ACRIN 6687

A Phase 2, Multicenter Evaluation of 18F-Fluoride PET as a Pharmacodynamic Biomarker for Dasatinib, a Src Kinase Inhibitor, in Men With Castration-Resistant Prostate Cancer and Bone Metastases (BMS #180-279)

Case Report Form Set

American College of Radiology Imaging Network **Study 6687**
Forms Index

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Please enter all data through the ACRIN website Data Center www.acrin.org. All data should be entered within two weeks of the visit. Any questions related to these forms should be directed to Data management. Please see Study Contact Personnel.

A0

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib, a Src Kinase Inhibitor

Visit 1: Registration/Eligibility Checklist

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √box. ☐

VISIT 1

DEMOGRAPHICS

Part I. The following questions will be asked at Study Registration:

1. Name of institutional person registering this case_____ [1]

2. Has Eligibility Checklist been completed? [2]

   O 1 No O 2 Yes

3. Is the participant eligible for this study? [3]

   O 1 No O 2 Yes

4. Date the study-specific consent form was signed (mm-dd-yyyy) **(Must be prior to study entry)** ___-___-___ [4]

5. Participant's Initials *(last, first) (L, F)* _____ [5]

6. Verifying physician (Site PI) _____ [6]

8. Date of birth *(mm-dd-yyyy)* ___-___-___ [8]

9. Ethnicity [9]

   O 1 Hispanic or Latino O 2 Not Hispanic or Latino O 9 Unknown

12. Participant's country of residence **(if other, complete Q12a)** [12]

   O 1 United States O 3 Other
   O 2 Canada O 9 Unknown

   12a. Other country, specify (completed if Q12 is coded **"other"**) _____ [18]

13. Zip Code **(5 digit code, US residents)** _____ [13]

14. Participant's insurance status [14]

   O 0 Other
   O 1 Private Insurance
   O 2 Medicare
   O 3 Medicare and Private Insurance
   O 4 Medicaid
   O 5 Medicaid and Medicare
   O 6 Military or Veteran's Administration
   O 7 Self Pay
   O 8 No means of payment
   O 9 Unknown/Decline to answer

15. Will any component of the participant's care be given at a military or VA facility? [15]

   O 1 No O 2 Yes O 9 Unknown

16. Calendar base date [Date of registration] *(mm-dd-yyyy)* ___-___-___ [16]

17. Date of registration (mm-dd-yyyy) ___-___-___ [17]

Race (check all that apply) ☐ =1 No, ☒ =2 Yes

19. ☐ American Indian or Alaskan Native [19]
20. ☐ Asian [20]
21. ☐ Black or African American [21]
22. ☐ Native Hawaiian or other Pacific Islander [22]
23. ☐ White [23]
24. ☐ Unknown [24]

A0

ACRIN 6687

Registration/Eligibility Checklist
Evaluation of ^{18}F-Fluoride PET for Dasatinib, a Src Kinase Inhibitor
Visit 1: Registration/Eligibility Checklist

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT 1

INCLUSION CRITERIA

25. Is the participant 18 years of age or older with metastatic castration-resistant prostate cancer enrolling onto the Febbo "Genomic Guided Therapy with Dasatinib or Nilutamide in Metastatic Castration Resistant Prostate Cancer" clinical trial (must meet all inclusion criteria for dasatinib treatment study and comply with requirements of that specific clinical trial). [28]
    O 1 No O 2 Yes

26. Is there histological confirmation of original prostate cancer diagnosis? [29]
    O 1 No O 2 Yes

27. Is there presence of at least one convincing bone metastasis as defined by bone scintigraphy, CT scan (MRI if indicated), or plain X-ray? [30]
    O 1 No O 2 Yes

28. Does the participant have castrate testosterone levels (< 50 ng/dL) from orchiectomy or maintenance on a LHRH agonist? [31]
    O 1 No O 2 Yes

29. If dasatinib treatment is stopped for reasons other than bone metastatic disease progression, is the participant willing to continue to undergo restaging bone scintigraphy and CT scans every 3 months until diagnosed with new bone metastasis? [32]
    O 1 No O 2 Yes

EXCLUSION CRITERIA

30. Is the participant enrolled on the nilutamide-only arm (Arm A of the clinical therapeutic trial)? [33]
    O 1 No (skip to Q31) O 2 Yes

    30a. If "Yes", did the patient cross-over from nilutamide at the time of progression to add Dasatinib therapy and meets all inclusion criteria for the trial? [34]
    O 1 No O 2 Yes

31. Are there any conditions that would alter the participant's mental status, prohibiting the basic understanding and/or authorization of informed consent? [35]
    O 1 No O 2 Yes

32. Is there a serious underlying medical condition that would otherwise impair the participant's ability to receive treatment and imaging studies? [36]
    O 1 No O 2 Yes

33. Is the participant's expected lifespan 12 weeks or less? [37]
    O 1 No O 2 Yes

34. Is there extremely poor intravenous access, prohibiting the placement of a peripheral IV line for injection of radiotracer? [38]
    O 1 No O 2 Yes

35. Has there been Initiation of bisphosphonate therapy less than 4 weeks from the first PET scan? [39]
    O 1 No O 2 Yes

A0

ACRIN 6687

Registration/Eligibility Checklist
Evaluation of ^{18}F-Fluoride PET for Dasatinib, a Src Kinase Inhibitor
Visit 1: Registration/Eligibility Checklist

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT 1

EXCLUSION CRITERIA cont'd

36. Has the participant received radiation treatment to bone less than 4 weeks from first PET scan? [40]
O 1 No O 2 Yes

37. Has the participant received radiopharmaceutical treatment to bone less than 4 weeks from first PET scan? [41]
O 1 No O 2 Yes

38. Has the participant received treatment with granulocyte-macrophage colony stimulating factor (GM-CSF) or granulocyte CSF (G-CSF) within 4 weeks prior to first PET scan? [42]
O 1 No O 2 Yes

39. Is the participant able to lie still for the imaging? [43]
O 1 No (ineligible) O 2 Yes (eligible)

40. Is the participant's weight > 300 lbs? [44]
O 1 No O 2 Yes

SCHEDULED PROCEDURES

(PET must be performed within 7 days prior to Dasatinib therapy)

41. Has the Dasatinib treatment date been scheduled? [45]
O 1 No **(PET must be performed within 7 days prior to dasatinib therapy)**
O 2 Yes (complete 41a)

41a. Expected start date of Dasatinib therapy? [46]
_____-_____-_____ (mm/dd/yyyy)

42. Has the PET Imaging date been scheduled? [47]
O 1 No **(PET must be performed within 7 days prior to dasatinib therapy)**
O 2 Yes (complete 42a)

42a. Expected date of PET imaging? [48]
_____-_____-_____ (mm/dd/yyyy)

_____ [49]
Initials of Oncologist determining eligibility

_____-_____-_____(mm/dd/yyyy) [50]
Date form completed

A0 Completion Instructions

The A0 Form is required to register each participant on the ACRIN 6687 study. Complete Part two/Eligibility Checklist prior to registration to determine and confirm study eligibility. At the time of enrollment, the participant must review, sign, and date the consent. Submit the A0 form via the ACRIN data center at www.acrin.org within 24 hours of consent and completion. Please contact ACRIN data management for manual study registration, in the event that the website is down.

All available dates should be reported as MM/DD/YYYY. Code all questions unless otherwise specified; do not leave mandatory questions blank. Please note that online logic requires the calendar base date, registration, and form completion dates to be after 08/29/2009.

Instructions and tips for completing this form are provided below. If further clarification is required for any question on the form, please contact the ACRIN Data Management Center.

Q4. Date the study-specific consent form was signed:
Patient must consent to study participation prior to study entry and registration – this date may not be in the future.

Q16. Calendar base date & Q17. Date of registration:
These are the dates the patient is registered to the trial and must be equal to each other and are no later than the current date.

Q30. Is the participant enrolled on the nilutamide-only arm (Arm A of the clinical therapeutic trial)? & 30a. If "Yes", did the patient cross-over from nilutamide at the time of progression to add Dasatinib therapy and meets all inclusion criteria for the trial?:
Only patients on ARM A of the therapeutic trial who progress, cross over and are scheduled for Dasatinib treatment are eligible to participate in the imaging trial. All participants on ARM B are eligible.

Q39. Is the participant able to lie still for the imaging?
If the patient is unable to lie still for imaging (Q39 1=no), then the participant is ineligible for the study.

Q41. Has the Dasatinib treatment date been scheduled? & Q42. Has the PET Imaging date been scheduled?
Since all eligible participants must receive Dasatinib therapy and a Baseline PET Imaging within 7 days prior to the start of therapy, it is expected that the dates of the start of Dasatinib therapy and Baseline PET Imaging will be known. However, to account for unforeseen anomalies, responses to these questions are not mandatory for registration completion but will be necessary for data analysis. Questions 41 and 42 are expected to be within 7 days of each other, or the patient is ineligible for participation.

CO

ACRIN 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib
Visit 1: Concomitant Medications

If this is a revised or corrected form, please √ box. ☐

ACRIN Study **6687**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT 1: CONCOMITANT MEDICATIONS

☐ None[13] Check "none" if there are no Concomitant Medications to report.

# of medication being reported.[1]	**Medication**[2] (Generic Name only)	**Start date** (mm/dd/yyyy) [3] [4] [5] Unknown[6]	**End date** (mm/dd/yyyy) [7] [8] [9] Unknown[10] Ongoing[11]	**Indication**[12] (reasons for use)
1		____/____/____ ☐ Unknown	____/____/____ ☐ Unknown ☐ Ongoing	
2		____/____/____ ☐ Unknown	____/____/____ ☐ Unknown ☐ Ongoing	
3		____/____/____ ☐ Unknown	____/____/____ ☐ Unknown ☐ Ongoing	
4		____/____/____ ☐ Unknown	____/____/____ ☐ Unknown ☐ Ongoing	
5		____/____/____ ☐ Unknown	____/____/____ ☐ Unknown ☐ Ongoing	
6		____/____/____ ☐ Unknown	____/____/____ ☐ Unknown ☐ Ongoing	
7		____/____/____ ☐ Unknown	____/____/____ ☐ Unknown ☐ Ongoing	
8		____/____/____ ☐ Unknown	____/____/____ ☐ Unknown ☐ Ongoing	
9		____/____/____ ☐ Unknown	____/____/____ ☐ Unknown ☐ Ongoing	
10		____/____/____ ☐ Unknown	____/____/____ ☐ Unknown ☐ Ongoing	

*****List additional Concomitant Medications on Supplemental CO form.*****

CO

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib

Visit 1: Supplemental Concomitant Medications Form

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution ____________ Institution No. ____________

Participant Initials ____________ Case No. ____________

VISIT 1: SUPPLEMENTAL CONCOMITANT MEDICATIONS

☐ None[13] Check "none" if there are no Concomitant Medications to report.

# of medication being reported.[1]	Medication[2] (Generic Name only)	Start date (mm/dd/yyyy) [3] [4] [5] Unknown[6]	End date (mm/dd/yyyy) [7] [8] [9] Unknown[10] Ongoing[11]	Indication[12] (reasons for use)
__	____________	__/__/____ ☐ Unknown	__/__/____ ☐ Unknown ☐ Ongoing	____________
__	____________	__/__/____ ☐ Unknown	__/__/____ ☐ Unknown ☐ Ongoing	____________
__	____________	__/__/____ ☐ Unknown	__/__/____ ☐ Unknown ☐ Ongoing	____________
__	____________	__/__/____ ☐ Unknown	__/__/____ ☐ Unknown ☐ Ongoing	____________
__	____________	__/__/____ ☐ Unknown	__/__/____ ☐ Unknown ☐ Ongoing	____________
__	____________	__/__/____ ☐ Unknown	__/__/____ ☐ Unknown ☐ Ongoing	____________
__	____________	__/__/____ ☐ Unknown	__/__/____ ☐ Unknown ☐ Ongoing	____________
__	____________	__/__/____ ☐ Unknown	__/__/____ ☐ Unknown ☐ Ongoing	____________
__	____________	__/__/____ ☐ Unknown	__/__/____ ☐ Unknown ☐ Ongoing	____________
__	____________	__/__/____ ☐ Unknown	__/__/____ ☐ Unknown ☐ Ongoing	____________

*****List additional Concomitant Medications on Supplemental CO form.*****

ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

Concomitant Medications Form

CO Completion Instructions

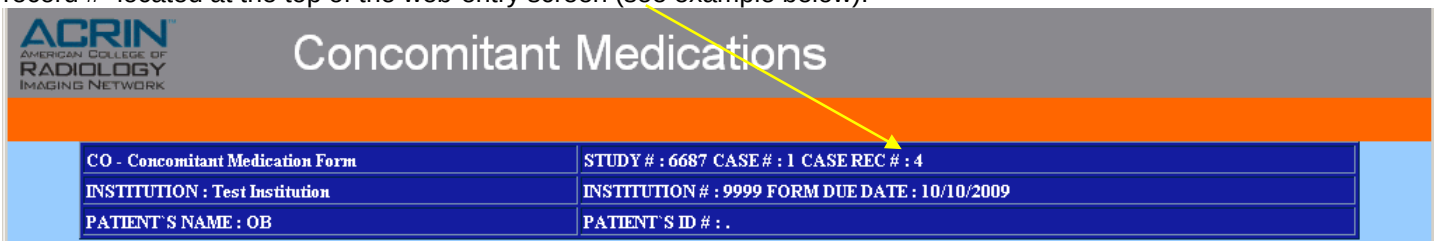
Note: These completion instructions only include questions that may need further clarification.

Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

The CO (Concomitant Medication) Form is required for each participant on the ACRIN 6687 study and is completed as part of the enrollment/baseline visit. The CO form is to be completed after the participant has signed the informed consent, been enrolled onto the study, "CO - Supplemental Concomitant Medications" form if there are more than 10 Concomitant Medications to record. The designated research staff must complete the form with the appropriate completed source documents. It is submitted via the ACRIN website at www.acrin.org. Dates are reported as mm/dd/yyyy.

If there are no Concomitant Medications to record, check "None" at the top of the form. If you are recording medication, leave "None" blank.

Medication Column:
***** Important***** When web-entering data, make sure that the "# of medication being reported" is equal to the "case record #" located at the top of the web-entry screen (see example below).



Start Date Column:
If either the month (mm) or day (dd) are unknown, record "99". If the year (yyyy) is unknown, record "9999".
Examples: 12/99/2008 or 01/15/9999.

Check "Unknown" if the entire date is unknown.

End Date Column:
If either the month (mm) or day (dd) are unknown, record "99". If the year (yyyy) is unknown, record "9999".
Examples: 12/99/2008 or 01/15/9999.

Check the "Unknown" box if the entire date is unknown.

Check the "Ongoing" box if the participant is currently taking the medication.

Select "Submit" to complete record entry. Select "complete form" on the subsequent screen and the CO form in the "Data Collection" screen to record subsequent Concomitant Medications; (example: # of medication being recorded: #2 - case record #2). Until further notice, this process must be followed for every Concomitant Medication being recorded.

I1

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib

Visit 1: Initial Evaluation

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT 1

1. Clinical trial time point:[1] O Visit 1

2. Date of Evaluation[2] _____-_____-_____ (mm-dd-yyyy)

3. Indicate planned treatment for Febbo Study[3]**:** O Dasatinib O Dasatinib after Nilutamide

Study Procedures: Details of assessments must be recorded in source.

4. Study procedures completed and/or assessed as part of Visit 1

[mark all that apply: ☐ = 1 Not Marked, ☑ = 2 Marked]

- ☐ Medical History Reviewed[4]
- ☐ Physical Exam[5]
- ☐ Concomitant Medications documented[6]
- ☐ Pathology Reports (metastatic bone biopsy)[7]
- ☐ Prostate-specific antigen measures[8]
- ☐ Bone alkaline phosphatase[9]
- ☐ Urine N-telopeptide[10]
- ☐ Bone Scan (submit images to ACRIN)[11]
- ☐ CT Scan (submit images to ACRIN)[12]
- ☐ MRI Scan (submit images to ACRIN)[13]
- ☐ X-Ray Scan (submit images to ACRIN)[14]
- ☐ Other imaging[15], specify (submit images to ACRIN)

_____[16]

5. Was Metastatic Biopsy performed?[17] O No O Yes (Answer Q5a -c)

5a. Date biopsy performed (mm-dd-yyyy)[18] _____-_____-_____

5b. Date histopathology reported (mm-dd-yyyy)[19] _____-_____-_____

5c. Indicate metastatic area[20] _____

6. ECOG Performance Status[21]

O Normal activity. Fully active, able to continue all predisease performance without restrictions.

O Symptoms, but ambulatory. Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (eg. light housework, office work)

O In bed <50% of the time. Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.

7. Prostate-Specific Antigen Measurements (≤ 60 days prior to registration)

7a. Date[22] _____-_____-_____

7b. Value[23] ☐☐☐.☐☐

7c. Unit of Measure[24]

O n/mg O ng/dL
O ng/mL O mcg/L
O U/L

7d. Method of Assay[25]

O Abbott O Hybritech
O Bayer O Other
O DPC O Unknown

8. Bone Alkaline Phosphatase (≤ 60 days prior to registration)

8a. Date[26] _____-_____-_____ *(mm/dd/yyyy)*

8b. Value[27] (ng/ml) ☐☐.☐☐

9. Urine N-telopeptide (uNTx) (≤ 60 days prior to registration)

9a. Date[28] _____-_____-_____ *(mm/dd/yyyy)*

9b. Value[29] (nmol/L) ☐☐☐.☐

VISIT 1

10. Number of tumors identified[30] ☐☐

11. How were tumors seen on imaging? (check all that apply)

☐ MRI[31] ☐ X-Ray[32] ☐ CT[33] ☐ Bone scan[34] ☐ Other[35], specify_____[36]

12. TNM Staging Classification (AJCC)

T[37] *(select one)*

O TX
O T0
O T1
O T2
O T3

N[38] *(select one)*

O NX
O N0
O N1

M[39] *(select one)*

O MX
O M0
O M1
O M1a
O M1b

13. Has the patient received prior therapy/treatment for cancer?[40]

O No O Yes (complete TX form) O Unknown

_____ _____-_____-_____

Initials of person(s) completing this form[41] Date form completed *(mm-dd-yyyy)*[42]

ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

Initial Evaluation Form

I1 Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

The I1 Form is required for each participant on the ACRIN 6687 study and is completed as part of the enrollment/baseline visit.

2. Date of Evaluation: This is the date the participant completed all of the study specified enrollment procedures as described in Section 9.1 of the protocol:

Obtain a signed informed consent;
Assess for eligibility as outlined in Section 6.0;
Review medical history;
Conduct a physical examination;
Document concomitant medications;
Review the standard clinical test results which were completed within 60 days prior to enrollment, which includes:

- Metastatic bone biopsy;
- Bone scan;
- CT and/or MRI scan(s) of chest, abdomen, and pelvis;
- Any other scans performed for evaluation, e.g. x-rays, if indicated;
- Prostate-specific antigen (PSA) measures;
- Bone alkaline phosphatase;
- Urine N-telopeptide.

If these procedures/assessments occurred over more than one day, the last day should be recorded.

3. Indicate planned treatment for Febbo Study: Patients on the nilutamide-only arm (Arm A of the therapeutic trial) are not eligible for this companion imaging protocol. However, if a patient crosses-over from nilutamide at the time of progression to add dasatinib therapy, he will then be eligible for this 18F-fluoride PET imaging protocol if all inclusion criteria for this study have been met.

Baseline Visit Study Procedures:

4. Study procedures completed and/or assessed as part of Visit 1:

- Please check routine clinical follow-up assessed. **Note:** Details of assessments will be verified during routine monitoring and auditing
- All scans and other imaging must be submitted to ACRIN Imaging Department.
- *If protocol defined baseline visit procedures were not assessed, submit a PR form and provide reason on RE form.* Assessment of medical history, concomitant medications, and physical exam are protocol defined required procedures.

5a. Date biopsy performed: The date the biopsy procedure was performed is required.

5b. Date histopathology reported: The date of the pathology report is required.

5c. Indicate metastatic area: The location of metastatic biopsy is required.

6. ECOG Performance Status: If performance status is greater than 2, reassess eligibility.

7. Prostate-Specific Antigen Measurements: PSA data must have been acquired within 60 days of registration on the 6687 study. Responses to questions 7a, b and c are also required.

8. Bone Alkaline Phosphatase: BAP data must have been acquired within 60 days of registration on the 6687 study.

9. Urine N-telopeptide: Data must have been acquired within 60 days of registration on the 6687 study.

10. **Number of tumors identified:** Provide total number of tumors seen up to 99.

12. **Staging Classification (AJCC):** Indicate T stage for the primary tumor only. Indicate one N and M stage.

13. **Has the patient received prior therapy/treatment for cancer:** If the response is “Yes”, report on TX (prior therapies) form.

MH

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib

Baseline Medical History Abnormalities

If this is a revised or corrected form, please √box. ☐

ACRIN Study **6687**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT 1: BASELINE MEDICAL HISTORY ABNORMALITIES

NOTE: Do not record any prior cancer treatment/therapies on this form. Record all on the Prior Therapies (TX) form.

Check "none" if there are no abnormalities to report.

☐ None[1]

Sequence # [2]	Condition / Event [3]	Online CTCAE/MedDRA Term [4]	Grade (1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatning or disabling) [5]
1			O 1 O 2 O 3 O 4
2			O 1 O 2 O 3 O 4
3			O 1 O 2 O 3 O 4
4			O 1 O 2 O 3 O 4
5			O 1 O 2 O 3 O 4
6			O 1 O 2 O 3 O 4
7			O 1 O 2 O 3 O 4
8			O 1 O 2 O 3 O 4
9			O 1 O 2 O 3 O 4
10			O 1 O 2 O 3 O 4
11			O 1 O 2 O 3 O 4
12			O 1 O 2 O 3 O 4

*****Important: If there are additional records to report, list on Supplemental MH form.*****

MH

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib

Supplemental Baseline Medical History Abnormalities

If this is a revised or corrected form, please √box. ☐

ACRIN Study **6687**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT 1: SUPPLEMENTAL BASELINE MEDICAL HISTORY ABNORMALITIES

NOTE: Do not record any prior cancer treatment/therapies on this form. Record all on the Prior Therapies (TX) form.

Check "none" if there are no abnormalities to report.

☐ None[1]

Sequence # [2]	Condition / Event [3]	Online CTCAE/MedDRA Term [4]	Grade (1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatning or disabling) [5]
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4
___			O 1 O 2 O 3 O 4

*****Important: If there are additional records to report, list on Supplemental MH form.*****

ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

Baseline Medical History Abnormalities Form

MH Completion Instructions

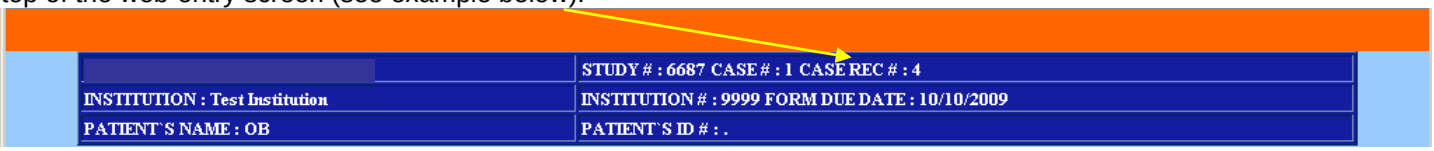
Note: These completion instructions only include questions that may need further clarification.

Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

The MH (Baseline Medical History Abnormalities) Form is required for each participant on the ACRIN 6687 study and is completed as part of the enrollment/baseline visit. The MH form is to be completed after the participant has signed the informed consent, been enrolled onto the study, and *prior to* any study procedures. This form is completed to report the participant's medical history. Use the "Supplemental Baseline Medical History Abnormalities" form if there are more than 12 Abnormalities to record. The designated research staff must complete the form with the appropriate completed source documents. It is submitted via the ACRIN website at www.acrin.org.

If there are no Baseline Medical Abnormalities to record, check "None" at the top of the form. If you are recording Baseline Medical Abnormalities, leave "None" blank.

"Sequence #" Column:
***** Important***** When web-entering data, make sure that the "Sequence #" is equal to the "case record #" located at the top of the web-entry screen (see example below).



"Online CTCAE/MedDRA Term" Column: This column will be left blank on the paper form. On the web-entry screen, this field requires an online look-up into the National Cancer Institute's (NCI) Common Toxicology Criteria for Adverse Events (CTCAE) data table.

1. Select the blue 'Adverse Event' button next to the "AE Short Name (online look-up)" field.
2. You will then be taken to another page with three fields:
   a. Category: you can select the drop down list which will include all terms in the selected category;

      OR

   b. Code Description: you can filter further by entering partial term and or the entire term;

      OR

   c. MedDRA Term: you can filter further by entering partial term and/or the entire term.
3. Select the blue 'Retrieve' button to obtain a list of code descriptions.
4. Review the code description and MedDRA term and select the appropriate code number of the reported AE.
5. Once selected, the system will automatically populate the AE Short Name field with the MedDra code number. The corresponding MedDRA term will be displayed in red to the right of the AE Short Name field on the web entry screen when you are returned to the form.

"Grade": Select the abnormality grade based on the National Cancer Institute's (NCI) Common Toxicology Criteria for Adverse Events (CTCAE).

Grade 1 = Mild

Grade 2 = Moderate

Grade 3 = Severe

Grade 4 = Life threatening or disabling

Select the MH form in the “Data Collection” screen to record subsequent Baseline Medical History Abnormalities; (example: Sequence #: 2 - case record #2). Until further notice, this process must be followed for every Abnormality being recorded for this visit.

TX

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib

Prior Therapies

If this is a revised or corrected form, please √box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

1. Did the participant ever receive any type of cancer treatment (chemotherapy, hormonal therapy, surgery, vaccine, etc)? [1]

O No, initial and date form
O Yes, complete table

Therapy Type	Any Therapy?				# Prior Chemo Regimens
Anti-Retroviral Therapy	O No	O Yes	O Unknown	[2]	
Antisense	O No	O Yes	O Unknown	[3]	
Bone Marrow transplant	O No	O Yes	O Unknown	[4]	
Chemotherapy (NOS)	O No	O Yes	O Unknown	[5]	[6]
Chemotherapy multiple agents systemic	O No	O Yes	O Unknown	[7]	[8]
Chemotherapy non-cytotoxic	O No	O Yes	O Unknown	[9]	[10]
Chemotherapy single agent systemic	O No	O Yes	O Unknown	[11]	[12]
Drug and/or immunotherapy	O No	O Yes	O Unknown	[13]	
Gene Transfer	O No	O Yes	O Unknown	[14]	
Hematopoietic stem cell transplantation	O No	O Yes	O Unknown	[15]	
Hormonal therapy	O No	O Yes	O Unknown	[16]	
Image directed local therapy	O No	O Yes	O Unknown	[17]	
Oncolytic Virotherapy	O No	O Yes	O Unknown	[18]	
Prior Therapy (NOS)	O No	O Yes	O Unknown	[19]	
Radiation Therapy	O No	O Yes	O Unknown	[20]	
Surgery	O No	O Yes	O Unknown	[21]	
Therapy (NOS)	O No	O Yes	O Unknown	[22]	
Vaccine	O No	O Yes	O Unknown	[23]	

_____ [24]
Initials of person(s) completing this form

_____-_____-_____ [25]
Date form completed *(mm-dd-yyyy)*

TX Completion Instructions

The TX form is required for all participants. The form should be completed as part of the registration visit/eligibility assessment. It collects any prior cancer related therapy/treatment the participant has had in their lifetime.

Note: Ideally all prior therapy would be made available in the participants medical history, however it is understood that there may be unknowns to some of the listed therapies.

1. Did the participant ever receive any type of cancer treatment (chemotherapy, hormonal therapy, surgery, vaccine, etc.?

No: The participant has not had any prior cancer related treatment. Initial and date the form.

Yes: The participant has received some type of cancer related treatment. Complete the entire table

Note: Any prior cancer treatment the participant may have received to make them eligible for this study should be reported on this form. (Eg., Nilutamide or Dasatinib)

Completing the Prior Therapies Table

NOS = Not Otherwise Specified

Therapy Type Please see table below for the definitions and examples of the listed therapy types

Any Therapy? **No:** Select if it is known that participant has not received the corresponding therapy type.
Yes: Select if it is known that the participant has received the corresponding therapy type. Note that yes can be selected for more than one type.
Unknown: Select if it is unknown whether the participant has ever had the corresponding therapy type.

 # Prior Chemo Regimens A regimen is described as a distinctive planned collection of agent(s) and or modalitie(s) to be utilized together during a cycle or course of therapy. The total number should include chemotherapy that was discontinued for any reason. If a prior treatment was ABVD/CHOP, it should be coded as one chemotherapy regiment.

Note: The total number of other prior therapy types (e.g., surgery) is not required here and should not be included in this number.

Therapy Type	CDUS Meaning	Examples
Anti-Retroviral Therapy	Agents administered to control the replication and/or spread of viruses	TAT therapy for HIV-1
Antisense	Treatment with an agent that prevents or impairs the translation of the genetic message for production of a specific protein.	
Bone Marrow Transplant	High dose chemotherapy combined with transplantation of bone marrow cells	allogeneic, syngeneic, autologous bone marrow or peripherhal blood stem cell transplantation
Chemotherapy (NOS)	Non-systemic chemotherapy treatment (e.g., intra-peritoneal, intra-cavitary, intra-thecal), or chemotherapy not described by Chemotherapy Single Agent Systemic or Multi-Agent Systemic.	
Chemotherapy multiple agents systemic	Systemic chemotherapy with a regimen containing multiple agents. A regimen is described as a distinctive collection of agent(s) and/or modalities to be utilized together during a cycle or course of therapy. All routes of administration are acceptable as long as the agent is intended for systemic therapy.	
Chemotherapy non-cytotoxic	Prior therapy with agents that are not known to cause damage to cycling cells	endostatin, mmpi, bevacizumad

Therapy Type	CDUS Meaning	Examples
Chemotherapy single agent systemic	Systemic chemotherapy with a single agent regimen. A regimen is described as a distinctive collection of agent(s) and/or modalities to be utilized together during a cycle or course of therapy. All routes of administration are acceptable as long as the agent is intended for systemic therapy.	
Drug and/or immunotherapy	Biologic cancer therapy. Manipulation of the body's immune system, either directly or indirectly, with therapeutic intent, e.g., tumor vaccines, monoclonal antibodies, cytokines . Do not include biologic therapy as supportive care (e.g., G-CSF for immuno-protection).	interferons, interleukins, tumor necrosis factor
Gene Transfer	Treatment of human disease by gene transfer	
Hematopoietic Stem Cell Transplantation	The intravenous infusion of autologous or allogeneic stem cells collected from the bone marrow, peripheral blood, or umbilical cord blood to re establish hematopoietic function in patients with damaged or defective bone marrow or immune systems.	
Hormonal Therapy	Cancer therapy which incorporates hormonal manipulation	tamoxifen, androgen deprivation
Image directed local therapy	A technique whereby an imaging method is used to diagnose, localize and/or treat a carcinogenic lesion, for example, a breast lump. A non-palpable carcinoma may be diagnosed by image directed biopsy or needle localization. Breast conserving surgery can be conducted with pre surgical localization with a guide wire using a diagnostic imaging method.	
Oncolytic Virotherapy	Anticancer treatment with a live, replication-competent virus.	
Prior Therapy (NOS)	Prior therapy not otherwise specified	
Radiation Therapy	Targeted ionizing radiation therapy utilizing radioactive implants or seeds. Radiation Therapy combines the following therapies: *Extensive Radiation*: Cancer therapy using ionizing radiation to a significant (>50%) portion of the body. *Limited Radiation*: Cancer therapy using ionizing radiation to a limited (<50%) portion of the body.	(e.g., craniospinal, total body irradiation, or pelvic radiation)
Surgery	Surgical procedure, or operation, with therapeutic intent. Do not include diagnostic procedures (e.g., biopsy).	
Therapy (NOS)	A therapy used prior for which none of these selections is appropriate.	Cryotherapy, phototherapy
Vaccine	Substance or group of substances administered to induce the immune system to recognize and destroy tumors or microorganisms.	

EX **ACRIN 6687**
Imaging Agent Administration
Treatment Exposure Form

ACRIN Study **6687**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Imaging Agent: ^{18}F-Fluoride

If this is a revised or corrected form, please √ box. ☐

Exam Data

1. Planned time point:[1]
- o Visit 2: Pre-Treatment
- o Visit 4: Post-Treatment

2. Was imaging agent administered?[2]
- o No (Initial & date form)
- o Yes

3. Imaging agent name:[3]
- o ^{18}F-Fluoride

4. Administration date:[4]
_____ - _____ - _____ (mm-dd-yyyy)

Imaging Agent Procurement

5. Identification number (Lot #):[5] _____

6. Source of agent:[6]
- o Prepared in-house (provide method by which agent is synthesized, complete Q6a)
- o Obtained from outside supplier (complete Q6b)

6a. Method:[7] _____

6b. Supplier:[8] _____

Administration Information

7. Route of administration:[9] ● IV

8. Activity in full syringe before injection: ___.___ mCi[10]

8a. Time of assay of full syringe before injection: __:__ (military time)[11] ☐ Unknown[12]

9. Time of injection: __:__ (military time)[13] ☐ Unknown[14]

10. Residual activity in syringe after injection: ___.___ mCi[15] ☐ Unknown[16] (if unk, skip to Q12)

10a. Time of assay of residual activity after injection: __:__ (military time)[17] ☐ Unknown[18]

11. Net activity administered (Dosage Amount): ___.___ mCi[19]

12. Site of injection:[20]
- O Right antecubital
- O Right wrist
- O Right foot
- O Indwelling central catheter
- O Left antecubital
- O Left wrist
- O Left foot
- O Unknown
- O Other, specify[21] _____

13. Any infiltration at injection site noted?[22]
- O None
- O Minor (estimated to be less than or equal to 20% of dose)
- O Severe (estimated to be more than 20% of dose)

_____
Initials of person who completed form[23]

_____-_____-_____
Date form completed (mm-dd-yyyy)[24]

ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

Treatment Exposure Form

EX Completion Instructions

The EX Form is required for each study scan. The PET/CT Technologist should complete the form at the time of each scan (Visit 2 and Visit 4).

NOTE: These form completion guidelines only address certain specific form questions.
Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

Question 1: Study Time Point *Please verify the correct time point is selected since subsequent web entry may be affected.*

Visit 2: Pre-treatment
Visit 4: Post treatment

Question 2: Was imaging agent administered?

No: Select if the participant was not given the imaging agent. Complete additional form questions as appropriate (eg., Q4)
Yes: Select if the imaging agent was administered to the participant.

Question 4: Administration Date (PET/CT imaging appointment): This question is required if the participant came to the imaging center and should be provided even in the event they were not injected/imaged.

Administration Information Section:

Question 8: Activity in full syringe before injection: must be recorded **in mCi** to the nearest 0.1 mCi. Units should not be entered on web form.

Question 8a: Time of assay of full syringe before injection: must be recorded in military time. If "Unknown" a PR form must be submitted explaining the reason and proposed corrective action.

Question 9: Time of injection: must be recorded in military time. If "Unknown", submit a PR form.

Question 10: Residual activity in syringe after injection: required if more than 0.1mCi remains. This value must be recorded in mCi. Units should not be web entered. If the response is "Unknown", leave questions 10a and 11 blank and submit a PR form.

Question 10a: Time of assay of residual activity after injection: must be recorded in military time. If "Unknown" submit a PR form.
Question 11: Net activity administered: must be recorded to nearest 0.1 mCi. Units should not be web entered.

Initials of Person(s) completing this form *The source document* must have the signature and date of the person responsible for the data (PET technologist).

P2

ACRIN 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib
Visit 2: PET/CT Imaging Form

If this is a revised or corrected form, please √box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INSTRUCTIONS: PET imaging will be interpreted and the form completed by a **Radiologist**. Submit this form via the **ACRIN** website.

Part I - PET Scan

1. **Clinical trial time point:**[1] O Visit 2: Pre-Treatment
2. **Date of PET Exam:**[2] _____-_____-_____ (mm-dd-yyyy)
3. **Date of PET Interpretation:**[3] _____-_____-_____ (mm-dd-yyyy)
4. **Name of Reader:**[4] _____
5. **Reader ID:**[5] _____
6. **Expected Dasatinib treatment date** (mm-dd-yyyy)[6] _____-_____-_____
7. **Image Quality Interpretable?**[7]
   - O 1 Adequate (proceed to **Q8**)
   - O 2 Uninterpretable (proceed to **Q7a**)

   7a. Reason [mark all that apply]:
   mark all that apply ☐=1 Not Marked, ☑ = 2 Marked
   - ☐ 1 Motion[8]
   - ☐ 2 Artifacts[9]
   - ☐ 3 Contrast Media[10]
   - ☐ 4 DICOM header[11]
   - ☐ 5 Lost Images[12]
   - ☐ 6 Poor S/N[13]
   - ☐ 7 Incomplete Anatomic Coverage[14]
   - ☐ 8 Other[15], specify[16] _____
8. **Were minimal guidelines for scanning followed per protocol?**[17]
   O 1 No O 2 Yes O 9 Unknown

Part II - Tumors (in Dynamic FOV)

1. **Total number of tumors visible:** _____[18]

List up to the 5 most prominant tumors in column 1 (ex: T1, T2, etc.), and identify anatomic site from Table 1 in column 2.

Table 1 - Anatomic Site (in column 2)

1 Skull	12 Sternum
2 C-Spine	13 T-spine
3 Humerus (right)	14 L-spine
4 Humerus (left)	15 Pelvis (left)
5 Radius/ulna (right)	16 Pelvis (right)
6 Radius/ulna (left)	17 Sacrum
7 Hand (right)	88 Other, specify*
8 Hand (left)	
9 Ribs (right)	
10 Ribs (left)	
11 Scapula / Clavicle	

Tumor ID #	Anatomic Site (select code from table 1) (*If "Other" (88) specify below)	Site Description (ex: L-3 index)	Indicate PET Slices (ex: 21-23)	SUV$_{max}$ (weight-based SUV$_{max}$ in g/mL or g/cm^3)	PET/CT Uptake for Bone mets (1 Definitely not present, 2 Probably not present, 3 Indeterminate, 4 Probably present, 5 Definitely present)
T _____[19]	[20] _____[21]	[22]	[23]	[24]	[25]
T _____[26]	[27] _____[28]	[29]	[30]	[31]	[32]
T _____[33]	[34] _____[35]	[36]	[37]	[38]	[39]
T _____[40]	[41] _____[42]	[43]	[44]	[45]	[46]
T _____[47]	[48] _____[49]	[50]	[51]	[52]	[53]

Part III - Normal Bone Matched to Tumor

1. **Total number of tumor-matched normal bone regions to report** _____[54]

List identifying normal bone MATCHED to TUMOR in column 1.

Identify anatomic site using Table 1 (above), and description of site in column 2.

Indicate the slices on the PET image corresponding to the normal bone region.

Initials of person completing form[85] _____

Date form completed[86] _____-_____-_____ (mm-dd-yyyy)

Normal Bone ID #	Anatomic Site (select from table 1) (*If "Other" specify below)	Site Description (ex: L-3 index)	Indicate PET Slices (ex: 21-23)	SUV$_{max}$ (weight-based SUV$_{max}$ in g/mL or g/cm^3)
N _____[55]	[56] _____[57]	[58]	[59]	[60]
N _____[61]	[62] _____[63]	[64]	[65]	[66]
N _____[67]	[68] _____[69]	[70]	[71]	[72]
N _____[73]	[74] _____[75]	[76]	[77]	[78]
N _____[79]	[80] _____[81]	[82]	[83]	[84]

P2 Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

The P2 Form is required for each participant on the ACRIN 6687 study and is completed as part of the Pre-treatment ^{18}F-Fluoride PET/CT imaging (Visit 2). PET imaging will be interpreted and this form is to be completed by the study radiologist. Dates must be in the mm-dd-yyyy format. Submit this form within 2 weeks of PET via the ACRIN website. Submit paper form only for revisions or corrections.

Part I – PET Scan

1. **Clinical trial time point:** Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; Visit 2: Pre-Treatment.
2. **Date of PET Exam:** Mandatory. Record the date that the PET Exam was performed (date must not be in the future).
3. **Date of PET Interpretation:** Mandatory. Record the date the PET was interpreted by the radiologist. Date must not be prior to the Date of PET Exam or a future date.
4. **Name of Reader:** Mandatory. Insert reader name.
5. **Reader ID:** This 7 alphanumeric character user specific ID is required.
6. **Expected Dasatinib treatment date:** This date should be within seven days after the PET scan as indicated in section 9.0 of the protocol.
7. **Image Quality Interpretable:** Record image quality information in Q7 & 7a as appropriate.
8. **Were minimal guidelines for scanning followed per protocol?** Follow the guidelines outlined in the protocol.

Part II – Tumors (in Dynamic FOV)

1. **Total number of tumors visible:** Record up to 99 as appropriate

CHART INSTRUCTIONS:

Column 1 - Tumor ID#: Record as 1-5, as needed, in numerical order. The system will accept up to 5 bone tumors but not less than the number recorded in Q1. List the most prominent bone tumors in order of prominence whose treatment response will be evaluated.

Column 2 - Anatomic Site: Use "Table 1 – Anatomic Site" to the left of the chart to record anatomic site. If response is "88 – Other specify", indicate the other anatomic site location on the line in column 2.

Column 3 - Site Description: Provide a brief description of the site.

Column 4 – Indicate PET Slices: Indicate the PET slices containing the tumor.

Column 5 - SUV Max: Provide weight-based SUV_{max}.

Column 6 - PET/CT Uptake for bone metastasis: Select the appropriate response

Part III – Normal Bone Matched to Tumor

1. **Total number of tumor-matched normal bone regions to report:** Report up to five as appropriate.

CHART INSTRUCTIONS:

Column 1 - Normal Bone ID#: List identifying normal bone matched to Part II tumors. ID #s can be record as 1-5. ID numbers can be repeated if the same normal bone is the best match for multiple tumors. For example, the ID #2 and its corresponding information can be recorded in rows 2 and 3 if it applies to both to tumor T2 and T3. The total number of unique normal bone ID #s must match the number of normal bone recorded in Q1. Also, if normal bone cannot be found to match a tumor in Part II, the corresponding row in Part III should be left blank.

Column 2 - Anatomic Site: Use "Table 1 – Anatomic Site" located under Part II (to the left of the chart on the web) to record anatomic site. If response is "88 – Other specify", indicate the other anatomic site location on the line in column 2.

Column 3 - Site Description: Provide a brief description of the site.

Column 4 – Indicate PET Slices: Indicate the PET slices containing the normal bone region.

Column 5 - SUV Max: Provide weight-based SUV_{max}.

SA

ACRIN 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib
^{18}F-Fluoride Safety Assessment Form

ACRIN Study 6687
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √box. ☐

1. Timepoint *(check one)* [1]

O 1 Visit 2
O 2 Visit 4

Part I. Monitoring for Physiologic Effects of ^{18}F-Fluoride *Complete entire table for each ^{18}F-Fluoride imaging scan*

Time Point of Vital Sign Reading	Time Taken *Military time*	Pulse	Blood Pressure *Systolic/Diastolic*	Respirations *Check one*	Temperature
Prior to Injection	__ __ : __ __ [2] *hh:mm* ☐ Unknown [3]	_____ bpm [4] ☐ Unknown [5]	_____ / _____ mmHg [6] [7] ☐ Unknown [8]	O Labored [9] O Unlabored O Unknown	_____ . _____ °C [10] ☐ Unknown [11]
Completion of PET Imaging	__ __ : __ __ [12] *hh:mm* ☐ Unknown [13]	_____ bpm [14] ☐ Unknown [15]	_____ / _____ mmHg [16] [17] ☐ Unknown [18]	O Labored [19] O Unlabored O Unknown	_____ . _____ °C [20] ☐ Unknown [21]

1. Did the participant require any additional monitoring of vital signs? [22]

O 1 No
O 2 Yes

1a. If yes, provide the last reading of vital signs taken before the participant left the PET facility:

Time Taken *Military time*	Pulse	Blood Pressure *Systolic/Diastolic*	Respirations *Check one*	Temperature
__ __ : __ __ [23] *hh:mm* ☐ Unknown [24]	_____ bpm [25] ☐ Unknown [26]	_____ / _____ mmHg [27] [28] ☐ Unknown [29]	O Labored [30] O Unlabored O Unknown	_____ . _____ °C [31] ☐ Unknown [32]

Part II. Adverse Events *Refer to Section 11.0 of the protocol*

1. Were any AE's reported *(as part of this Imaging visit)*? [33]

O 1 No
O 2 Yes *(Report on a AE Form)*

_____ [38]
Initials of person(s) completing this form

_____-_____-_____ [39]
Date form completed *(mm-dd-yyyy)*

SA Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

The SA Form is required for each participant on the ACRIN 6687 study and is completed as part of the ^{18}F-Fluoride PET/CT imaging (Visit 2 & Visit 4).

Part I. Monitoring for Physiologic Effects of ^{18}F-Fluoride

All elements of the table are required.

1. Did the participant require any additional monitoring of vital signs?

(1) No Skip to Part II

(2) Yes The patient should be monitored until the site investigator (or his/her delegate) judges that the patient may safely leave the PET facility. The reading of vital signs taken before the patient leaves should be recorded in Q1a.

1a. If yes, provide the last reading of vital signs taken before the participant left the PET facility:

All elements of the table are required (time, pulse, blood pressure, respirations, and temperature)
NOTE: If any treatment is deemed necessary, it must be documented in source.

Part II. Adverse Events

1. Were any adverse events reported?

(1) No Initial and date the form

(2) Yes Refer to Section 11.0 of the protocol and contact HQ to report AE

Any subject who has a serious adverse event during or after infusion of ^{18}F-Fluoride, such that imaging cannot be completed safely, in the judgment of the site investigator, will be withdrawn from the study (must also be recorded on a DS form).

TA

ACRIN 6687
^{18}F-Fluoride PET/CT
PET/CT Local Technical Assessment Form

ACRIN Study 6687
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Imaging Agent: ^{18}F-Fluoride

If this is a revised or corrected form, please ✓ box. ☐

Exam Data

1. Clinical trial time point [1]
- o Visit 2: Pre-Treatment
- o Visit 4: Post-Treatment

2. Imaging Agent Name [2]
- o ^{18}F-Fluoride

3. Was imaging exam completed? [4]
- o No, imaging not completed (complete Q3a, then form as applicable)
- o Yes (proceed to Q4 and continue with form)

3a. *If Imaging not completed, provide reason: [5]
- o Scheduling problem
- o Equipment failure
- o Participant refusal
- o Medical reason
- o Injection site complications
- o Claustrophobia
- o Participant withdrew consent
- o Progressive disease
- o Imaging agent not administered
- o Adverse event (complete AE form)
- o Participant death
- o Unknown
- o Other, specify: _____ [6]

4. Date of imaging: [7] (mm-dd-yyyy)

_____ - _____ - _____

5. Weight

|_|_|_| . |_| kg [8]

☐ Unknown [9]

6. Height

|_|_|_| cm [10]

☐ Unknown [11]

7. Was Foley Catheter in place for study? [19]
- o No (complete Q8-Q9)
- o Yes (skip to next section)

8. Patient voided immediately pre-imaging? [20]
- o No
- o Yes
- o Unknown

9. Patient voided immediately post-imaging? [21]
- o No
- o Yes
- o Unknown

Scanner

☐ Not Done [22]

2. Has the scanner used for <u>this study</u> been qualified by ACRIN? [24]
- o No, specify reason and complete Q3: _____ [25]
- o Yes, provide ACRIN Scanner ID# (skip to Q4): _____ [26]

3. Scanner used for this exam:

3a. Manufacturer

_____ [27]

3b. Manufacturer model name/or number

_____ [28]

4. Date of last PET Scanner SUV validation: [29]

_____ - _____ - _____ (mm-dd-yyyy)

5. Daily scanner QC run on date of study? [30]
- o No
- o Yes

TA

ACRIN 6687
^{18}F-Fluoride PET/CT
PET/CT Local Technical Assessment Form

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Imaging Agent: ^{18}F-Fluoride

If this is a revised or corrected form, please √ box. ☐

CT Image Acquisition or Transmission Scan

☐ Not Done[37]

1. Type of attenuation correction used?[38]
- o CT (complete Q2 thru 6)
- o Ge-68 Segmentation (complete Q7)
- o Cs-137 Segmentation (complete Q7)

2. Was oral contrast administered?[39]
- o No (skip to Q3)
- o Yes, if used specify type:[40] o Positive o Negative

2a. Amount[41] ____ ml ☐ Unknown[42]

3. Was IV contrast administered?[43]
- o No (skip to Q4)
- o Yes

3a. Amount[44] ____ ml ☐ Unknown[45]

3b. Time of injection[46]
____:____ (military time) ☐ Unknown[47]

4. kVp
____[48]
☐ Unknown[49]

5. mAs
____[50]
☐ Unknown[51]

6. Slice Thickness of reconstructed images
__.__ mm[52]
☐ Unknown[53]

7. Length of Transmission Scan: ____ (minutes)[54] ☐ Unknown[55]

Dynamic PET Emission Scan

☐ Not Done[56]

1. Acquisition mode[57] o 2D o 3D

2. Number of bed positions scanned ____[58]

PET Emission Scan: **Type of Scan** **Start Time** (military time) **Stop Time** (military time)

Type of Scan:
1 Dynamic

3a. ____[59] **3b.** ____:____[60] **3c.** ____:____[61]

Reconstructed Images: **4. Pixel Size:** __.__mm[62] **5. Thickness:** __.__mm[63]

Additional CT Image Acquisition or Transmission Scan

☐ Not Done[64]

**** Complete section if needed for dynamic imaging ****

1. Type of attenuation correction used?[65]
- o CT (complete Q2 thru 4)
- o Ge-68 Segmentation (complete Q5)
- o Cs-137 Segmentation (complete Q5)

2. kVp
____[66]
☐ Unknown[67]

3. mAs
____[68]
☐ Unknown[69]

4. Slice Thickness of reconstructed images
__.__ mm[70]
☐ Unknown[71]

5. Length of Transmission Scan: ____ (minutes)[72] ☐ Unknown[73]

TA

ACRIN 6687
^{18}F-Fluoride PET/CT
PET/CT Local Technical Assessment Form

Imaging Agent: ^{18}F-Fluoride

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Whole Body PET Emission Scan

☐ Not Done [74]

1. Acquisition mode [75] o 2D o 3D

2. Number of bed positions scanned ___ [76]

PET Emission Scan:	**Type of Scan**	**Start Time** (military time)	**Stop Time** (military time)
Type of Scan: 2 Whole Body	**3a.** ___ [77]	**3b.** ___ : ___ [78]	**3c.** ___ : ___ [79]

Reconstructed Images: **4. Pixel Size:** ___ . ___ mm [80] **5. Thickness:** ___ . ___ mm [81]

_____ [84]
Initials of person completing this form

_____ - _____ - _____ [85]
Date form completed (mm-dd-yyyy)

TA Completion Instructions

Refer to Section 10.0 of the protocol for Detailed Criteria/Specifications for Performance of PET/CT Scans

A TA Form is required for each study scan. The PET/CT Technologist should complete the form at the time of each scan (Visit 2 and Visit 4). All scans are required per protocol. Please refer to the Protocol for further details.

NOTE: These form completion guidelines do not address each question found on the form.
Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

1. Clinical trial time point: *Please verify the correct time point is selected since subsequent web entry may be affected.*
Visit 2: Pre-treatment
Visit 4: Post treatment

3. Was imaging exam completed?
No, imaging not completed: Select if the participant was given the imaging agent and imaging was started but could not be completed. Complete Q3a and the remainder of the form as applicable.

Yes: Select if the participant was given the imaging agent and imaging was completed. Each section of the TA form must be completed.

4. Date of imaging: This question is required if the participant came to the imaging center and should be provided even in the event they are not injected/imaged.

5. Weight: This must be recorded in kg and taken on the day of the PET/CT scan.

6. Height: This must be recorded in cm and taken on the day of the PET/CT scan.

"Not Done" located at the beginning of each section, should be check ***ONLY*** if it was not performed and there is no data to record.

Initials of Person(s) completing this form *The source document* must have the signature and date of the person responsible for the data (PET technologist).

C3

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib

Visit 3: Concomitant Medication Change Form

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution ____________ Institution No. ________

Participant Initials ____________ Case No. ________

VISIT 3: CONCOMITANT MEDICATION CHANGE FORM

☐ None[1] Check "none" if there are no changes or new Concomitant Medications to report.

Medication[2] (Generic Name only)	**Start Date** (mm/dd/yyyy) [3] [4] [5] Unk [6]	**End Date** (mm/dd/yyyy) [7] [8] [9] Unk[10] Ongoing[11]	**Reason** [12] (Provide reason for change) 1 Completed; 2 Disease Progression, relapse during active treatment; 3 Adverse event/side effects/ complications; 4 New medication; 5 Participant decision; 6 PCP decision; 7 Increased dose regimen; 8 Decreased dose regimen; 88 Other* (specify reason)[13]; 99 Unknown
____________	___-___-___ ☐ Unknown	___-___-___ ☐ Unknown ☐ Ongoing	O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8 O 88 O 99 *Specify other, ____________
____________	___-___-___ ☐ Unknown	___-___-___ ☐ Unknown ☐ Ongoing	O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8 O 88 O 99 *Specify other, ____________
____________	___-___-___ ☐ Unknown	___-___-___ ☐ Unknown ☐ Ongoing	O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8 O 88 O 99 *Specify other, ____________
____________	___-___-___ ☐ Unknown	___-___-___ ☐ Unknown ☐ Ongoing	O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8 O 88 O 99 *Specify other, ____________
____________	___-___-___ ☐ Unknown	___-___-___ ☐ Unknown ☐ Ongoing	O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8 O 88 O 99 *Specify other, ____________

*****Important: If there are additional changes to report, list on additional C3 forms.*****

ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

Concomitant Medications Form

C3 Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

The C3 (Concomitant Medication Change) Form is required for each participant on the ACRIN 6687 study and is completed as part of the Telephone Contact during visit 3. This form is completed to report changes in concomitant medication since visit 1. Use the additional C3 forms if there are more than 5 changes to previously recorded Concomitant Medications. The designated research staff must complete the form with the appropriate completed source documents. It is submitted via the ACRIN website at www.acrin.org within two weeks of visit 3. Dates are reported as mm/dd/yyyy.

If there are no changes to Concomitant Medications, check "None" located at the top right of the form. If you are recording changes to medication, leave "None" blank.

Instructions are provided below. If further clarification is required for any question on the form, please contact the ACRIN Data Management Center.

Medication Column: Indicate Generic name only.

Start Date Column: If either the month (mm) or day (dd) are unknown, record "99". If the year (yyyy) is unknown, record "9999".

Examples: 12/99/2008 or 01/15/9999.

Check "Unknown" if the entire date is unknown.

End Date Column: If either the month (mm) or day (dd) are unknown, record "99". If the year (yyyy) is unknown, record "9999".

Examples: 12/99/2008 or 01/15/9999.

Check the "Unknown" box if the entire date is unknown.

Check the "Ongoing" box if the participant is currently taking the medication.

Reason: Indicate the reason for the change in concomitant medications recorded since visits 1..

- Completed – Select if participant completed concomitant medication regimen.
- Disease Progression, relapse during active treatment – Select if concomitant medication regimen is a result disease progression (does not have to be related to cancer, other diseases/conditions may apply, ex kidney disease, etc.).
- Adverse event/side effects/complications – Select if change is a result of AE, side affect or complication.
- New medication – Select if new medication is prescribed/administered since last visit.
- Participant decision – Select if participant made adjustments or discontinued medication regimen without physician's knowledge.
- PCP decision – Select if PCP discontinued medication regimen.
- Increased dose regimen – Select if physician increased medication dosage.
- Decreased dose regimen – Select if physician decreased medication dosage.
- Other* (specify reason) – Select if no other reason for change applies. Other reason must be provided.
- Unknown – Select if reason for change is unknown.

*****Important*** -** Select "Submit" to complete record entry. Select "complete form" on the subsequent screen and the C3 form in the "Data Collection" screen to continue recording subsequent Concomitant Medication changes. Until further notice, this process must be followed for every Concomitant Medication being recorded. **Example**: When recording changes since visit 1, select C3 form in the "Data Collection" screen and input changes and be sure to re-select the C3 form for additional medication change recorded in visit 3.

OA

ACRIN 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib
Telephone Contact Form

ACRIN Study 6687
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ box. ☐

1. Telephone Contact Timepoint *(check one)* [1]

- **O** Visit 3 (24 hours after Pre-treatment PET Scan)
- **O** Visit 5 (24 hours after Post-treatment PET Scan)

2. Was the study participant (patient) or proxy successfully contacted by phone? [2]

- O No (complete Q2a, initial and date form) (detail attempts on RE form)
- O Yes (skip to Q3 and complete form)

2a. Reason [3]

- O Participant deceased
- O No response, multiple contacts attempted made but participant has not replied
- O Participant / Proxy refused follow-up
- O No attempt made to administer follow-up
- O Physical illness / cognitive impairment
- O Other, specify _____ **[4]**

3. Provide date and time of follow-up telephone call for AE and Concomitant medication assessments
(if the participant is unable to be reached detail attempts on RE form)

3a. Date of telephone contact ____-____-____ *(mm-dd-yyyy)* [5] ☐ Unknown [6]

3b. Time *(Military Time)* ___ ___ : ___ ___ *hh:mm* [7] ☐ Unknown [8]

4. Did the participant experience any AE's, including the following, as a result of the ^{18}F-Fluoride PET Scan at this timepoint *(within 24 hours after PET scan)***?** [9]

- O No *(skip to Q5)*
- O Yes *(complete Q4a, review protocol and/or contact HQ for AE reporting)*

4a. Events:

mark all that apply ☐ =1 Not Marked, ☑ = 2 Marked

- ☐ Bruising [10]
- ☐ Bleeding [11]
- ☐ Muscle Aches [12]
- ☐ Hemorrhage [13]
- ☐ Infection [14]
- ☐ Soreness [15]
- ☐ Allergic Reaction [16]
- ☐ Other [17], specify [18] _____

5. Any changes to concomitant medications provided at previous timepoint? [19]

- O No (sign and date form)
- O Yes *(Report changes on C3 (visit 3) or C5 (visit 5) forms)*

_____ [20]
Initials of person(s) completing this form

_____-_____-_____ [21]
Date form completed *(mm-dd-yyyy)*

ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

Telephone Report Form

OA Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

The OA Form is required for each participant on the ACRIN 6687 study and is completed as part of the Telephone Contact Visit (Visits 3 & 5) which occur 24 hours after Pre and Post-treatment PET Scans.

1. Telephone Contact Timepoint: (Please be careful to select the appropriate timepoint).

2. Was the study participant (patient) or proxy successfully contacted by phone?
- **(1) No:** Answer Q2a and provide details of contact attempts on the RE form.
- **(2) Yes:** Skip to Q3.

3. Provide date and time of follow-up telephone call for AE and Concomitant medication assessments.

4. Did the participant experience any AE's, including the following, as a result of the 18F-Fluoride PET Scan at this timepoint *(within 24 hours after PET scan)***?**
- **(1) No:** Skip to Q5
- **(2) Yes:** Complete Q4a, **r**efer to section 11.0 of the protocol, and/or contact HQ for AE reporting

5. Any changes to concomitant medications provided at previous timepoint?
- **(1) No:** sign and date form
- **(2) Yes:** record Concomitant Medication changes on the C3 (visit 3) or C5 (visit 5) forms.

EX **ACRIN 6687**
Imaging Agent Administration
Treatment Exposure Form

ACRIN Study **6687**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Imaging Agent: ^{18}F-Fluoride

If this is a revised or corrected form, please √ box. ☐

Exam Data

1. Planned time point:[1]
- o Visit 2: Pre-Treatment
- o Visit 4: Post-Treatment

2. Was imaging agent administered?[2]
- o No (Initial & date form)
- o Yes

3. Imaging agent name:[3]
- o ^{18}F-Fluoride

4. Administration date:[4]
_____ - _____ - _____ (mm-dd-yyyy)

Imaging Agent Procurement

5. Identification number (Lot #):[5] _____

6. Source of agent:[6]
- o Prepared in-house (provide method by which agent is synthesized, complete Q6a)
- o Obtained from outside supplier (complete Q6b)

6a. Method:[7] _____

6b. Supplier:[8] _____

Administration Information

7. Route of administration:[9] ● IV

8. Activity in full syringe before injection: ___.___ mCi[10]

8a. Time of assay of full syringe before injection: __:__ (military time)[11] ☐ Unknown[12]

9. Time of injection: __:__ (military time)[13] ☐ Unknown[14]

10. Residual activity in syringe after injection: ___.___ mCi[15] ☐ Unknown[16] (if unk, skip to Q12)

10a. Time of assay of residual activity after injection: __:__ (military time)[17] ☐ Unknown[18]

11. Net activity administered (Dosage Amount): ___.___ mCi[19]

12. Site of injection:[20]
- O Right antecubital
- O Right wrist
- O Right foot
- O Indwelling central catheter
- O Left antecubital
- O Left wrist
- O Left foot
- O Unknown
- O Other, specify[21] _____

13. Any infiltration at injection site noted?[22]
- O None
- O Minor (estimated to be less than or equal to 20% of dose)
- O Severe (estimated to be more than 20% of dose)

_____
Initials of person who completed form[23]

_____-_____-_____
Date form completed (mm-dd-yyyy)[24]

ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

Treatment Exposure Form

EX Completion Instructions

The EX Form is required for each study scan. The PET/CT Technologist should complete the form at the time of each scan (Visit 2 and Visit 4).

NOTE: These form completion guidelines only address certain specific form questions.
Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

Question 1: Study Time Point *Please verify the correct time point is selected since subsequent web entry may be affected.*

Visit 2: Pre-treatment
Visit 4: Post treatment

Question 2: Was imaging agent administered?

No: Select if the participant was not given the imaging agent. Complete additional form questions as appropriate (eg., Q4)
Yes: Select if the imaging agent was administered to the participant.

Question 4: Administration Date (PET/CT imaging appointment): This question is required if the participant came to the imaging center and should be provided even in the event they were not injected/imaged.

Administration Information Section:

Question 8: Activity in full syringe before injection: must be recorded **in mCi** to the nearest 0.1 mCi. Units should not be entered on web form.

Question 8a: Time of assay of full syringe before injection: must be recorded in military time. If "Unknown" a PR form must be submitted explaining the reason and proposed corrective action.

Question 9: Time of injection: must be recorded in military time. If "Unknown", submit a PR form.

Question 10: Residual activity in syringe after injection: required if more than 0.1mCi remains. This value must be recorded in mCi. Units should not be web entered. If the response is "Unknown", leave questions 10a and 11 blank and submit a PR form.

Question 10a: Time of assay of residual activity after injection: must be recorded in military time. If "Unknown" submit a PR form.
Question 11: Net activity administered: must be recorded to nearest 0.1 mCi. Units should not be web entered.

Initials of Person(s) completing this form *The source document* must have the signature and date of the person responsible for the data (PET technologist).

I4

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib

Visit 4: Post-treatment Evaluation

If this is a revised or corrected form, please √box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Visit 4: Post-treatment

1. Clinical trial time point:[1] O Visit 4: Post-Treatment

2. Date of Evaluation:[2] _____-_____-_____ (mm-dd-yyyy)

Study Procedures: Details of assessments must be recorded in source.

3. Study procedures completed and/or assessed as part of Visit 4

[mark all that apply: ☐ = 1 Not Marked, ☑ = 2 Marked]

- ☐ Medical History Reviewed[4]
- ☐ Physical Exam[5]
- ☐ Concomitant Medications documented[6]
- ☐ Pathology Reports (metastatic bone biopsy)[7]
- ☐ Prostate-specific antigen measures[8]
- ☐ Bone alkaline phosphatase[9]
- ☐ Urine N-telopeptide[10]
- ☐ Bone Scan (submit images to ACRIN)[11]
- ☐ CT Scan (submit images to ACRIN)[12]
- ☐ MRI Scan (submit images to ACRIN)[13]
- ☐ X-Ray Scan (submit images to ACRIN)[14]
- ☐ Other imaging[15], specify (submit images to ACRIN)

_____[16]

4. ECOG Performance Status[21]

- O 0 Normal activity. Fully active, able to continue all predisease performance without restrictions.
- O 1 Symptoms, but ambulatory. Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature (eg. light housework, office work)
- O 2 In bed <50% of the time. Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.
- O 3 Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours.
- O 4 Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair.
- O 5 Dead

5. Prostate-Specific Antigen Measurements

5a. Date[22] _____-_____-_____

5b. Value[23] ☐☐☐.☐☐

5c. Unit of Measure[24]

- O n/mg
- O ng/mL
- O U/L
- O ng/dL
- O mcg/L

5d. Method of Assay[25]

- O Abbott
- O Bayer
- O DPC
- O Hybritech
- O Other
- O Unknown

6. Bone Alkaline Phosphatase

6a. Date[26] _____-_____-_____ *(mm/dd/yyyy)*

6b. Value[27] (ng/ml) ☐☐.☐☐

7. Urine N-telopeptide (uNTx)

7a. Date[28] _____-_____-_____ *(mm/dd/yyyy)*

7b. Value[29] (nmol/L) ☐☐☐.☐

8. Number of tumors identified[30] ☐☐

9. How were tumors seen on imaging? (check all that apply)

☐ MRI[31] ☐ X-Ray[32] ☐ CT[33] ☐ Bone scan[34] ☐ Other[35], specify_____[36]

If this is a revised or corrected form, please √ box. ☐

ACRIN Study **6687**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Visit 4: Post-treatment

10. TNM Staging Classification (AJCC)

T$_{[37]}$ *(select one – size of primary tumor only)*

- O TX
- O T0
- O T1
- O T2
- O T3

N$_{[38]}$ *(sele*

- O NX
- O N0
- O N1

M$_{[39]}$ *(select one)*

- O MX
- O M0
- O M1
- O M1a
- O M1b

_____

Initials of person(s) completing this form$_{[41]}$

_____-_____-_____

Date form completed *(mm-dd-yyyy)*$_{[42]}$

I4 Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

The I4 Form is required for each participant on the ACRIN 6687 study and is completed as part of the Post-Treatment visit.

2. Date of Evaluation: This is the date the post-treatment visit.

Study Procedures:

3. Study procedures completed and/or assessed as part of Visit 4:

- Participant completed all of the study specified Post-Treatment procedures as described in Section 9.4 of the protocol: Review the standard clinical test results performed after enrollment, which includes:
  - Physical examination;
  - Metastatic bone biopsy, if additional biopsy was ordered;
  - Bone scan;
  - CT and/or MRI scan(s) of chest, abdomen, and pelvis;
  - Any other scans performed for evaluation, e.g. x-rays, if indicated;
  - Prostate-specific antigen (PSA) measures;
  - Bone alkaline phosphatase;
  - Urine N-telopeptide.
- Please check routine clinical follow-up assessed. **Note:** Details of assessments will be verified during routine monitoring and auditing
- All scans and other imaging must be submitted to ACRIN Imaging Department.
- *If protocol defined Post-treatment visit procedures were not assessed, provide reason on RE form.* Assessment of physical exam is a protocol defined required procedures.

8. Number of tumors identified: Provide total number of tumors seen up to 99.

10. Staging Classification (AJCC): Indicate T stage for the primary tumor only. Indicate one N and M stage.

P4

ACRIN 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib
Visit 4: PET/CT Imaging Form

If this is a revised or corrected form, please √box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INSTRUCTIONS: PET imaging will be interpreted and the form completed by a **Radiologist**. Submit this form via the **ACRIN** website.

Part I - PET Scan

1. **Clinical trial time point:**[1] O Visit 4: Post-Treatment
2. **Date of PET Exam:**[2] _____-_____-_____ (mm-dd-yyyy)
3. **Date of PET Interpretation:**[3] _____-_____-_____ (mm-dd-yyyy)
4. **Name of Reader:**[4] _____
5. **Reader ID:**[5] _____
6. **Actual Dasatinib treatment date** (mm-dd-yyyy)[6] _____-_____-_____
7. **Image Quality Interpretable?**[7]
   - O 1 Adequate (proceed to **Q8**)
   - O 2 Uninterpretable (proceed to **Q7a**)

   7a. Reason [mark all that apply]:

   mark all that apply ☐=1 Not Marked, ☑ = 2 Marked

   - ☐ 1 Motion[8]
   - ☐ 2 Artifacts[9]
   - ☐ 3 Contrast Media[10]
   - ☐ 4 DICOM header[11]
   - ☐ 5 Lost Images[12]
   - ☐ 6 Poor S/N[13]
   - ☐ 7 Incomplete Anatomic Coverage[14]
   - ☐ 8 Other[15], specify[16] _____

8. **Were minimal guidelines for scanning followed per protocol?**[17]
   O 1 No O 2 Yes O 9 Unknown

Part II - Tumor (in Dynamic FOV)

1. **Total number of tumors visible:** _____[18]

List up to the 5 most prominant tumors in column 1 (ex: T1, T2, etc.) as recorded on the P2 form, and identify anatomic site from Table 1 in column 2.

Table 1 - Anatomic Site (in column 2)

1	Skull	12	Sternum
2	C-Spine	13	T-spine
3	Humerus (right)	14	L-spine
4	Humerus (left)	15	Pelvis (left)
5	Radius/ulna (right)	16	Pelvis (right)
6	Radius/ulna (left)	17	Sacrum
7	Hand (right)	88	Other, specify*
8	Hand (left)		
9	Ribs (right)		
10	Ribs (left)		
11	Scapula / Clavicle		

Tumor ID #	Anatomic Site (select code from table 1) (*If "Other" (88) specify below)	Site Description (ex: L-3 index)	Indicate PET Slices (ex: 21-23)	SUV$_{max}$ (weight-based SUV$_{max}$ in g/mL or g/cm^3)	PET/CT Uptake for Bone mets 1 Definitely not present 2 Probably not present 3 Indeterminate 4 Probably present 5 Definitely present
T _____[19]	[20] _____[21]	[22]	[23]	___ ___ ___ • ___ [24]	[25]
T _____[26]	[27] _____[28]	[29]	[30]	___ ___ ___ • ___ [31]	[32]
T _____[33]	[34] _____[35]	[36]	[37]	___ ___ ___ • ___ [38]	[39]
T _____[40]	[41] _____[42]	[43]	[44]	___ ___ ___ • ___ [45]	[46]
T _____[47]	[48] _____[49]	[50]	[51]	___ ___ ___ • ___ [52]	[53]

Part III - Normal Bone Matched to Tumor

1. **Total number of tumor-matched normal bone regions to report:** _____[54]

List identifying normal bone MATCHED to TUMOR in column 1.

Identify anatomic site using Table 1 (above), and description of site in column 2.

Indicate the slices on the PET image corresponding to the normal bone region.

Initials of person completing form[85] _____

Date form completed[86] _____-_____-_____ (mm-dd-yyyy)

Normal Bone ID #	Anatomic Site (select from table 1) (*If "Other" specify below)	Site Description (ex: L-3 index)	Indicate PET Slices (ex: 21-23)	SUV$_{max}$ (weight-based SUV$_{max}$ in g/mL or g/cm^3)
N _____[55]	[56] _____[57]	[58]	[59]	___ ___ ___ • ___ [60]
N _____[61]	[62] _____[63]	[64]	[65]	___ ___ ___ • ___ [66]
N _____[67]	[68] _____[69]	[70]	[71]	___ ___ ___ • ___ [72]
N _____[73]	[74] _____[75]	[76]	[77]	___ ___ ___ • ___ [78]
N _____[79]	[80] _____[81]	[82]	[83]	___ ___ ___ • ___ [84]

P4 Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

The P4 Form is required for each participant on the ACRIN 6687 study and is completed as part of the Post-treatment ^{18}F-Fluoride PET/CT imaging (Visit 4). PET imaging will be interpreted and this form is to be completed by the study radiologist. Dates must be in the mm-dd-yyyy format. Submit this form within 2 weeks of PET via the ACRIN website. Submit paper form only for revisions or corrections. ***Important: Complete a row in the corresponding table for every tumor ID and normal bone # that was recorded on the P2 form, even if tumors are no longer visible on imaging.**

Part I – PET Scan

1. Clinical trial time point: Record the appropriate response. The response to this question is mandatory and the default is set according to the form being completed; Visit 4: Post-Treatment.

2. Date of PET Exam: Mandatory. Record the date that the PET Exam was performed (date must not be in the future).

3. Date of PET Interpretation: Mandatory. Record the date the PET was interpreted by the radiologist. Date must not be prior to the Date of PET Exam or a future date.

4. Name of Reader: Mandatory. Insert reader name.

5. Reader ID: This 7 alphanumeric character user specific ID is required.

6. Actual Dasatinib treatment date: Record start date of Dasatinib.

7. Image Quality Interpretable: Record image quality information in Q7 & 7a as appropriate.

8. Were minimal guidelines for scanning followed per protocol? Follow the guidelines outlined in the protocol.

Part II – Tumors (in Dynamic FOV)

1. Total number of tumors visible: Record up to 99 as appropriate

CHART INSTRUCTIONS: INCLUDE ALL TUMORS RECORDED ON THE P2 FORM (even if no longer visible)

Column 1 - Tumor ID#: Record as 1-5, as needed, in numerical order. The system will accept up to 5 bone tumors but not less than the number recorded in Q1. Only list tumors recorded on the P2 form.

Column 2 - Anatomic Site: Use "Table 1 – Anatomic Site" to the left of the chart to record anatomic site. If response is "88 – Other specify", indicate the other anatomic site location on the line in column 2.

Column 3 - Site Description: Provide a brief description of the site.

Column 4 – Indicate PET Slices: Indicate the PET slices containing the tumor.

Column 5 - SUV Max: Provide weight-based SUV_{max}.

Column 6 - PET/CT Uptake for bone metastasis: Select the appropriate response

Part III – Normal Bone Matched to Tumor

1. Total number of tumor-matched normal bone regions to report: Report up to five as appropriate.

CHART INSTRUCTIONS: INCLUDE ALL NORMAL BONE RECORDED ON THE P2 FORM (even if now diseased)

Column 1 - Normal Bone ID#: List identifying normal bone using the same normal bone ID #s and located in the same sites as previously reported on the P2 form. Rows left blank on the P2 form should also be left blank on this P4 form. ID numbers can be repeated if the same normal bone is the best match for multiple tumors. For example, the ID #2 and its corresponding information can be recorded in rows 2 and 3 if it applies to both to tumor T2 and T3. The total number of unique normal bone ID #s must match the number of normal bone recorded in Q1.

Column 2 - Anatomic Site: Use “Table 1 – Anatomic Site” located under Part II (to the left of the chart on the web) to record anatomic site. If response is “88 – Other specify”, indicate the other anatomic site location on the line in column 2.

Column 3 - Site Description: Provide a brief description of the site including the phrase 'Not Normal' if disease is suspected to have spread to the previously normal site.

Column 4 – Indicate PET Slices: Indicate the PET slices containing the normal bone region.

Column 5 - SUV Max: Provide weight-based SUV_{max}.

SA

ACRIN 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib
^{18}F-Fluoride Safety Assessment Form

ACRIN Study 6687
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √box. ☐

1. Timepoint *(check one)* [1]

O 1 Visit 2
O 2 Visit 4

Part I. Monitoring for Physiologic Effects of ^{18}F-Fluoride *Complete entire table for each ^{18}F-Fluoride imaging scan*

Time Point of Vital Sign Reading	Time Taken *Military time*	Pulse	Blood Pressure *Systolic/Diastolic*	Respirations *Check one*	Temperature
Prior to Injection	__ __ : __ __ [2] *hh:mm* ☐ Unknown [3]	_____ bpm [4] ☐ Unknown [5]	_____ / _____ mmHg [6] [7] ☐ Unknown [8]	O Labored [9] O Unlabored O Unknown	_____ . _____ °C [10] ☐ Unknown [11]
Completion of PET Imaging	__ __ : __ __ [12] *hh:mm* ☐ Unknown [13]	_____ bpm [14] ☐ Unknown [15]	_____ / _____ mmHg [16] [17] ☐ Unknown [18]	O Labored [19] O Unlabored O Unknown	_____ . _____ °C [20] ☐ Unknown [21]

1. Did the participant require any additional monitoring of vital signs? [22]

O 1 No
O 2 Yes

1a. If yes, provide the last reading of vital signs taken before the participant left the PET facility:

Time Taken *Military time*	Pulse	Blood Pressure *Systolic/Diastolic*	Respirations *Check one*	Temperature
__ __ : __ __ [23] *hh:mm* ☐ Unknown [24]	_____ bpm [25] ☐ Unknown [26]	_____ / _____ mmHg [27] [28] ☐ Unknown [29]	O Labored [30] O Unlabored O Unknown	_____ . _____ °C [31] ☐ Unknown [32]

Part II. Adverse Events *Refer to Section 11.0 of the protocol*

1. Were any AE's reported *(as part of this Imaging visit)*? [33]

O 1 No
O 2 Yes *(Report on a AE Form)*

_____ [38]
Initials of person(s) completing this form

_____-_____-_____ [39]
Date form completed *(mm-dd-yyyy)*

SA Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

The SA Form is required for each participant on the ACRIN 6687 study and is completed as part of the ^{18}F-Fluoride PET/CT imaging (Visit 2 & Visit 4).

Part I. Monitoring for Physiologic Effects of ^{18}F-Fluoride

All elements of the table are required.

1. Did the participant require any additional monitoring of vital signs?

(1) No Skip to Part II

(2) Yes The patient should be monitored until the site investigator (or his/her delegate) judges that the patient may safely leave the PET facility. The reading of vital signs taken before the patient leaves should be recorded in Q1a.

1a. If yes, provide the last reading of vital signs taken before the participant left the PET facility:

All elements of the table are required (time, pulse, blood pressure, respirations, and temperature)
NOTE: If any treatment is deemed necessary, it must be documented in source.

Part II. Adverse Events

1. Were any adverse events reported?

(1) No Initial and date the form

(2) Yes Refer to Section 11.0 of the protocol and contact HQ to report AE

Any subject who has a serious adverse event during or after infusion of ^{18}F-Fluoride, such that imaging cannot be completed safely, in the judgment of the site investigator, will be withdrawn from the study (must also be recorded on a DS form).

TA

ACRIN 6687
^{18}F-Fluoride PET/CT
PET/CT Local Technical Assessment Form

ACRIN Study 6687
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Imaging Agent: ^{18}F-Fluoride

If this is a revised or corrected form, please ✓ box. ☐

Exam Data

1. Clinical trial time point [1]
- o Visit 2: Pre-Treatment
- o Visit 4: Post-Treatment

2. Imaging Agent Name [2]
- o ^{18}F-Fluoride

3. Was imaging exam completed? [4]
- o No, imaging not completed (complete Q3a, then form as applicable)
- o Yes (proceed to Q4 and continue with form)

3a. *If Imaging not completed, provide reason: [5]
- o Scheduling problem
- o Equipment failure
- o Participant refusal
- o Medical reason
- o Injection site complications
- o Claustrophobia
- o Participant withdrew consent
- o Progressive disease
- o Imaging agent not administered
- o Adverse event (complete AE form)
- o Participant death
- o Unknown
- o Other, specify: _____ [6]

4. Date of imaging: [7] (mm-dd-yyyy)

_____ - _____ - _____

5. Weight

|_|_|_| . |_| kg [8]

☐ Unknown [9]

6. Height

|_|_|_| cm [10]

☐ Unknown [11]

7. Was Foley Catheter in place for study? [19]
- o No (complete Q8-Q9)
- o Yes (skip to next section)

8. Patient voided immediately pre-imaging? [20]
- o No
- o Yes
- o Unknown

9. Patient voided immediately post-imaging? [21]
- o No
- o Yes
- o Unknown

Scanner

☐ Not Done [22]

2. Has the scanner used for <u>this study</u> been qualified by ACRIN? [24]
- o No, specify reason and complete Q3: _____ [25]
- o Yes, provide ACRIN Scanner ID# (skip to Q4): _____ [26]

3. Scanner used for this exam:

3a. Manufacturer

_____ [27]

3b. Manufacturer model name/or number

_____ [28]

4. Date of last PET Scanner SUV validation: [29]

_____ - _____ - _____ (mm-dd-yyyy)

5. Daily scanner QC run on date of study? [30]
- o No
- o Yes

TA

ACRIN 6687
^{18}F-Fluoride PET/CT
PET/CT Local Technical Assessment Form

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Imaging Agent: ^{18}F-Fluoride

If this is a revised or corrected form, please √ box. ☐

CT Image Acquisition or Transmission Scan

☐ Not Done[37]

1. Type of attenuation correction used?[38]
- o CT (complete Q2 thru 6)
- o Ge-68 Segmentation (complete Q7)
- o Cs-137 Segmentation (complete Q7)

2. Was oral contrast administered?[39]
- o No (skip to Q3)
- o Yes, if used specify type:[40] o Positive o Negative

2a. Amount[41] ____ ml ☐ Unknown[42]

3. Was IV contrast administered?[43]
- o No (skip to Q4)
- o Yes

3a. Amount[44] ____ ml ☐ Unknown[45]

3b. Time of injection[46]
____:____ (military time) ☐ Unknown[47]

4. kVp
____[48]
☐ Unknown[49]

5. mAs
____[50]
☐ Unknown[51]

6. Slice Thickness of reconstructed images
__.__ mm[52]
☐ Unknown[53]

7. Length of Transmission Scan: ____ (minutes)[54] ☐ Unknown[55]

Dynamic PET Emission Scan

☐ Not Done[56]

1. Acquisition mode[57] o 2D o 3D

2. Number of bed positions scanned ____[58]

PET Emission Scan: **Type of Scan** **Start Time** (military time) **Stop Time** (military time)

Type of Scan:
1 Dynamic

3a. ____[59] **3b.** ____:____[60] **3c.** ____:____[61]

Reconstructed Images: **4. Pixel Size:** __.__mm[62] **5. Thickness:** __.__mm[63]

Additional CT Image Acquisition or Transmission Scan

☐ Not Done[64]

**** Complete section if needed for dynamic imaging ****

1. Type of attenuation correction used?[65]
- o CT (complete Q2 thru 4)
- o Ge-68 Segmentation (complete Q5)
- o Cs-137 Segmentation (complete Q5)

2. kVp
____[66]
☐ Unknown[67]

3. mAs
____[68]
☐ Unknown[69]

4. Slice Thickness of reconstructed images
__.__ mm[70]
☐ Unknown[71]

5. Length of Transmission Scan: ____ (minutes)[72] ☐ Unknown[73]

TA

ACRIN 6687
^{18}F-Fluoride PET/CT
PET/CT Local Technical Assessment Form

Imaging Agent: ^{18}F-Fluoride

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Whole Body PET Emission Scan

☐ Not Done [74]

1. Acquisition mode [75] o 2D o 3D

2. Number of bed positions scanned ___ [76]

PET Emission Scan:	**Type of Scan**	**Start Time** (military time)	**Stop Time** (military time)
Type of Scan: 2 Whole Body	**3a.** ___ [77]	**3b.** ___ : ___ [78]	**3c.** ___ : ___ [79]

Reconstructed Images: **4. Pixel Size:** ___ . ___ mm [80] **5. Thickness:** ___ . ___ mm [81]

_____ [84]
Initials of person completing this form

_____ - _____ - _____ [85]
Date form completed (mm-dd-yyyy)

TA Completion Instructions

Refer to Section 10.0 of the protocol for Detailed Criteria/Specifications for Performance of PET/CT Scans

A TA Form is required for each study scan. The PET/CT Technologist should complete the form at the time of each scan (Visit 2 and Visit 4). All scans are required per protocol. Please refer to the Protocol for further details.

NOTE: These form completion guidelines do not address each question found on the form.
Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

1. Clinical trial time point: *Please verify the correct time point is selected since subsequent web entry may be affected.*
Visit 2: Pre-treatment
Visit 4: Post treatment

3. Was imaging exam completed?
No, imaging not completed: Select if the participant was given the imaging agent and imaging was started but could not be completed. Complete Q3a and the remainder of the form as applicable.

Yes: Select if the participant was given the imaging agent and imaging was completed. Each section of the TA form must be completed.

4. Date of imaging: This question is required if the participant came to the imaging center and should be provided even in the event they are not injected/imaged.

5. Weight: This must be recorded in kg and taken on the day of the PET/CT scan.

6. Height: This must be recorded in cm and taken on the day of the PET/CT scan.

"Not Done" located at the beginning of each section, should be check ***ONLY*** if it was not performed and there is no data to record.

Initials of Person(s) completing this form *The source document* must have the signature and date of the person responsible for the data (PET technologist).

C5

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib

Visit 5: Concomitant Medication Change Form

ACRIN Study 6687

PLACE LABEL HERE

Institution ____________ Institution No. ________

Participant Initials __________ Case No. __________

If this is a revised or corrected form, please √ box. ☐

VISIT 5: CONCOMITANT MEDICATION CHANGE FORM

☐ None[1] Check "none" if there are no changes or new Concomitant Medications to report since previous visits.

Medication[2] (Generic Name only)	Start Date (mm/dd/yyyy) [3] [4] [5] Unk [6]	End Date (mm/dd/yyyy) [7] [8] [9] Unk[10] Ongoing[11]	Reason [12] (Provide reason for change) 1 Completed 2 Disease Progression, relapse during active treatment 3 Adverse event/side effects/ complications 4 New medication 5 Participant decision 6 PCP decision 7 Increased dose regimen 8 Decreased dose regimen 88 Other* (specify reason)[13] 99 Unknown
____________	___-___-___ ☐ Unknown	___-___-___ ☐ Unknown ☐ Ongoing	O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8 O 88 O 99 *Specify other, ________
____________	___-___-___ ☐ Unknown	___-___-___ ☐ Unknown ☐ Ongoing	O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8 O 88 O 99 *Specify other, ________
____________	___-___-___ ☐ Unknown	___-___-___ ☐ Unknown ☐ Ongoing	O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8 O 88 O 99 *Specify other, ________
____________	___-___-___ ☐ Unknown	___-___-___ ☐ Unknown ☐ Ongoing	O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8 O 88 O 99 *Specify other, ________
____________	___-___-___ ☐ Unknown	___-___-___ ☐ Unknown ☐ Ongoing	O 1 O 2 O 3 O 4 O 5 O 6 O 7 O 8 O 88 O 99 *Specify other, ________

*****Important: If there are additional changes to report, list on additional C5 forms.*****

ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

Concomitant Medications Form

C5 Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

The C5 (Concomitant Medication Change Form) is required for each participant on the ACRIN 6687 study and is completed as part of Telephone Contact during visit 5. This form is completed to report changes in concomitant medication since visits 1 and 3. Include newly prescribed medication if not captured on the C3 form. Use additional C5 forms if there are more than 5 changes to previously recorded Concomitant Medications. The designated research staff must complete the form with the appropriate completed source documents. It is submitted via the ACRIN website at www.acrin.org within two weeks of visit 5. Dates are reported as mm-dd-yyyy.

If there are no changes or new Concomitant Medications to report since previous visits, check "None" located at the top right of the form. If you are recording changes to medication, leave "None" blank.

Instructions are provided below. If further clarification is required for any question on the form, please contact the ACRIN Data Management Center.

Medication Column: Indicate Generic name only.

Start Date Column: If either the month (mm) or day (dd) are unknown, record "99". If the year (yyyy) is unknown, record "9999".

Examples: 12/99/2008 or 01/15/9999.

Check "Unknown" if the entire date is unknown.

End Date Column: If either the month (mm) or day (dd) are unknown, record "99". If the year (yyyy) is unknown, record "9999".

Examples: 12/99/2008 or 01/15/9999.

Check the "Unknown" box if the entire date is unknown.

Check the "Ongoing" box if the participant is currently taking the medication.

Reason: Indicate the reason for the change in concomitant medications recorded since visits 1 and 3.

- Completed – Select if participant completed concomitant medication regimen.
- Disease Progression, relapse during active treatment – Select if concomitant medication regimen is a result disease progression (does not have to be related to cancer, other diseases/conditions may apply, ex kidney disease, etc.).
- Adverse event/side effects/complications – Select if change is a result of AE, side affect or complication.
- New medication – Select if new medication is prescribed/administered since last visit.
- Participant decision – Select if participant made adjustments or discontinued medication regimen without physician's knowledge.
- PCP decision – Select if PCP discontinued medication regimen.
- Increased dose regimen – Select if physician increased medication dosage.
- Decreased dose regimen – Select if physician decreased medication dosage.
- Other* (specify reason) – Select if no other reason for change applies. Other reason must be provided.
- Unknown – Select if reason for change is unknown.

*****Important*** -** Select "Submit" to complete record entry. Select "complete form" on the subsequent screen and the C5 form in the "Data Collection" screen to continue recording subsequent Concomitant Medication changes. Until further notice, this process must be followed for every Concomitant Medication being recorded. **Example**: When recording changes, select C5 form in the "Data Collection" screen and input changes and be sure to re-select the C5 form for additional medication change recorded in visit 5.

OA

ACRIN 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib
Telephone Contact Form

ACRIN Study 6687
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ box. ☐

1. Telephone Contact Timepoint *(check one)* [1]

- **O** Visit 3 (24 hours after Pre-treatment PET Scan)
- **O** Visit 5 (24 hours after Post-treatment PET Scan)

2. Was the study participant (patient) or proxy successfully contacted by phone? [2]

- O No (complete Q2a, initial and date form) (detail attempts on RE form)
- O Yes (skip to Q3 and complete form)

2a. Reason [3]

- O Participant deceased
- O No response, multiple contacts attempted made but participant has not replied
- O Participant / Proxy refused follow-up
- O No attempt made to administer follow-up
- O Physical illness / cognitive impairment
- O Other, specify _____ **[4]**

3. Provide date and time of follow-up telephone call for AE and Concomitant medication assessments
(if the participant is unable to be reached detail attempts on RE form)

3a. Date of telephone contact ____-____-____ *(mm-dd-yyyy)* [5] ☐ Unknown [6]

3b. Time *(Military Time)* ___ ___ : ___ ___ *hh:mm* [7] ☐ Unknown [8]

4. Did the participant experience any AE's, including the following, as a result of the ^{18}F-Fluoride PET Scan at this timepoint *(within 24 hours after PET scan)***?** [9]

- O No *(skip to Q5)*
- O Yes *(complete Q4a, review protocol and/or contact HQ for AE reporting)*

4a. Events:

mark all that apply ☐ =1 Not Marked, ☑ = 2 Marked

- ☐ Bruising [10]
- ☐ Bleeding [11]
- ☐ Muscle Aches [12]
- ☐ Hemorrhage [13]
- ☐ Infection [14]
- ☐ Soreness [15]
- ☐ Allergic Reaction [16]
- ☐ Other [17], specify [18] _____

5. Any changes to concomitant medications provided at previous timepoint? [19]

- O No (sign and date form)
- O Yes *(Report changes on C3 (visit 3) or C5 (visit 5) forms)*

_____ [20]
Initials of person(s) completing this form

_____-_____-_____ [21]
Date form completed *(mm-dd-yyyy)*

ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

Telephone Report Form

OA Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

The OA Form is required for each participant on the ACRIN 6687 study and is completed as part of the Telephone Contact Visit (Visits 3 & 5) which occur 24 hours after Pre and Post-treatment PET Scans.

1. Telephone Contact Timepoint: (Please be careful to select the appropriate timepoint).

2. Was the study participant (patient) or proxy successfully contacted by phone?
- **(1) No:** Answer Q2a and provide details of contact attempts on the RE form.
- **(2) Yes:** Skip to Q3.

3. Provide date and time of follow-up telephone call for AE and Concomitant medication assessments.

4. Did the participant experience any AE's, including the following, as a result of the 18F-Fluoride PET Scan at this timepoint *(within 24 hours after PET scan)***?**
- **(1) No:** Skip to Q5
- **(2) Yes:** Complete Q4a, **r**efer to section 11.0 of the protocol, and/or contact HQ for AE reporting

5. Any changes to concomitant medications provided at previous timepoint?
- **(1) No:** sign and date form
- **(2) Yes:** record Concomitant Medication changes on the C3 (visit 3) or C5 (visit 5) forms.

DS

ACRIN 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib

End of Study Disposition

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6687
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

1. Provide reason for study disposition by selecting *one* of the following: [1]

- O 1 Protocol defined follow-up completed
- O 2 Participant lost to follow-up
- O 3 Participant refused follow-up / withdrew
- O 4 Death *(complete Q1a)*
- O 5 Adverse Event / Side Effects / Complications
- O 6 Protocol variation/deviation *(complete Q1b)*
- O 7 Disease progression
- O 8 Study terminated by sponsor

1a. Death Information

Date of death: _____[2]/_____[3]/_____[4] *(mm/dd/yyyy)* ☐ Unknown[19]

Cause of death [5]

- O 2 Disease Progression
- O 88 Other, specify _____[6]

1b. Protocol Variation / Deviation Information *(check all that apply)*

- ☐ Did not meet eligibility[7]
- ☐ Technical problems[8]
- ☐ Related to study visits[9]
- ☐ Related to imaging[10]
- ☐ Related to randomization[11]
- ☐ Other[12] *(specify below)*

Specify reason: _____[13]

2. Date of disposition: _____/_____/_____ *(mm/dd/yyyy)* [14]

3. Did the investigator review and sign off on the participant's disposition? [15]

- O 1 No
- O 2 Yes

Comments: _____[16]

_____[17]
Initials of person completing the form

_____/_____/_____[18]
Date form completed (mm-dd-yyyy)

To the best of my knowledge, the data collected for the participant are accurate and complete.

Investigator's signature _____

DS Completion Instructions

A DS Form is required for all study participants on an ACRIN study and is completed to document when a participant goes off-study for any reason or at participants' trial completion. It should be submitted within 2 weeks of completion/disposition date. **Please contact Data Management for all form related questions.**

Examples of when the DS form is required are as follows:

- Participant completes all visits and follow-up per protocol
- Participant withdraws consent
- Participant dies before last trial time point
- Ineligible participant has been registered

1. Provide reason for study disposition by selecting *one* of the following:

Select the **primary** reason for the end of study disposition.

1 – Protocol defined follow-up completed: Select this option if the participant completes study procedures as defined in the protocol.

2 – Participant lost to follow-up: Select this option only after all possible effort have been made to contact the participant.

3 – Participant refused follow-up/withdrew: Select this option if the participant withdraws

4 – Death (complete Q1a): The participant died before completing all trial time points. Q3 is required.

5 – Adverse Event/Side Effects/Complications: If this option is selected, a corresponding form (i.e., AE, side effect, or complication form) must be completed. In the event that a non-reportable AE is the primary reason a participant is discontinued from the study, contact the ACRIN AE Coordinator.

6 – Protocol variation / deviation (complete Q1b): The participant is withdrawn from the trial due to a protocol violation, as recorded on a PR form.

7 – Disease Progression: Select this option if the participant is removed from the trial due to prostate cancer progression or bone metastases.

8 – Study terminated by sponsor:

1a. Death Information

Date of Death:

Date is required if "Death" is selected in Q1. Record month (mm), day (dd), and year (yyyy). If the day and/or month are unknown, record 99. Check "unknown" if entire death date is unknown. Data Management will query date of death if unknown so make every attempt to submit a complete date of death.

Cause of Death: Cause of death is required if "Death" is selected in Q1.

2 – Disease progression

This option should only be selected if the death was directly related to prostate cancer progression or bone metastases.

88 – Other, Specify Cause of Death:

Any other cause of death should be provided here

1b. Protocol Variation / Deviation Information:

Required if "Protocol Variation/Deviation" is selected in Q1. Select all protocol variation/deviation(s) that applies to the participant's disposition.

2. Date of disposition.

This is the date the site determines the participant has reached the end of study.

3. Did the investigator review and sign off on the participant's disposition?

The investigator must sign off on the participant's end of study source record (ex., medical record, DS paper form, DS entry confirmation, etc…)

AE

ACRIN Adverse Event Form
ACRIN Study 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib

ACRIN Study 6687 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ box. ☐

All Adverse Events (AEs) and Serious Adverse Events (SAEs) as defined in the protocol require routine reporting via web entry of the AE CRF. Only one AE is captured per form. For further instructions in completing the form, please refer to the AE completion instructions. Please note that source documentation (ACRIN AE log, ACRIN AE CRF, printed AE web confirmation, or participant's chart) must have the investigator's signature. For AE reporting requirements, please refer to the AE reporting section of the protocol. Contact ACRIN's AE coordinator for any questions.

AE Description _____ [1, 2]

AE Short Name (online look-up) _____ [3]

Grade [4]	**Attribution** [5]	**Expectedness** [6]	**Serious AE?** [42]	**Expedited Report Submitted** [7]	**Action Taken** (mark ☒ all that apply)	**Outcome** [9]	**Date of AE Onset and Resolution** (mm-dd-yyyy); mark ☒ the box "ongoing" if the AE is ongoing at the time of report
O Mild O Moderate O Severe O Life threatening or disabling O Fatal	O Unrelated O Unlikely O Possible O Probable O Definite	O Expected O Unexpected	O No O Yes	O No O Yes	☐ None [43] ☐ Medication therapy [44] ☐ Procedure [45] ☐ Hospitalization [46] ☐ Other [47]	O Recovered O Improved O Ongoing O Death O Unknown	Start date: ____ - ____ - ____ [10] Resolution date: ____ - ____ - ____ [11] ☐ Ongoing [12]

Comments: _____ [37], [38]

Additional AEs to report? [39]
- O No
- O Yes (Please complete an additional AE form)

Was the AE assessed, reviewed and signed by the investigator? [40]
- O No
- O Yes

____-____-____ [41]
Date form completed (mm-dd-yyyy)

_____ [50]
Investigator's initials

Investigator's signature _____ *(for external use only)*

AE Form Completion Instructions

An adverse event (AE) form is to be completed for each reportable AE that occurs during the study. The adverse event reporting section of the protocol will specify reporting requirements. This form should be submitted via the ACRIN data center at www.acrin.org. All available dates should be reported as MM-DD-YYYY. Code all questions unless otherwise specified; do not leave mandatory questions blank. Instructions are provided below for all questions that are not self-explanatory. If further clarification is required for any question on the form, please contact the ACRIN AE Coordinator.

If revisions are required, a paper case report form (CRF) must be submitted. Refer to the general form completion instructions for additional details. Please use Good Clinical Practice (GCP) in making data corrections; a single line should be drawn through the incorrect data with your initials and the date. Please note that when revising the AE form, the investigator must also initial and date any revisions.

AE Description: A 200 character field is provided to allow for adequate adverse event description. Please include the investigator's determination of what the AE is related to.

Note: On the paper AE form, you may notice the following "[1, 2]" which represents element numbers. Each question on the form is stored in ACRIN's database as an element number. Element 2 is no longer active as the character length has increased to 200 from the former version which captured 60 characters in elements 1 and 2.

AE Short Name: This field requires an online look-up into the National Cancer Institute's (NCI) Common Toxicology Criteria for Adverse Events (CTCAE) data table.

1. Select the blue 'Adverse Event' button next to the "AE Short Name (online look-up)" field.
2. You will then be taken to another page with three fields:
    a. Category: (Required to search for appropriate short name and code)

    This is also known as the System Organ Class (SOC) within the CTCAE version 4.0. You MUST select a category in order to proceed. If you are having difficulty finding the appropriate category, you can search the electronic PDF of the CTCAE version 4.0 or contact ACRIN's AE Coordinator.

    b. Code Description: (Optional to search will narrow down the choices) you can filter further by entering partial term and or the entire term;

    OR

    c. MedDRA Term: (Optional to search will narrow down the choices) you can filter further by entering partial term and or the entire term.
3. To search select the blue 'Retrieve' button to obtain a list of code descriptions.
4. Review the code description and MedDRA term and select the appropriate code number of the reported AE.
5. Once selected, MedDRA code number will be populated in the AE Short Name field. The MedDRA term will be displayed in red to the right of the AE Short Name field on the web entry screen when you are returned to the form.

In the event that a paper AE form is completed and sent to ACRIN Data Management for entry, please document the appropriate AE short name from the CTCAE. If you have question about which short name is applicable, please contact ACRIN's AE coordinator for assistance.

Grade: Select the investigator-determined grade based on the National Cancer Institute's (NCI) Common Toxicology Criteria for Adverse Events (CTCAE). If the AE worsens (e.g. Grade 2 (moderate) to Grade 3 (severe), a new AE form must be completed.

Grade 1 = Mild
Grade 2 = Moderate
Grade 3 = Severe
Grade 4 = Life threatening or disabling
Grade 5 = Fatal

Attribution: Select the investigator-determined relationship of the AE to the study.

Expectedness: Expected AEs are listed in section 11.0 of the protocol, informed consent or the investigator's brochure. Unexpected AEs refers to an adverse event that has not been previously observed.

Serious AE: A serious adverse event (SAE) is defined as any untoward medical occurrence that:

- results in death, or
- is life-threatening (at the time of the event), or
- requires inpatient hospitalization or prolongation of an existing hospitalization, or
- results in persistent or significant disability or incapacity, or
- is a congenital anomaly/birth defect.

Expedited Report Submitted: Refer to section 11.8.1 of the protocol for information on what events require expedited reporting.

Action Taken: Select all actions taken; if 'None' is selected, no other boxes may be marked. If "Other" is selected, please provide details in the comments section.

Outcome: Select the patient's outcome. If 'Ongoing' is selected, the AE 'Resolution Date' should be blank and the 'Ongoing?' box must be marked. Please note that "ongoing" AEs will be queried by ACRIN until resolution is reached. Once additional information for an AE is obtained, ACRIN must be notified and the AE form must be updated accordingly. If an expedited report was submitted, this will also need to be updated accordingly.

Start Date & Resolution Date: These dates are mandatory unless the stop date is ongoing. In the event that the start date and/or resolution date are unknown and/or partial dates, sites are required to document the reason for the date omission(s) and any details (e.g. partial dates or estimated dates) in the comments section. Please note that sites will be queried if dates are inconsistent or if adequate details are not provided in the comments section. Once additional information for an AE is obtained, ACRIN must be notified and the AE form must be updated accordingly. If an expedited report was submitted, this will also need to be updated accordingly.

Comments: The comment field is provided for sites to document relevant clinical or study notations, etc. The comments section is not intended for "actionable" information you need to relate to data management (DM) and is not intended for data analysis. Comments should be limited to 200 characters.

Additional AEs to report: Only one adverse event is captured per form. If there are multiple events to report, select 'Yes' and an additional AE form will be populated to the patient calendar.

Was the AE assessed, reviewed, and signed by the investigator?: This question eliminates the need for entering the investigator's name into the database. However if a paper form is completed (e.g. for revision purposes, a down web system or if the AE form is used as a source document), the investigator's signature on the paper form is required.

Investigator's initials: Enter the initials [e.g. John Smith: JS] of the investigator responsible for assessing, reviewing and signing off on the AE.

Investigator's Signature (for external use only): The field is available for the site PI to sign off in the event that the site completes a paper AE form. The information from this field will not be entered into the ACRIN's database. PI sign off is captured by question "Was the AE assessed, reviewed and signed by the investigator?"

IMPORTANT: Please note that source documentation (ACRIN AE log, ACRIN AE CRF, printed web confirmation or participant's chart) must have the investigator's signature.

ACRIN 6687 Imaging Transmittal Worksheet

A PHASE 2, MULTICEN TER EVALUATION OF 18F-FLUORIDE PET AS A PHARMACODYNAMIC BIOMARKER FOR DASATINIB, A SRC KINASE INHIBITOR, IN MEN WITH CASTRATION-RESISTANT PROSTATE CANCER AND BONE METASTASES

IM

Instructions: Imaging exams should be submitted to the ACRIN-Image Management Center after each time-point/visit. The Image Transmittal Worksheet MUST be submitted via the ACRIN Data Center at www.acrin.org within two weeks of the visit. Dates are reported as mm/dd/yyyy. For exams submitted via media, remember to affix the proper label to the jacket of the media to include: study name, site name, and case no., date of exam, time point, and type of imaging.

***Reminder for PET imaging: All PET exams should contain three trans-axial whole body series, attenuated and non-attenuated corrected PET and the CT images.**

For further information or image related questions, contact the ACRIN Imaging personnel specified on the 6687 ACRIN website.

Section I: Image Data Demographics

ACRIN Site Number: ____[1] **ACRIN Case Number:** ____[2]

Patient DOB: __-__ - 19__[3] **Study Date** __-__ - 20__[4] **Patient Initials** ____[5] **First M Last**

Image Submission:

- ☐ PET[6]
- ☐ PET/CT[7]
- ☐ Bone Scan[8]
- ☐ MRI[9]
- ☐ CT[10]
- ☐ X-ray[11]
- ☐ Other[12] _____[13]

Section II: Time point being submitted[14]

☐ Visit 2 Pre-treatment PET Scan ☐ Visit 4 Post-treatment PET Scan

Section III: Mode of Image Submission

☐ **Shipped on CD (enclosed)**[15] **Date Shipped** __-__ - 20__[16]

☐ **Electronic Transfer via Triad**[17] **Date Transferred** __-__ - 20__[18]

Institution Comments[19]**:**

Form Completed By:[20]	**Phone:**[21]	**Email:**[22]	**Date:**[23]

ACRIN Image Management Center
ACRIN 6687
American College of Radiology
1818 Market Street, Suite 1600
Philadelphia, PA 19103
Fax: 215-923-1737

RE

ACRIN 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib
Comments/Remarks Form

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ box. ☐

Form ID [1]	Date of event/procedure [2]	Comment [3]

****For additional comments, use another RE form ****

ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

Comments/Remarks Form

RE Completion Instructions

Note: These completion instructions only include questions that may need further clarification.

Additional form completion instructions can be found in the general form instructions document available on the ACRIN 6687 website. Contact data management for all form related questions/clarifications.

The RE (Comments/Remarks) Form should be accessed ***only*** when further data submission explanations are required. The RE form can be completed at any time during the trial after the participant has signed the informed consent and enrolled onto the study. The designated research staff completes the form with the appropriate completed source documents. It is submitted via the ACRIN website at www.acrin.org.

Form ID: Insert the two character CRF identifiers located in the top left corner of the form requiring additional comments/remarks (example: OA or TA)

Date of event/procedure: Record date as mm/dd/yyyy.

Comment: Record appropriate comments/remarks.

*****Important*** -** Select the RE form in the "Data Collection" screen to record additional comments as needed throughout the study. Until further notice, this process must be followed for every comment/remark being recorded.

PR

ACRIN 6687
Evaluation of ^{18}F-Fluoride PET for Dasatinib Protocol Variation Form

If this is a revised or corrected form, please √box. ☐

ACRIN Study 6687 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INSTRUCTIONS: In the instance a protocol requirement is not met, record the requested information below. Complete a separate form for each case and for each deviation. Submit this form via the ACRIN web site; retain the form in the case study file.

1. Check the Protocol Event Being Reported: *(select only one)* [1]

- O 1 Inclusion/exclusion criteria not met at time of registration
- O 2 Study activity performed prior to participant signing study consent form
- O 3 Imaging-related deviation (complete 1b)
- O 4 Visit or follow-up procedures not performed per protocol (specify visit in Q6)
- O 5 Case enrolled under expired IRB approval/FWA
- O 6 Therapy/Agent not given
- O 7 Participant following other treatment preference
- O 88 Other, specify: _____ [2]

1b. Image Deviation: *(select only one)* [3]

- O 1 PET/CT interpretation guidelines not followed
- O 2 PET scan performed at an non-ACRIN qualified institution
- O 3 PET scan performed on a non-ACRIN qualified scanner
- O 4 PET/CT Scan not performed according to protocol specific guidelines
- O 5 PET images lost or unavailable
- O 6 Time between injection and start of scan is unknown
- O 88 Other, specify: _____ [4]

2. Date the protocol deviation occurred: ____ - ____ - **20**____ (mm-dd-yyyy) [5]

3. Date the protocol deviation was discovered: ____ - ____ - **20**____ (mm-dd-yyyy) [6]

4. Describe the protocol deviation:

_____ [7]

_____ [8]

5. What was done to rectify the situation and/or prevent future occurrence:

_____ [9]

_____ [10]

PR

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib

Protocol Variation Form

If this is a revised or corrected form, please √box. ☐

ACRIN Study 6687 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

6. Please provide the time point this Study Deviation applies to: [11]

- O 1 Visit 1: Registration Visit
- O 2 Visit 2: (within 7 days prior to treatment)
- O 3 Visit 3: (telephone visit after 24 hours from PET scan)
- O 4 Visit 4: (12 weeks post treatment)
- O 5 Visit 5: (telephone visit after 24 hours from PET scan)
- O 6 Follow-up Time Point, specify (check only one): [12]

O 3 month follow up	O 15 month follow up	O 27 month follow up
O 6 month follow up	O 18 month follow up	O 30 month follow up
O 9 month follow up	O 21 month follow up	O 33 month follow up
O 12 month follow up	O 24 month follow up	O 36 month follow up

_____ [13]

Initials of person responsible for data (RA, study staff)

_____ - _____ - **20**____ (mm-dd-yyyy) [14]

Date Form Completed

Investigator's signature _____ *(for external use only)*

ACRIN 6687 PR FORM COMPLETION INSTRUCTIONS

PR: Protocol Deviation Form

The PR Form is used to report protocol deviations to ACRIN. The PR form should be completed by the study site when/if a protocol deviation is discovered. Complete a separate PR Form for each case and for each deviation. Each institution's IRB may also have separate reporting requirements for protocol deviations. Please be sure to follow your IRB's policies.

The data is submitted via the ACRIN web site. Only submit the paper form for revisions, corrections or in the event that the ACRIN website is inaccessible. All available dates should be reported as mm-dd-yyyy. Online logic prevents the entry of future dates. Code all questions unless otherwise specified. Do not leave mandatory questions blank. The original paper CRF can serve as the source document for the interpretation and should be retained in the study file. Please note that instructions are not listed for each question. These instructions are for questions that require additional clarification. If a question requires further clarification, please contact ACRIN headquarters at 215-574-3150 and ask for the ACRIN 6687 Data Manager.

1. Check The Protocol Event Being Reported:
Select the protocol deviation being reported. Report only one protocol deviation per form.

- **Inclusion criteria not met at time of registration**: Ineligible participant registered. Select this response when it is discovered that registration of participant who did not meet eligibility criteria at the time of registration. Eligibility is established at the time of registration based on the protocol-specified inclusion/exclusion criteria. Please reference the protocol for inclusion/exclusion criteria.
- **Study activity performed prior to participant signing study consent form:** Participant completed study activity before signing consent. Select this response when it is discovered that a participant completed a study activity before signing a consent form. If the participant withdrew study consent, provide documentation. Document this event on the End of Study (DS) Form.
- **Imaging-related deviation**: Select appropriate response in 1b.
- **Visit or follow-up procedures not performed per protocol:** Select appropriate response in Q6.
- **Other, specify**: Select this response if there is a violation of the study protocol. In the event that another type of violation/deviation from the protocol occurs, please specify the type of occurrence on this part of the form. In the event that you still have questions regarding the type of violation please contact the 6687 ACRIN data manager prior to submitting the form.

4. Describe the protocol deviation:
There is a 200-character limit on this required field. Provide a description of the protocol deviation. The description should include the following elements:

- How the protocol deviation was discovered
- How the protocol deviation occurred
- Ramifications for the participant

5. What was done to rectify the situation and/or prevent future occurrence:
There is a 200-character limit on this required field. Provide information on what was done to rectify the situation and or prevent future occurrence. (ie, additional training, etc.)

6. Please provide the time point this Study Deviation applies to: Verify that the correct time point is selected since subsequent web entry may be affected.

Initials of Person responsible for the data: Legible initials of the person responsible for collating/reviewing the data and ensuring completion of the CRF (paper or web). If completing a web CRF only without completing a paper CRF, the electronic summary must be printed and signed by the person responsible for the data.

ACRIN 6687 PR FORM COMPLETION INSTRUCTIONS

Date Form Completed
Record the date the original CRF, whether paper or web, was completed. If completing a paper CRF this refers to the date the data was originally recorded on the paper CRF; the date/time of web entry is automatically recorded by the database. If completing the web CRF only, without completing a paper CRF, this refers to the date the data was originally recorded in the web module.

Make sure data was assessed, reviewed and approved by study investigator.

COMMUNICATION MEMO (CM)

Instructions: Be sure to properly identify the study, case, form ID, calendar due date and reason code your memo refers to. A case specific label can be affixed within the section below for convenience and study/case identification.

Use this memo to:

- Communicate non-submission of a required calendar item (data form, study report, etc.).
- Communicate information pertinent to a forms due request.
- Communicate case specific information that cannot be reported or needs to be revised on a data form or query.

USE A SEPARATE MEMO FOR EACH CASE

Institution Name or No. #:	ACRIN Protocol #:
Case #:	Participant Initials:

Form ID	Calendar Due Date (mm-dd-yyyy)	Reason Code	Explanation / Comments
	____ - ____ - 20____		
	____ - ____ - 20____		
	____ - ____ - 20____		
	____ - ____ - 20____		
	____ - ____ - 20____		
	____ - ____ - 20____		
	____ - ____ - 20____		
	____ - ____ - 20____		

If Communication Memo is in reference to a Forms Due Report, date of report: ____ - ____ - 20_____

Additional Comments / Reporting Other Case-Specific Information:

Reason Codes for Communication Memo

101 = Site data revision *(attach initialed & dated form)*	108 = Source data lost (i.e., images, medical records, etc.)
102 = Complete form needs entry *(attach form)*	109 = Participant is no longer in the study
103 = Query response correction *(attach query)*	110 = Deceased
104 = Calendar correction / inadvertently entered	111 = Equipment failure
105 = Audit QC finding correction	112 = Duplicate registration
106 = Unable to contact participant	113 = Other
107 = Study procedure not done (i.e., refused, missed appointment, etc.)	

_____ ____ - ____ - 20_____

Signature of person completing this form — Date form completed

ACRIN – CM COMPLETION INSTRUCTIONS

CM Completion Instructions

The Communication Memo (CM) is completed by the site.

(1) when a protocol/calendar required item is unavailable or unable to be submitted to ACRIN;
(2) to communicate information pertinent to a forms due request;
(3) to communicate case-specific data corrections which were inadvertently entered via the online Web system
(4) to communicate audit or monitor findings which resulted in a data correction

Each communication memo should be case specific. Use a separate memo for each case. Retain the CM in the participants study file and fax/mail a copy to ACRIN Data Management Center (DMC).

An ACRIN case specific label can be affixed to each communication memo. In lieu of a label, the 'Participants Initials', 'Case #', and 'Institution Number/Name' should be recorded in the space provided.

Form ID: Required data field if CM is related to a calendar-required item. Please indicate the item (data form, report, image, etc.) by the two-character Form ID (i.e., C1, M1, etc.) in the box provided.

Calendar Due Date: Required data field if CM is related to a calendar-required item. Indicate the applicable form due date in the space provided; record date as month, day, year. The calendar due date is located on the 'Patient Confirmation/Calendar'.

Reason Code: Choose a reason code from the list provided on the lower portion of the CM. A reason is required for each form type listed. If reporting **'Other',** provide a short explanation in the additional comments section of the CM.

Explanation / Comments: Provide explanation/comments as appropriate.

If Communication Memo is in reference to a 'Forms Due Report', date of report: When applicable, if CM is in response to a 'Forms Due Report', provide the date of the report. Format the date as month, day, & year.

Additional Comments / Reporting Other Case Specific Information: Provide additional comments as appropriate, in support of the information reported above.

Reason Codes for Communication Memo: Choose a reason code from the list provided on the lower portion of the CM. A reason/explanation is required for each entry listed. If reporting **'Other',** provide a short explanation in the additional comments section of the CM.

101 = Site data revision:
Use this code if the site research staff needs to inform the Data Management Center of a data revision(s) that needs to be applied to a submitted form. This code is also applicable to subsequent data revisions of an online submitted form.

.

102 = Complete form needs entry:
Use this code if submitting a form which was unable to be entered through the online Data Center and needs to be entered by the DMC.

103 = Query response correction:
Use this code if a submitted query response needs to be revised.

104 = Calendar correction / inadvertently entered:
If a correction needs to be made for a calendared entry, use this code.

105 = Audit QC finding correction:
Use this code if a revision needs to be made to a submitted form as a result of an ACRIN audit.

106 = Unable to contact participant:
Provide an explanation/comment of why this code is being used.

107 = Study procedure not done:
Provide an explanation/comment when using this code.

108 = Source data lost:
Provide an explanation/comment when using this code.

109 = Participant is no longer in the study:
.
110 = Deceased:

111 = Equipment failure:
Provide an explanation/comment when using this code.

112 = Duplicate registration:
Provide an explanation/comment when using this code. Also provide the duplicate case numbers.

113 = Other:
Provide an explanation/comment when using this code.

Signature of person completing this form: Required element. Provide a legible signature of the person whom completed the form.

Date form completed: Record the date that the CM was completed; record date as month, day, & year.

OI

ACRIN 6687

Evaluation of ^{18}F-Fluoride PET for Dasatinib

Off Study Form

If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6687

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: If a participant is not able to receive both the pre-treatment and the post-treatment 18F-fluoride PET scans, he will be replaced with other eligible participants to ensure full accrual. Participants going off study for incomplete imaging will not undergo study follow-up visits. **Both** Technical Assessment (TA) forms and the End of Study Form (DS) must also be submitted for these participants.

1. **Was the participant removed from the study for any of the following reasons as specified in the protocol specific off-study criteria?** [1]
   - O No (Sign and date form)
   - O Yes (Complete Q2 & 3)

2. **Pre- and/or post- imaging studies not complete due to:** ☐ =1 Not Marked, ☑ = 2 Marked
   *(Check all that apply. Complete **both** Technical Assessment (TA) forms and the End of Study Form (DS))*
   - ☐ Clinical progression[2] **- only for participant physically incapable of completing scan**
   - ☐ Participant withdrawal[3]
   - ☐ Participant non-compliant with treatment regimen with dasatinib, imaging protocol or sample acquisition.[4]
   - ☐ At the discretion of the investigators ifphysician feels it to be in their best medical interest.[5]
   - ☐ Radiation therapy necessary during the interval between PET scans.[6]
   - ☐ Participant receives another systemic therapy for prostate cancer before the second PET is obtained.[7]
   - ☐ Participant missed more than 4 weeks of Dasatinib during the interval between PET scans.[8]
   - ☐ Participant received GM-CSF or G-CSF during the interval between the first and second PET imaging studies.[9]
   - ☐ Other[10], specify _____[11]

3. **Date participant taken off study:** _____-_____-_____[12] *mm-dd-yyyy*

_____[13]
Initials of person(s) completing this form

_____-_____-_____ [14]
Date form completed *(mm-dd-yyyy)*

Signature of person completing this form _____ *(for external use only)*

OI Completion Instruction

This form is required if a participant is not able to receive both the pre-treatment and the post-treatment 18F-fluoride PET scans. Participants going off study for incomplete imaging will not undergo study follow-up visits and will be replaced with other eligible participants to ensure full accrual. Technical Assessment (TA) forms for both 'Visit 2: pre-treatment' and 'Visit 4: post-treatment' and the End of Study Form (DS) must also be submitted for these participants. The remaining forms will be suppressed on the calendar.

*****Please make every attempt to perform the second PET Scan*****

1. **Was the participant removed from the study for any of the following reasons as specified in the protocol specific off-study criteria?**
   No: The participant was not removed from the study. Initial and date the form.
   Yes: The participant was removed per protocol specific off-study criteria. Select all that apply in Q2.

2. **Pre- and/or post- imaging studies not complete due to:**
   - **Clinical progression - only for participant physically incapable of completing scan.** Do not complete form if participant is able to complete both scans.
   - **Participant withdrawal:** Select if participant withdraws from study prior to obtaining the second PET scan.
   - **Participant non-compliant with treatment regimen with dasatinib, imaging protocol or sample acquisition.**
   - **At the discretion of the investigators if physician feels it to be in their best medical interest.**
   - **Radiation therapy necessary during the interval between PET scans.** If this occurs, do not obtain a second PET scan as this will hamper the ability to assess response to dasatinib.
   - **Participant receives another systemic therapy for prostate cancer before the second PET is obtained.** If this occurs, do not obtain a second PET scan as this will hamper the ability to assess response to dasatinib.
   - **Participant missed more than 4 weeks of Dasatinib during the interval between PET scans.** If this occurs, do not obtain a second PET scan as this will hamper the ability to assess response to dasatinib.
   - **Participant received GM-CSF or G-CSF during the interval between the first and second PET imaging studies.** If this occurs, do not obtain a second PET scan as this will hamper the ability to assess response to dasatinib.
   - **Other:** Contact Data Management prior to form completion to determine if off study reason is valid.
     - Specify other reason.

3. **Date participant taken off study:** Provide date (mm-dd-yyyy)