET images reviewed
   - Baseline PET
   - Week 1 PET
   - Week 4 or week 8 PET

   If one or more PET studies not done, specify time point(s) (i.e., baseline, week 1, week 4 or week 8)

   2. Reader ID
   3. Reader Name:

Part III Semi-Quantitative Assessment

4. PET FDG uptake analysis (completed for baseline only)

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<th>ROI Number (1 = lesion, 2-5 = background)</th>
<th>Image Plane</th>
<th>Number of Pixels</th>
<th>Min (SUV) Simple</th>
<th>Max (SUV) Simple</th>
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</table>
5. Complete the following question for 1 week time point.

Have new lesions been visualized since baseline imaging?
1. No
2. Yes***

***If yes, record new sites visualized during follow-up imaging in table 5a as lesion #4, 5, and 6 as necessary.

5a. PET FDG uptake analysis (at 1 week time point)

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6. Complete the following question at pre-surgery time point.

Have new lesions been visualized since week 1 imaging?
1. No
2. Yes***

***If yes, record new sites visualized during follow-up imaging in table 6a as lesion #4, 5, and 6 as necessary.

6a. PET FDG uptake analysis (at pre-surgery time point)

<table>
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COMMENTS: [534]

PRINT NAME (PERSON COMPLETING FORM)
ACRIN PET Imaging/Primary and Recurrent Operable Malignant GIST Supplemental PET Technical Assessment Form

If this is a revised or corrected form, indicate by checking box.

Instructions: Form is to be completed by R. Badawi upon receipt of TA form, CT images PET images and CT report. The completed form is mailed to the ACRIN data management center for each time point. Dates are reported as mm-dd-yyyy.

PET TIME-POINT INFORMATION

1. [1] Protocol Imaging time point (if Q1 is coded 4, complete Q4 and sign/date form)
   1. Baseline PET (pre-Gleevec therapy)
   2. Week 1 PET (at 24 hrs to 7 days post-initiation of Gleevec therapy)
   3. Week 4 or week 8 PET (prior to surgery)
   4. PET imaging not done, specify time point and complete item 4 (i.e., baseline, week 1, week 4 or week 8) [2]

2. Date of PET imaging mm dd yyyy [3]

3. Date of PET image transfer mm dd yyyy [4]

PET IMAGING DATA QUALITY ASSESSMENT

4. [5] Image quality (If image quality is suboptimal, or inadequate code reason)
   1. Adequate
   2. Suboptimal*
      [6]
      1. Entire study not complete
      2. Noisy images
      3. Patient motion
      4. Radiotracer infiltration
      5. TA form incomplete
      6. SUVs cannot be calculated (specify reason) [7]
      7. Other, specify [8]
   3. Inadequate
      [9]
      1. Entire study not complete
      2. Noisy images
      3. Patient motion
      4. Radiotracer infiltration
      5. TA form incomplete
      6. SUVs cannot be calculated (specify reason) [10]
      7. Other, specify [11]

5. If image quality suboptimal or inadequate, complete the following

5a. [12] Originating site contacted
   1. No
   2. Yes

5b. Contact date mm dd yyyy [13]

5c. Originating site contact person [14]

CT IMAGING INFORMATION

6. [15] CT imaging performed
   1. No
   2. Yes*
   (*If yes, complete 7, 8 & 9)

7. Date of CT imaging mm dd yyyy [16]

8. [17] CT report received
   1. No
   2. Yes

9. [18] CT image received in following format
   0. Not received
   1. Digital, DICOM
   2. Digital, not DICOM
   3. Hardcopy

COMMENTS: [19]

[20]

SIGNATURE (PERSON COMPLETING FORM) [21]

DATE FORM COMPLETED
### ACRIN Study 6665 Case #

**PLACE LABEL HERE**

<table>
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<th>Institution</th>
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<th>Patient's Name</th>
<th>Patient's I.D. No.</th>
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**PLACE LABEL HERE**

**Instructions:** Form is to be completed by the Core Lab Reader(s) and sent to the ACR office. All dates must be reported as mm-dd-yyyy. All time fields must be reported in military format [i.e. 1:00pm = 13:00 hrs]. Code all questions unless otherwise specified.

### PET IMAGING REVIEW INFORMATION

1. **Dates of PET images reviewed**
   - Baseline PET [1]
   - Week 1 PET [2]
   - Week 4 or week 8 PET [3]

   If one or more PET studies not done, specify time point(s) (i.e., baseline, week 1, week 4 or week 8) [4]

2. **[5]** Reader ID

3. **[6]** Reader Name
   - 1. Annick D. Van den Abbeele, M.D.
   - 2. Barry A. Siegel, M.D.
   - 3. Other, specify [7]

### Part I (Blinded Qualitative Assessment)

Date PET images reviewed at Core Lab [8]

#### Uptake scale
- 0: Not imaged, cannot evaluate
- 1: Definitely normal
- 2: Probably normal
- 3: Indeterminate
- 4: Probably abnormal
- 5: Definitely abnormal

#### Change in uptake scale** (compare to baseline)
- 0: No uptake
- 1: Marked decrease in uptake
- 2: Slight decrease in uptake
- 3: No change in uptake
- 4: Slight increase in uptake
- 5: Marked increase in uptake

#### Change in lesion volume***
- 0: Lesion borders not visible, cannot evaluate
- 1: Marked decrease in lesion volume
- 2: Slight decrease in lesion volume
- 3: No change in lesion volume
- 4: Slight increase in lesion volume
- 5: Marked increase in lesion volume

### Table: PET Imaging Data

<table>
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<tr>
<th>LESION #</th>
<th>ANATOMIC SITE</th>
<th>BASELINE UPTAKE SCALE*</th>
<th>WEEK1 UPTAKE SCALE*</th>
<th>WEEK1 CHANGE IN UPTAKE SCALE** (0 TO 5)</th>
<th>WEEK1 CHANGE IN LESION VOLUME*** (0 TO 5)</th>
<th>PRE-SURGERY UPTAKE SCALE*</th>
<th>PRE-SURGERY CHANGE IN UPTAKE SCALE** (0 TO 5)</th>
<th>PRE-SURGERY CHANGE IN LESION VOLUME*** (0 TO 5)</th>
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**COMMENTS:** [89]
### Part II (Unblinded Qualitative Assessment)

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<th>Uptake scale*</th>
<th>Change in uptake scale**(compare to baseline)**</th>
<th>Change in lesion volume***</th>
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<td>0 Not imaged, cannot evaluate</td>
<td>0 No uptake</td>
<td>0 Lesion borders not visible, cannot evaluate</td>
</tr>
<tr>
<td>1 Definitely normal</td>
<td>1 Marked decrease in uptake</td>
<td>1 Marked decrease in lesion volume</td>
</tr>
<tr>
<td>2 Probably normal</td>
<td>2 Slight decrease in uptake</td>
<td>2 Slight decrease in lesion volume</td>
</tr>
<tr>
<td>3 Indeterminate</td>
<td>3 No change in uptake</td>
<td>3 No change in lesion volume</td>
</tr>
<tr>
<td>4 Probably abnormal</td>
<td>4 Slight increase in uptake</td>
<td>4 Slight increase in lesion volume</td>
</tr>
<tr>
<td>5 Definitely abnormal</td>
<td>5 Marked increase in uptake</td>
<td>5 Marked increase in lesion volume</td>
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5. Primary tumor and metastatic disease uptake assessment as visualized on PET and CT imaging

<table>
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<tr>
<th>LESION #</th>
<th>ANATOMIC SITE</th>
<th>BASELINE UPTAKE SCALE* (0 TO 5)</th>
<th>WEEK1 UPTAKE SCALE* (0 TO 5)</th>
<th>WEEK1 CHANGE IN UPTAKE SCALE** (0 TO 5)</th>
<th>WEEK1 CHANGE IN LesION VOLUME*** (0 TO 5)</th>
<th>PRE-SURGERY UPTAKE SCALE* (0 TO 5)</th>
<th>PRE-SURGERY CHANGE IN UPTAKE SCALE** (0 TO 5)</th>
<th>PRE-SURGERY CHANGE IN LESION VOLUME*** (0 TO 5)</th>
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6. Provide date(s) of CT images reviewed for the unblinded qualitative assessment.

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COMMENTS: 175

PRINT NAME (PERSON COMPLETING FORM)