American College of Radiology Imaging Network

Forms Index

ACRIN Study 6682

^{64}Cu-ATSM in Cervical Cancer

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Please enter all data through ACRIN website Data Center. All data should be entered within 2 weeks of the visit. Any questions related to these forms should be directed to Data Manager.

A0

ACRIN 6682

Registration/Eligibility Checklist

^{64}Cu-ATSM PET/CT in Cervical Cancer

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: The eligibility checklist (A0**) Part II** and **Part III** must be completed prior to registration to determine and confirm participant eligibility. If any of the questions are answered in a way different than the **prompts** provided at the start of each question, the participant is **ineligible** and should not be enrolled. If the participant is being enrolled, they are to review, sign and date the consent. The data is submitted via the ACRIN website.

DEMOGRAPHICS

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

_____ 1. Name of institutional person registering this case [1]

_____ 2. Has the Eligibility Checklist been completed? [2]
1 No
2 Yes

_____ 3. Is the participant eligible for this study? [3]
1 No
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]
1 Hispanic or Latino
2 Not Hispanic or Latino
9 Unknown

_____ 11. Gender [11]
1 Male
2 Female

_____ 12. Participant's country of residence **(if other, complete Q12a)** [12]
1 United States
2 Canada
3 Other

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

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

DEMOGRAPHICS, contd.

_____ 14. Participant's insurance status [14]

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

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

1 No
2 Yes
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]

INCLUSION CRITERIA

Part II

_____ 25. Does the participant have histologically proven invasive cervical cancer (Stages IB2-IVA)? [28]

1 No
2 Yes (complete Q25a and Q25b)

25a. Please indicate date diagnosis was reported to patient and/or PCP ___-___-___ (mm-dd-yyyy) [29]

_____ 25b. Please indicate participants FIGO stage: [30]

1.	II	7.	IIA
2.	III	8.	IIB
3.	IA1	9.	IIIA
4.	IA2	10.	IIIB
5.	IB1	11.	IVA
6.	IB2	12.	IVB

_____ 26. Does the participant have Karnofsky performance status of $\geq$ 70? [31]

1 No
2 Yes (complete Q26a)

_____ 26a. Please indicate Karnofsky Performance Status Rating [32]

1.	100	6.	50
2.	90	7.	40
3.	80	8.	30
4.	70	9.	20
5.	60	10.	10

_____ 27. Does the participant meet one of the following criteria as determined by the baseline FDG PET/CT? [33]

a. PET or CT shows only pelvic nodal (or no nodal disease), and participant will undergo standardized concurrent pelvic radiation therapy and cisplatin chemotherapy

and/or

b. PET or CT shows para-aortic nodal metastasis and participant will undergo standardized concurrent pelvic radiation therapy and cisplatin chemotherapy as well as radiotherapy to para-aortic nodes

1 No
2 Yes

_____ 28. Did the participant have a FDG PET/CT scan performed within 4 weeks of enrollment on an ACRIN qualified scanner? [34]

1 No
2 Yes (complete Q28a)

28a. Provide date of scan ___-___-___ (mm-dd-yyyy) [35]

INCLUSION CRITERIA, contd.

_____ 29. Was the participants FDG PET/CT scan performed as part of the baseline visit? [36]

1. No (continue to Q30)
2. Yes (complete Q29a)

_____ 29a. If yes, was a pregnancy test performed within 7 days prior to the scan? [37]

1. No
2. Yes(complete Q29b)
3. Participant is not of childbearing potential as defined by protocol
4. Participant is not sexually active

29b. Provide date of pregnancy test ___-___-___ *(mm-dd-yyyy)* [38]

_____ 30. Is the participant an adult female 18 years of age or older? [39]

1. No
2. Yes

_____ 31. Is the patient of child-bearing potential? [40]

1. No (complete Q31a, then continue to Q32)
2. Yes (skip Q31a and continue to Q31b)

_____ 31a. If subject is not of child bearing potential please provide justification [41]

1. Post menopausal, amenorrhic for at least 12 consecutive months
2. Hysterectomy
3. Tubal ligation at least 12 months ago

88. Other

_____ 31b. Does the participant agree to use medically appropriate contraception if sexually active? [42]

1. No
2. Yes
3. Not sexually active

_____ 32. Is the participant able to tolerate PET Imaging that is required by the protocol (i.e. lie flat for the duration of PET/CT scan)? [43]

1. No
2. Yes

_____ 33. Is the participant able to give study specific IRB approved informed consent including authorization for release of personal health information? [44]

1. No
2. Yes

EXCLUSION CRITERIA

Part III

_____ 34. Does the participant have Stage IVB disease with confirmed distant metastasis and/or supraclavicular metastasis shown on baseline whole body FDG-PET/CT? [45]
1 No
2 Yes

_____ 35. Does the participant have recurrent invasive carcinoma of the uterine cervix (regardless of previous treatment)? [46]
1 No
2 Yes

_____ 36. Does the participant have known metastases to lungs, supraclavicular lymph nodes or metastases to other organs outside of the pelvis or abdominal lymph nodes, at the time of the original clinical diagnosis? [47]
1 No
2 Yes

_____ 37. Has the participant had a prior pelvic or abdominal lymphadenectomy performed for any reason? [48]
1 No
2 Yes

_____ 38. Has the participant received prior pelvic radiation therapy for any reason? [49]
1 No
2 Yes

_____ 39. Is the participant pregnant or breast feeding? [50]
1 No
2 Yes

_____ 40. Does the participant have septicemia or severe infection? [51]
1 No
2 Yes

_____ 41. Does the participant have uncontrolled or poorly controlled diabetes? [52]
1 No
2 Yes

_____ 42. Does the participant have any circumstances that will not permit completion of the imaging studies or required clinical follow up? [53]
1 No
2 Yes

EXCLUSION CRITERIA, contd.

_____ 43. Has the participant had (or have) any other invasive malignancies (with the exception of non-melanoma skin cancer)? [54]

1 No (initial and date form)
2 Yes (complete Q43a and Q43b)

_____ 43a. Have they had any evidence of the other cancer within the last 5 years? [55]

1. No
2. Yes

_____ 43b. Does their previous cancer treatment contraindicate this protocol therapy? [56]

1. No
2. Yes

_____ [57]
Initials of person(s) who determined eligibility

_____ [58]
Initials of person(s) responsible for data

_____-_____-_____ [59]
Date form completed *(mm-dd-yyyy)*

I0

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer
Initial Evaluation

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

INITIAL EVALUATION

Instructions: The Initial Evaluation Form is to be Completed after registration to collect details of the baseline visit procedures as detailed in the protocol. The form is to be completed by the study Research Associate. Dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via web at www.acrin.org.

Date of Baseline visit

_____-_____-_____ (mm-dd-yyyy) [1]

(If visit occurred over more than 1 day, please provide the last day baseline study procedures were performed)

Part I. Cervical Biopsy

Please complete the following questions pertaining to the cervical biopsy in which the diagnosis of cervical squamous cell carcinoma was determined.

1. **Date cervical biopsy performed** _____-_____-_____ [2] (mm-dd-yyyy)

2. **Date histopathology reported** _____-_____-_____ [3] (mm-dd-yyyy)

3. **Have cervical biopsy slides been sent to Washington University Pathology lab for hypoxic markers analysis?** [4]
   - O 1 No (provide reason in Q3a)
   - O 2 Yes (continue to Q3c)

3a. Reason slides not sent

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Slides not available [5]
- ☐ Slides lost [6]
- ☐ Administrative reasons [7]
- ☐ Slides will be sent on future date (please provide tentative date in Q3b) [8]
- ☐ Other, [9] specify _____ [10]
- ☐ Unknown [11]

3b. Tentative date slides will be sent _____-_____-_____ [12] (mm-dd-yyyy)

3c. Date slides sent _____-_____-_____ (mm-dd-yyyy) [13]

Part II. Blood Specimen Collection

Please complete the following questions pertaining to the whole blood sample consent and, if applicable, collection.

1. **Did the participant consent to blood sampling for future correlative studies?** [14]
   - O 1 No (continue to Part III)
   - O 2 Yes

2. **Were blood samples collected?** [15]
   - O 1 No (provide reason in Q2a)
   - O 2 Yes (continue to Q2b)

2a. Reason blood samples not collected

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Patient withdrew blood sample consent [16]
- ☐ Medical reasons [17]
- ☐ Administrative reasons [18]
- ☐ Time constraints [19]
- ☐ Other, [20] specify _____ [21]
- ☐ Unknown [22]

2b. Date blood samples collected _____-_____-_____ [23] (mm-dd-yyyy)

3. **Have the blood samples been sent to Washington University?** [24]
   - O 1 No (continue to Q3a)
   - O 2 Yes (continue to Q3c)

3a. Reason(s) samples not sent

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Sample Lost [25]
- ☐ Sample Damaged [26]
- ☐ Administrative reasons [27]
- ☐ Sample will be sent on future date (please provide tentative date in Q3b) [28]
- ☐ Other, [29] specify _____ [30]
- ☐ Unknown [31]

3b. Tentative date samples will be sent _____-_____-_____ [32] (mm-dd-yyyy)

3c. Date samples sent _____-_____-_____ (mm-dd-yyyy) [33]

I0

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer
Initial Evaluation

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

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part III. Baseline Visit Study Procedures

Complete the following questions regarding the visit procedures. **Protocol defined procedures at the baseline visit are: collection of medical history, collection of concomitant medication, and physical exam. *Details should be recorded in source*.**

1. Please check routine clinical follow-up assessed

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Physical exam [34]
- ☐ Laboratory test [35]
- ☐ Medical history [36]
- ☐ Concomitant medication [37]
- ☐ CT [38]
- ☐ PET [39]
- ☐ FDG PET/CT [40]
- ☐ Other imaging, [41] specify

_____ [42]

- ☐ Other, [43] specify

_____ [44]

1a. If protocol defined Baseline visit procedures (medical history collection, concomitant medication collection, and/or physical examination) were not assessed, provide reason

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Participant Refusal [45]
- ☐ Time constraints [46]
- ☐ Not clinically indicated per treating physician [47]
- ☐ Other, [48] specify

_____ [49]

- ☐ Unknown [50]

Comments: _____

_____

_____

_____ [51]

_____ [52]
Initials of person(s) completing this form

_____-_____-_____ [53]
Date Form Completed (mm-dd-yyyy)

TX

ACRIN 6682
^{64}Cu-ATSM in Cervical Cancer
Prior Therapies

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

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]	☐ Unknown [26] [6]
Chemotherapy multiple agents systemic	O **No** O **Yes** O **Unknown** [7]	☐ Unknown [27] [8]
Chemotherapy non-cytotoxic	O **No** O **Yes** O **Unknown** [9]	☐ Unknown [28] [10]
Chemotherapy single agent systemic	O **No** O **Yes** O **Unknown** [11]	☐ Unknown [29] [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)*

TD

ACRIN 6682

^{64}Cu-ATSM in Cervical Cancer

FDG-PET Imaging-Related Drug History

ACRIN Study 6682 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

1. Clinical trial time point: [1] O Registration / eligibility Visit (baseline) O Visit 4 (3 months post TX)

2. Is the participant a known diabetic? [2] O No O Yes, *complete Q2a*

2a. Were any drugs taken by the participant or administered to the participant on the day of PET study for control of blood glucose level? [3]

O No O Yes, check drug(s) used O Unknown

- ☐ A sulfonylurea, [4] drug name _____ [5] given ____ ____ [6] hours before FDG
- ☐ Metformin [7] given ____ ____ [8] hours before FDG
- ☐ Other oral agent (s) [9] drug name _____ [10] given ____ ____ [11] hours before FDG
  drug name _____ [12] given ____ ____ [13] hours before FDG
- ☐ Short-acting insulin [14] given, ____ ____ [15] hours before FDG, given (check one) [16] O Intravenously O Subcutaneously O Inhaled
  Record 99 if hours unknown
- ☐ Intermediate or long-acting insulin [17] given ____ ____ [18] hours before FDG
- ☐ Insulin Pump [19] *(check one)* [20] O On during FDG injection and uptake period
  O Off during FDG injection and uptake period, off ____ ____ [21] hours before FDG
- ☐ Other injectable agent [22] specify _____ [23] given ____ ____ [24] hours before FDG
  Record 99 if hours unknown
- ☐ Unknown [25]

3. Were any drugs administered as part of the PET imaging procedure? [26] *In addition to any listed in Q2a*

O No O Yes, check drug(s) used: O Unknown

- ☐ A benzodiazepine to decrease brown fat FDG uptake, [27] drug name _____ [28]
- ☐ A beta-blocker to decrease brown fat FDG uptake, [29] drug name _____ [30]
- ☐ A diuretic to decrease urinary tract activity, [31] drug name _____ [32]
- ☐ Sedation or anesthesia [33]
- ☐ Other drug(s), [34] drug name (s) _____ [35]
- ☐ Unknown [36]

4. Is the participant currently being treated with corticosteroids? [37] O No O Yes O Unknown

Taken ____ ____ [38] hours before FDG

5. Has the participant received a bone marrow stimulating agent in the last 2 months? [39] O No O Yes, *complete Q5a* O Unknown

5a. Agent Name: _____ [40]

Given approximately ____ ____ days ago [41]

☐ Unknown [42]

_____ [43]
Initials of Person(s) Completing this Form

__-__-__ [44]
Date form completed (mm-dd-yyyy)

TA

ACRIN 6682

^{64}Cu-ATSM PET/CT in Cervical Cancer
PET/CT Technical Assessment Form

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

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: This form is to be completed, by the Technologist for each timepoint specified in the protocol. All images are to be transmitted to ACRIN as detailed in the study protocol. All times must be reported in military format (i.e., 2:45pm = 1445 hours).

1. Study time point [1]

- O 1 Baseline FDG-PET/CT (complete Part I and Part III)
- O 2 Visit 1 - ^{64}Cu-ATSM (complete Part II and Part III)
- O 3 Visit 4 - post-treatment FDG-PET/CT (complete Part I and Part III)

Part I. FDG scan (Baseline Visit and Visit 3 only)

1. Was blood glucose testing done? [2]

- O 1 No (complete Q1a and Q2, then skip to Part III)
- O 2 Yes (continue to Q2)

1a. If no, provide reason *(check all that apply)*

- ☐ Imaging not completed [3]
- ☐ Participant refusal [4]
- ☐ Unknown [5]
- ☐ Other, [6] specify: _____ [7]

2. Duration of participant fasting pre-PET/CT imaging: [8]

☐☐ **Hours**
(up to time of FDG injection; if unknown record 99)

3. Blood glucose before injection of FDG

☐☐☐.☐ mg/dL [9]
☐ Unknown [10]

4. Time blood sample was obtained for glucose measurement

(military time) ☐☐:☐☐ [11]

5. ^{18}F-FDG Source [82]

- O Purchase, *provide;*
  Name of licensed pharmacy:
  _____ [83]
- O Synthesized, *provide:*
  Method:
  _____ [84]

Pyrogen test result [85]

- O Passed
- O Failed
- O Not done

Radiochemical purity test result:

☐☐.☐ % [86]

Part II. ^{64}Cu-ATSM scan (Visit 1 only)

1. ^{64}Cu-ATSM underwent quality control and passed? [87]

- O 1 No
- O 2 Yes

If ^{64}Cu-ATSM fails any part of the quality control (or if quality control is not completed), the radiopharmaceutical should NOT be injected into the participant. Complete rest of form as instructed in Part III. Q1.

Part III. All Scans

1. Was PET/CT imaging completed? [19]

- O No, radiotracer not given and imaging not done (Q1a and Q2 required, then initial and date form)
- O No, radiotracer given, imaging not started (Q1a-Q10 required, complete Q11 if applicable)
- O No, radiotracer given, imaging not completed (Q1a-Q17 required, complete Q18-27 as applicable)
- O Yes, radiotracer given and imaging completed (Q2-Q27 required)

1a. *If PET/CT Imaging not completed, provide reason *(check all that apply)*:

- ☐ ^{64}Cu-ATSM did not pass QC [20]
- ☐ Scheduling problem [21]
- ☐ Equipment failure [22]
- ☐ Participant refusal [23]
- ☐ Medical reason [24]
- ☐ Injection site complications [25]
- ☐ Claustrophobia [26]
- ☐ Blood glucose level [27]
- ☐ Participant withdrew consent [28]
- ☐ Progressive disease [29]
- ☐ Participant death [30]
- ☐ Other, [31] specify: _____ [32]
- ☐ Unknown [33]

2. Date of PET/CT imaging (appointment):

_____ - _____ - _____(mm-dd-yyyy) [34]
☐ Participant missed imaging appointment [88]

TA

ACRIN 6682

^{64}Cu-ATSM PET/CT in Cervical Cancer
PET/CT Technical Assessment Form

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

3. Subject weight (measured on day of scan) [35]

___.___ kg

☐ Unknown [36]

4. Subject height (measured on day of scan) [80]

___ cm

☐ Unknown [81]

5. Full activity in syringe before injection

___.___ **mCi** [37]

5a. Time of assay of full syringe before injection

(military time) ___:___ [38]

☐ Unknown [39]

6. Time of injection (military time)

___:___ [40]

☐ Unknown [41]

7. Residual activity in syringe after injection

___.___ **mCi** [42]

7a. Time of assay of residual activity after injection

(military time) ___:___ [43]

☐ Unknown [44]

8. Net Administered activity ___.___ **mCi** [45]

9. Location of injection site [46]

- O 1 Right antecubital
- O 2 Right wrist
- O 3 Left antecubital
- O 4 Left wrist
- O 5 Right foot
- O 6 Left foot
- O 88 Other, specify: _____ [47]
- O 99 Unknown

10. Any radiotracer infiltration at injection site noted? [48]

- O 1 None
- O 2 Minor (estimated to be less than 20% of dose)
- O 3 Severe (estimated to be more than 20% of dose)

11. Was Foley catheter in place for study? [49]

- O 1 No (complete Q12-Q13)
- O 2 Yes (skip to Q14)

12. Patient voided immediately pre-imaging? [50]

- O 1 No
- O 2 Yes
- O 99 Unknown

13. Patient voided immediately post-imaging? [51]

- O 1 No
- O 2 Yes
- O 99 Unknown

Scanner

14. Has the scanner used for <u>this study</u> been qualified by ACRIN? [52]

- O 1 No, specify reason: _____ [53] (complete Q15)
- O 2 Yes, provide ACRIN Scanner ID# (skip to Q16)

_____ [54]

15. PET/CT Scanner used for this exam:

Manufacturer _____ [55]

Manufacturer model name/or number

_____ [56]

16. Date of last PET/CT Scanner SUV calibration/validation:

_____ - _____ - _____(mm-dd-yyyy) [57]

17. Daily scanner QC run on date of study? [58]

- O 1 No
- O 2 Yes

TA

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer
PET/CT Technical Assessment Form

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Image Acquisition

Transmission Scan

18. CT transmission scan:

18a. Was Oral contrast used? [59]
- O 1 No (skip to Q18c)
- O 2 Yes, specify type [60]
  - O 1 Positive contrast
  - O 2 Negative contrast

18b. Amount of Oral contrast ingested [61]

|_|_|_|_| ml

☐ Unknown [62]

18c. Was IV contrast used? [63]
- O 1 No (skip to Q19)
- O 2 Yes

18d. Amount of IV contrast injected [64]

|_|_|_| ml

☐ Unknown [65]

18e. Time IV contrast injection [66]

|_|_|:|_|_| (military time)

☐ Unknown [67]

19. kVp |_|_|_| [68]

20. mAs |_|_|_| [69]

21. Slice Thickness of reconstructed images

|_|.|_|_| mm [70]

PET Emission Scan

22. Emission acquisition mode [71]
- O 1 2D
- O 2 3D

23. |_|_| **Number of bed positions scanned** [72]

PET Emission Scan

24. Emission scan start time: (military time) |_|_|:|_|_| [73]

25. Emission scan stop time: (military time) |_|_|:|_|_| [74]

26. Pixel Size of Reconstructed images |_|.|_|_| **mm** [75]

27. Thickness of Reconstructed images |_|.|_|_| **mm** [76]

Comments: _____

_____

_____

_____ [77]

_____ [78]
Initials of person(s) completing this form

_____ - _____ - _____ [79]
Date form completed (mm-dd-yyyy)

PT

ACRIN 6682

^{64}CU-ATSM in Cervical Cancer PET/CT Local Reader Form

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: This PT form is to be completed by the study Radiologist/Nuclear Medicine Physician for all scans. All dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN at www.acrin.org.

This PET/CT Reader corresponds to: [1]

- O 1 Baseline FDG-PET/CT (complete Part I and Part II)
- O 2 Visit 1 Cu-ATSM PET/CT (complete Part I and Part III)
- O 3 Visit 4 FDG-PET/CT (complete Part I and Part II)

Part I. All Scans

1. Image quality [2]

- O 1 Uninterpretable (complete Q1a, then initial and date form)
- O 2 Adequate (continue to Q2)

1a. Reason *(check all that apply):*

- ☐ Missing images [3]
- ☐ Noisy images [4]
- ☐ Patient motion [5]
- ☐ Artifact [6]
- ☐ Non-diagnostic [7]
- ☐ Other, [9] specify _____ [10]

2. Date of Imaging _____-_____-_____ *(mm-dd-yyyy)* [11]

3. Date of PET/CT Interpretation _____-_____-_____ *(mm-dd-yyyy)* [12]

4. Reader ID |__|__|__|__|__|__|__|__| [13]

PT

ACRIN 6682

^{64}CU-ATSM in Cervical Cancer PET/CT Local Reader Form

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

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part II. FDG-PET/CT

Site	Uptake Scale 0 Not imaged; cannot evaluate 1 Definitely not tumor 2 Probably not tumor 3 Indeterminate 4 Probably tumor 5 Definitely tumor
Primary Tumor	[14]
Pelvic Lymph Nodes	[15]
Common Iliac Lymph Nodes	[16]
Para-aortic Lymph Nodes	[17]
Mediastinal Lymph Nodes	[18]
Supraclavicular Lymph Nodes	[19]
Other, specify _____ _____ [20]	[21]
Other, specify _____ _____ [22]	[23]
Other, specify _____ _____ [24]	[25]

Part III. ^{64}Cu-ATSM PET/CT

1. Was the primary tumor included in the field of view? [26]

O 1 No (please complete Q1a)
O 2 Yes (initial and date form)

1a. Please provide reason *(check all that apply)*:

☐ Image not adequate (as described in part I Q1a) [27]

☐ Other, [28] specify _____ [29]

Comments: _____

_____

_____ [30]

_____ _____-_____-_____ [32]

Radiologist/Nuclear Medicine physician Responsible for this Data — Date form completed

_____ [33]

Initials of Person(s) completing this form

TS

ACRIN 6682
^{64}Cu-ATSM in Cervical Cancer
Tissue Slides Transmittal Form

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Part A. Completed and Web Entered by Site

1. Did the site request the tissue slides? [7]

O No, complete Q1a
O Yes, skip to Q2

1a. If no, provide reason then initial and date form [8]

O Central pathology lab requesting slides directly
O Other, specify _____ [9]

2. Number of tissue sample slides sent: _____ _____ [1]

Before sending the slides, please check to confirm:

☐ ALL study participants' personal identifying information (participant name, medical record number, SS#, etc.) on all of the material is marked out [2]

☐ Each slide is labeled with the study number, patient case number, and numbered per the pathology specimen process [3]

The **pathology specimens and a copy of this form** should be shipped to the central pathology laboratory at:

Denfeng Cao, MD PhD.
Director, Research Immunohistochemical Laboratory
Division of Anatomic and Molecular Pathology
Washington University in Saint Louis
660 South Euclid Ave
Campus Box 8118
Saint Louis, MO 63110

Re: ACRIN 6682 Pathology

3. Date slides sent to path lab: _____-_____-_____ *mm-dd-yyyy* [4]

_____ [5]
Initials of person(s) from site completing this form

_____-_____-_____ [6]
Date form completed *(mm-dd-yyyy)*

Signature of person from site _____ *(for external use only)*

V1

ACRIN 6682

^{64}Cu-ATSM PET/CT in Cervical Cancer Visit 1 Evaluation

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

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

VISIT 1

INSTRUCTIONS: The V1 form is to be completed after the participant completes the Cu-ATSM scan by the study Research Associate. Dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via web at www.acrin.org

1. Was Visit 1 - ^{64} Cu-ATSM PET/CT performed? [1]

O 1 No (indicate reason in Q1a, then initial and date form. Complete DS form)
O 2 Yes (continue to Q2)

1a. Reason visit 1 not done

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

☐ Scheduling problem [2]
☐ Participant refusal [3]
☐ Participant withdrew consent [4]
☐ Participant death [5]
☐ Other, [6] specify _____ [7]
☐ Unknown [8]

2. Date of Visit 1: _____ - _____ - _____ (mm-dd-yyyy) [9]

Part I. ^{64}Cu-ATSM PET/CT

1. Was a pregnancy test performed within 7 days of ^{64} Cu-ATSM PET/CT? [10]

O 1 No (skip to Q2, complete PR form)
O 2 Yes (complete Q1a)
O 3 Participant is not of childbearing potential as defined by protocol (skip to Q2)

1a. Please provide date of pregnancy test

_____ - _____ - _____ (mm-dd-yyyy) [11]

2. Were any AE(s) associated with investigational radiotracer reported? [12]

O 1 No
O 2 Yes, please report AE(s) per protocol

Part II. Visit 1 Study Procedures

Complete the following questions regarding the visit procedures. **Protocol defined procedures at visit 1 are: collection of concomitant medication**. ***Details should be recorded in source.***

1. Please check routine clinical follow-up assessed

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

☐ Physical exam [13]
☐ Laboratory test [14]
☐ Medical history [15]
☐ Concomitant medication [16]
☐ Other, [17] specify

_____ [18]

1a. If protocol defined Visit 1 procedures (concomitant medication collection) were not assessed, provide reason

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

☐ Participant Refusal [19]
☐ Time constraints [20]
☐ Not clinically indicated per treating physician [21]
☐ Other, [22] specify

_____ [23]

☐ Unknown [24]

Comments: _____

_____ [25]

_____ [26]
Initials of person(s) completing the form

_____-_____-_____ [27]
Date form completed *(mm-dd-yyyy)*

MH

ACRIN 6682

^{64}Cu-ATSM in Cervical Cancer

Baseline Medical History Form

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

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT 1: BASELINE 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, 99 = Unknown) [6]
1			O 1 O 2 O 3 O 4 O 99
2			O 1 O 2 O 3 O 4 O 99
3			O 1 O 2 O 3 O 4 O 99
4			O 1 O 2 O 3 O 4 O 99
5			O 1 O 2 O 3 O 4 O 99
6			O 1 O 2 O 3 O 4 O 99
7			O 1 O 2 O 3 O 4 O 99
8			O 1 O 2 O 3 O 4 O 99
9			O 1 O 2 O 3 O 4 O 99
10			O 1 O 2 O 3 O 4 O 99
11			O 1 O 2 O 3 O 4 O 99
12			O 1 O 2 O 3 O 4 O 99

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

CO

ACRIN 6682

^{64}Cu-ATSM in Cervical Cancer

Visit 1: Concomitant Medications

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

ACRIN Study 6682

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.*****

BR

ACRIN 6682
^{64}Cu-ATSM in Cervical Cancer
Batch Record Form
Process and Production Record

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

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: All dates are recorded as mm-dd-yyyy. All times must be reported in military format (i.e, 2:45pm=14:45 hours). Refer to form completion guidelines for further instruction. **Record Retention Requirements- Original signed document must be maintained at site for at least 7 years and be made available in the event of an audit.**

Part 1. Materials and Equipment Note the lot numbers of the items used and obtain a verification check

Table A. Materials and Equipement

Item	Manufacturer	Lot Number	Expiration Date	Verified / Initials
$^{64}CuCl_2$	MIR, Cyclotron Facility	[1]		[2]
ATSM lyophilized vial	PTI	[58]	[59]	[60]
Reconstitution solution	PTI	[61]	[62]	[63]
0.22 µm Sterile Filter Units	[10]	[11]	[64]	[12]

Part 2. Drug Preparation

2. Method of ^{64}Cu-ATSM Preparation [65]

☐ Version 2 PTI Kit Formulation ***Preferred Method*** *Complete Table B, then skip to Part 3*

☐ Version 1 PTI Kit Formulation *Skip to Table C*

Table B. Version 2 Method *Per Appendix 1 of the Investigator's Brochure*

Drug Preparation		
Step	**Activity**	**Verified / Initials**
1	Record the volume and reference the time ATSM added to $^{64}CuCl_2$ Activity added _____ mCi [66] Time __ __ : __ __ [68] Volume added _____ mL [67]	[69]
2	Sterile filtration performed Time Completed __ __ : __ __ [70]	[71]
3	Radioactivity assay in Product Vial: _____ mCi [72] Time of measurement __ __ : __ __ [73]	[74]

Skip to Part 3

Table C. Version 1 Method *Per Appendix 2 of the Investigator's Brochure*

Drug Preparation		
Step	**Activity**	**Verified / Initials**
1	Record the volume and reference the time $^{64}CuCl_2$ added to ATSM kit. Activity added _____ mCi [46] Time __ __ : __ __ [15] Volume added _____ mL [47]	[16]
2	Sterile filtration performed Time Completed __ __ : __ __ [17]	[18]
3	Radioactivity assay in Product Vial: _____ mCi [56] Time of measurement __ __ : __ __ [35]	[36]

Continue to next page

BR

ACRIN 6682
^{64}Cu-ATSM in Cervical Cancer
Batch Record Form
Process and Production Record

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

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part 3. Radiochemical Purity

3. Method of ^{64}Cu-ATSM Radiochemical Purity Measurement [75]

☐ Paper Chromatography Method ***Preferred Method*** *Complete Table D, then skip to Part 4*
☐ Oasis Cartridge Method *Skip to Table E*

Table D. Paper Chromatography Method *Per Appendix 3 of the Investigator's Brochure*

Radiochemical Purity Measurement		
Step	**Activity**	**Verified / Initials**
1	Time of spotting: _____ [76] Start time of chromatographic development: ___ ___ : ___ ___ [77] Finish time of chromatographic development: ___ ___ : ___ ___ [78] Solvent front distance: _____ cm [79]	[80]
2	Time of radioactivity analysis: _____ [81] Check method of analysis: [82] ☐ Radiochromatographic scanner ☐ Sectional assay *Retain radiochromatogram scans or section assay worksheet as source document. Record results in Question 8.*	[83]

Skip to Part 4

Table E. Oasis Cartridge Method *Per Appendix 4 of the Investigator's Brochure*

Materials and Equipment			
Item	**Manufacturer**	**Lot Number**	**Verified / Initials**
Oasis Cartridge	**Waters Corporation**	[8]	[9]

Radiochemical Purity Measurement		
Step	**Activity**	**Verified / Initials**
1	Background dose calibrator reading: Activity _____ µCi [48] Time ___ ___ : ___ ___ [20]	[21]
2	Dose calibrator measurements of fractions a. Activity C1 ___ ___ ___ . ___ µCi [49] Net Activity ___ ___ ___ . ___ [50] Time ___ ___ : ___ ___ [24] b. Activity C2 ___ ___ ___ . ___ µCi [51] Net Activity ___ ___ ___ . ___ [52] Time ___ ___ : ___ ___ [27] c. Activity C3 ___ ___ ___ . ___ µCi [53] Net Activity ___ ___ ___ . ___ [54] Time ___ ___ : ___ ___ [30]	[31]
3	Percentage purity of ^{64}Cu-ATSM = C3/ (C1+C2+C3) x 100% Radiochemical purity ___ ___ ___ . ___ % [55] *Also record results in Question 8.*	[33]

Part 4. Release Specifications for ^{64}Cu-ATSM

Table F. Oasis Cartridge Method

Test	Acceptance Criteria	Procedure	Testing result	Verified / Initials
Radiochemical Purity	≥ 95%		[57]	[84]
Bacterial Endotoxin	≤ 175 EU/V (where V is the maximum total dose)	☐ Chromogenic method or ☐ Gel clot method [38]	☐ Pass or ☐ Fail [39]	[85]

^{64}Cu-ATSM prepared by: _____ Date prepared: ___-___-___ [41]

QC performed by: _____ Date performed: ___-___-___ [43]

Data reviewed by: _____ Date reviewed: ___-___-___ [86]

SA

ACRIN 6682
^{64}Cu-ATSM in Cervical Cancer
Safety Assessment Form

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

ACRIN Study 6682
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: The safety assessment form is to be completed as part of the Cu-ATSM visit. Refer to the form completion guidelines for further instruction.

Part I.

Provide the vital sign readings taken part of the ^{64}Cu-ATSM scan. All elements in this table are required.

Time Point of Reading	Prior to Injection	15 Minutes Post Injection *Before patient goes into scanner*	75 Minutes Post Injection *After completion of scan, before the patient leaves the PET facility*
Time taken *Military Time*	____ ____ : ____ ____ hh:mm [1]	____ ____ : ____ ____ hh:mm [7]	____ ____ : ____ ____ hh:mm [13]
Pulse	____ ____ ____ bpm [2]	____ ____ ____ bpm [8]	____ ____ ____ bpm [14]
Blood pressure *Systolic / Diastolic*	_____ / _____ mmHg [3] [4]	_____ / _____ mmHg [9] [10]	_____ / _____ mmHg [15] [16]
Respirations *Check one*	O Labored O Unlabored [5]	O Labored O Unlabored [11]	O Labored O Unlabored [17]
Temperature	____ ____ ____ . ____ ^{O}C [6]	____ ____ ____ . ____ ^{O}C [12]	____ ____ ____ . ____ ^{O}C [18]

Part II.

1. Were there any significant changes in vital signs accompanied by signs or symptoms suggesting an adverse reaction? [19]

O 1 No (Initial and date form)
O 2 Yes (Provide vital signs in Q1a. Complete an AE form)

1a. If yes, provide the last reading of vital signs in the table below (taken before the patient leaves the PET facility)

Time Taken *Military Time*	Pulse	Blood Pressure *Systolic / Diastolic*	Respirations *Check one*	Temperature
____ ____ : ____ ____ hh:mm [20]	____ ____ ____ bpm [21]	_____ / _____ mmHg [22] [23]	O Labored O Unlabored [24]	____ ____ ____ . ____ ^{O}C [25]

Part III. Follow up AE Assessment *within 24 hours of Cu-ATSM injection*

1. Were any AE's reported? [29]

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

Provide date and time of follow-up telephone call for AE assessment (if the participant is unable to be reached detail attempts in comments field)

2. Date _____-_____-_____ *(mm-dd-yyyy)* [30] ☐ Unknown [31]

3. Time *(Military Time)* ____ ____ : ____ ____ *hh:mm* [32] ☐ Unknown [33]

Comments: _____

_____ [26]

_____ [27]
Initials of person(s) completing this form

_____-_____-_____ [28]
Date form completed

TA

ACRIN 6682

^{64}Cu-ATSM PET/CT in Cervical Cancer
PET/CT Technical Assessment Form

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

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: This form is to be completed, by the Technologist for each timepoint specified in the protocol. All images are to be transmitted to ACRIN as detailed in the study protocol. All times must be reported in military format (i.e., 2:45pm = 1445 hours).

1. Study time point [1]

- O 1 Baseline FDG-PET/CT (complete Part I and Part III)
- O 2 Visit 1 - ^{64}Cu-ATSM (complete Part II and Part III)
- O 3 Visit 4 - post-treatment FDG-PET/CT (complete Part I and Part III)

Part I. FDG scan (Baseline Visit and Visit 3 only)

1. Was blood glucose testing done? [2]

- O 1 No (complete Q1a and Q2, then skip to Part III)
- O 2 Yes (continue to Q2)

1a. If no, provide reason *(check all that apply)*

- ☐ Imaging not completed [3]
- ☐ Participant refusal [4]
- ☐ Unknown [5]
- ☐ Other, [6] specify: _____ [7]

2. Duration of participant fasting pre-PET/CT imaging: [8]

☐☐ **Hours**
(up to time of FDG injection; if unknown record 99)

3. Blood glucose before injection of FDG

☐☐☐.☐ mg/dL [9]
☐ Unknown [10]

4. Time blood sample was obtained for glucose measurement

(military time) ☐☐:☐☐ [11]

5. ^{18}F-FDG Source [82]

- O Purchase, *provide;*
  Name of licensed pharmacy:
  _____ [83]
- O Synthesized, *provide:*
  Method:
  _____ [84]

Pyrogen test result [85]

- O Passed
- O Failed
- O Not done

Radiochemical purity test result:

☐☐.☐ % [86]

Part II. ^{64}Cu-ATSM scan (Visit 1 only)

1. ^{64}Cu-ATSM underwent quality control and passed? [87]

- O 1 No
- O 2 Yes

If ^{64}Cu-ATSM fails any part of the quality control (or if quality control is not completed), the radiopharmaceutical should NOT be injected into the participant. Complete rest of form as instructed in Part III. Q1.

Part III. All Scans

1. Was PET/CT imaging completed? [19]

- O No, radiotracer not given and imaging not done (Q1a and Q2 required, then initial and date form)
- O No, radiotracer given, imaging not started (Q1a-Q10 required, complete Q11 if applicable)
- O No, radiotracer given, imaging not completed (Q1a-Q17 required, complete Q18-27 as applicable)
- O Yes, radiotracer given and imaging completed (Q2-Q27 required)

1a. *If PET/CT Imaging not completed, provide reason *(check all that apply)*:

- ☐ ^{64}Cu-ATSM did not pass QC [20]
- ☐ Scheduling problem [21]
- ☐ Equipment failure [22]
- ☐ Participant refusal [23]
- ☐ Medical reason [24]
- ☐ Injection site complications [25]
- ☐ Claustrophobia [26]
- ☐ Blood glucose level [27]
- ☐ Participant withdrew consent [28]
- ☐ Progressive disease [29]
- ☐ Participant death [30]
- ☐ Other, [31] specify: _____ [32]
- ☐ Unknown [33]

2. Date of PET/CT imaging (appointment):

_____ - _____ - _____(mm-dd-yyyy) [34]
☐ Participant missed imaging appointment [88]

TA

ACRIN 6682

^{64}Cu-ATSM PET/CT in Cervical Cancer
PET/CT Technical Assessment Form

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

3. Subject weight (measured on day of scan) [35]

___.___ kg

☐ Unknown [36]

4. Subject height (measured on day of scan) [80]

___ cm

☐ Unknown [81]

5. Full activity in syringe before injection

___.___ **mCi** [37]

5a. Time of assay of full syringe before injection

(military time) ___:___ [38]

☐ Unknown [39]

6. Time of injection (military time)

___:___ [40]

☐ Unknown [41]

7. Residual activity in syringe after injection

___.___ **mCi** [42]

7a. Time of assay of residual activity after injection

(military time) ___:___ [43]

☐ Unknown [44]

8. Net Administered activity ___.___ **mCi** [45]

9. Location of injection site [46]

- O 1 Right antecubital
- O 2 Right wrist
- O 3 Left antecubital
- O 4 Left wrist
- O 5 Right foot
- O 6 Left foot
- O 88 Other, specify: _____ [47]
- O 99 Unknown

10. Any radiotracer infiltration at injection site noted? [48]

- O 1 None
- O 2 Minor (estimated to be less than 20% of dose)
- O 3 Severe (estimated to be more than 20% of dose)

11. Was Foley catheter in place for study? [49]

- O 1 No (complete Q12-Q13)
- O 2 Yes (skip to Q14)

12. Patient voided immediately pre-imaging? [50]

- O 1 No
- O 2 Yes
- O 99 Unknown

13. Patient voided immediately post-imaging? [51]

- O 1 No
- O 2 Yes
- O 99 Unknown

Scanner

14. Has the scanner used for <u>this study</u> been qualified by ACRIN? [52]

- O 1 No, specify reason: _____ [53] (complete Q15)
- O 2 Yes, provide ACRIN Scanner ID# (skip to Q16)

_____ [54]

15. PET/CT Scanner used for this exam:

Manufacturer _____ [55]

Manufacturer model name/or number

_____ [56]

16. Date of last PET/CT Scanner SUV calibration/validation:

_____ - _____ - _____(mm-dd-yyyy) [57]

17. Daily scanner QC run on date of study? [58]

- O 1 No
- O 2 Yes

TA

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer
PET/CT Technical Assessment Form

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Image Acquisition

Transmission Scan

18. CT transmission scan:

18a. Was Oral contrast used? [59]
- O 1 No (skip to Q18c)
- O 2 Yes, specify type [60]
  - O 1 Positive contrast
  - O 2 Negative contrast

18b. Amount of Oral contrast ingested [61]

|_|_|_|_| ml

☐ Unknown [62]

18c. Was IV contrast used? [63]
- O 1 No (skip to Q19)
- O 2 Yes

18d. Amount of IV contrast injected [64]

|_|_|_| ml

☐ Unknown [65]

18e. Time IV contrast injection [66]

|_|_|:|_|_| (military time)

☐ Unknown [67]

19. kVp |_|_|_| [68]

20. mAs |_|_|_| [69]

21. Slice Thickness of reconstructed images

|_|.|_|_| mm [70]

PET Emission Scan

22. Emission acquisition mode [71]
- O 1 2D
- O 2 3D

23. |_|_| **Number of bed positions scanned** [72]

PET Emission Scan

24. Emission scan start time: (military time) |_|_|:|_|_| [73]

25. Emission scan stop time: (military time) |_|_|:|_|_| [74]

26. Pixel Size of Reconstructed images |_|.|_|_| **mm** [75]

27. Thickness of Reconstructed images |_|.|_|_| **mm** [76]

Comments: _____

_____

_____

_____ [77]

_____ [78]
Initials of person(s) completing this form

_____ - _____ - _____ [79]
Date form completed (mm-dd-yyyy)

PT

ACRIN 6682

^{64}CU-ATSM in Cervical Cancer PET/CT Local Reader Form

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: This PT form is to be completed by the study Radiologist/Nuclear Medicine Physician for all scans. All dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN at www.acrin.org.

This PET/CT Reader corresponds to: [1]

- O 1 Baseline FDG-PET/CT (complete Part I and Part II)
- O 2 Visit 1 Cu-ATSM PET/CT (complete Part I and Part III)
- O 3 Visit 4 FDG-PET/CT (complete Part I and Part II)

Part I. All Scans

1. Image quality [2]

- O 1 Uninterpretable (complete Q1a, then initial and date form)
- O 2 Adequate (continue to Q2)

1a. Reason *(check all that apply):*

- ☐ Missing images [3]
- ☐ Noisy images [4]
- ☐ Patient motion [5]
- ☐ Artifact [6]
- ☐ Non-diagnostic [7]
- ☐ Other, [9] specify _____ [10]

2. Date of Imaging _____-_____-_____ *(mm-dd-yyyy)* [11]

3. Date of PET/CT Interpretation _____-_____-_____ *(mm-dd-yyyy)* [12]

4. Reader ID |__|__|__|__|__|__|__|__| [13]

PT

ACRIN 6682

^{64}CU-ATSM in Cervical Cancer PET/CT Local Reader Form

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

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part II. FDG-PET/CT

Site	Uptake Scale 0 Not imaged; cannot evaluate 1 Definitely not tumor 2 Probably not tumor 3 Indeterminate 4 Probably tumor 5 Definitely tumor
Primary Tumor	[14]
Pelvic Lymph Nodes	[15]
Common Iliac Lymph Nodes	[16]
Para-aortic Lymph Nodes	[17]
Mediastinal Lymph Nodes	[18]
Supraclavicular Lymph Nodes	[19]
Other, specify _____ _____ [20]	[21]
Other, specify _____ _____ [22]	[23]
Other, specify _____ _____ [24]	[25]

Part III. ^{64}Cu-ATSM PET/CT

1. Was the primary tumor included in the field of view? [26]

O 1 No (please complete Q1a)
O 2 Yes (initial and date form)

1a. Please provide reason *(check all that apply)*:

☐ Image not adequate (as described in part I Q1a) [27]

☐ Other, [28] specify _____ [29]

Comments: _____

_____

_____ [30]

_____ _____-_____-_____ [32]

Radiologist/Nuclear Medicine physician Responsible for this Data — Date form completed

_____ [33]

Initials of Person(s) completing this form

V2

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer
Visit 2 Evaluation

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

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT 2

INSTRUCTIONS: The V2 form is to be completed by the study Research Associate regarding initiation of chemoradiotherapy. Dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via web at www.acrin.org.

1. Was Visit 2 performed? [1]

O 1 No (indicate reason in Q1a)
O 2 Yes (continue to Q2)

1a. Reason visit 2 not done

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Scheduling problems [2]
- ☐ Participant refusal [3]
- ☐ Participant withdrew consent [4]
- ☐ Participant death (please complete DS form) [5]
- ☐ Other, [6] specify _____ [7]
- ☐ Unknown [8]

2. Date of Visit 2: _____ - _____ - _____ (mm-dd-yyyy) [9]

Part I. Chemoradiotherapy

1. Was treatment initiated per protocol (within 4 weeks of ^{64}Cu-ATSM PET/CT)? [10]

O 1 No (continue to Q1a)
O 2 Yes (continue to Q1b)

1a. Please provide reason

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Adverse event/side effects/complications [11]
- ☐ Scheduling problems [12]
- ☐ Participant refusal [13]
- ☐ Progressive disease [14]
- ☐ Participant withdrew consent (complete DS form) [15]
- ☐ Participant death [16]
- ☐ Not done per treating physician discretion [17]
- ☐ Treatment delayed per treating physician [18]
- ☐ Treatment delayed per patient [19]
- ☐ Participant too ill [20]
- ☐ Other medical reason, [21] specify _____ [22]
- ☐ Alternative therapy, specify [23] _____ [24]
- ☐ Other, [25] specify _____ [26]
- ☐ Unknown [27]

2. Please provide initiation date of treatment:

_____ - _____ - _____ (mm-dd-yyyy) [28]

or ☐ Treatment not initiated as of this visit [29]

3. Please check the type of treatment this initiation date corresponds to *(check all that apply)*

- ☐ Chemotherapy [34]
- ☐ Radiation [35]
- ☐ Other, [36] specify _____ [37]

Part II. Adverse Events

Please provide AE information in relation ***only*** to the Cu-ATSM scan.

1. Were any AEs associated with investigational radiotracer reported (within 24 hours of scan)? [30]

O 1 No
O 2 Yes, please report AE(s) per protocol.

Comments: _____

_____

_____

_____ [31]

_____ [32]

Initials of person(s) completing the form

_____-_____-_____ [33]

Date form completed *(mm-dd-yyyy)*

V3

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer
Visit 3 Evaluation

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

VISIT 3

INSTRUCTIONS: The V3 form is to be completed 4 weeks after completion of chemoradiotherapy. Dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via web at www.acrin.org.

1. Was Visit 3 conducted? [1]

O 1 No (indicate reason in Q1a)
O 2 Yes (continue to Q2)

1a. Reason visit 3 not done

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Scheduling problem [2]
- ☐ Participant refusal [3]
- ☐ Participant withdrew consent [4]
- ☐ Participant death (please complete DS form) [5]
- ☐ Other, [6] specify _____ [7]
- ☐ Unknown [8]

2. Date of Visit 3: _____ - _____ - _____ (mm-dd-yyyy) [9]
Should occur 4 weeks after completion of chemoradiotherapy

1a. If protocol defined Visit 3 procedures (physical examination and/or laboratory tests) were not assessed, provide reason

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Participant Refusal [16]
- ☐ Time constraints [17]
- ☐ Not clinically indicated per treating physician [18]
- ☐ Other, [19] specify

_____ [20]

- ☐ Unknown [21]

Part I. Visit 3 Study Procedures

Complete the following questions regarding the routine clinical follow-up conducted as part of this visit. **Protocol defined clinical follow-up at this visit are: physical examination and clinical lab tests**. ***Details of this clinical follow-up should be recorded in source.***

1. Please check routine clinical follow-up assessed

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Physical exam [10]
- ☐ Laboratory test [11]
- ☐ Medical history [12]
- ☐ Concomitant medication [13]
- ☐ Other, [14] specify

_____ [15]

Comments: _____

_____ [22]

_____ [23]
Initials of person(s) completing the form

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

CR

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer Chemotherapy and Radiation Treatment

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

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

CHEMORADIOTHERAPY FORM

Instructions: At the completion of chemotherapy and radiation, complete this form for all participants. All dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via the web at www.acrin.org

1. Did the participant receive the protocol defined chemoradiotherapy? [1]
i.e. definitive irradiation (both external beam radiation and intracavitary brachytherapy) and concurrent cisplatinum chemotherapy (6 weekly cycles).

O 1 No (complete Q2 and Q3)
O 2 Yes (skip to Part I)

2. Was Radiation Given? [2]

O 1 No (provide reason in Q2a, then continue to Q3)
O 2 Yes (continue to Q3, then provide details of radiation in Part I)

2a. Primary Reason Radiation Not Given (complete PR and DS form) [3]

O 1 Adverse event/complications
O 2 Scheduling problems
O 3 Participant refusal
O 4 Participant withdrew consent
O 5 Not done per treating physicians discretion
O 88 Other, specify _____ [4]
O 99 Unknown

3. Was Concurrent Chemotherapy Given? [5]

O 1 No (please provide reason in Q3a)
O 2 Yes (provide details in Part II)

3a. Primary Reason Concurrent Chemotherapy Not Given (complete PR and DS form) [6]

O 1 Adverse event/complications
O 2 Scheduling problems
O 3 Participant refusal
O 4 Participant withdrew consent
O 5 Not done per treating physicians discretion
O 88 Other, specify _____ [7]
O 99 Unknown

CR

ACRIN 6682

^{64}Cu-ATSM PET/CT in Cervical Cancer Chemotherapy and Radiation Treatment

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

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

CHEMORADIOTHERAPY FORM

Part I. Radiation

Part Ia. Brachytherapy

1. Indicate type of brachytherapy [8]

- O 1 LDR
- O 2 HDR
- O 3 Participant did not receive any brachytherapy (skip to part Ib)
- O 88 Other, specify _____ [9]

2. Start date _____-_____-_____ (mm-dd-yyyy) [10]

☐ Unknown [11]

3. End date _____-_____-_____ (mm-dd-yyyy) [12]

☐ Unknown [13]

4. Total dose to point A ___ ___ . ___ ___ Gy [14]

5. Status [15]

- O 1 Completed as Planned
- O 2 Treatment not completed
- O 88 Other, specify _____ [16]

Part Ib. External Radiation

1. Indicate type of external radiation [17]

- O 1 3D Conformal
- O 2 IMRT
- O 3 2D External Beam
- O 4 Participant did not receive any external radiation (if applicable skip to Part II, otherwise skip to Part III)
- O 88 Other, specify _____ [18]

2. Start date _____-_____-_____ (mm-dd-yyyy) [19]

☐ Unknown [20]

3. End date _____-_____-_____ (mm-dd-yyyy) [21]

☐ Unknown [22]

4. Total dose to Pelvis/Pelvic Nodes ___ ___ . ___ ___ Gy [23]

5. Total dose to Para-Aortic Nodes ___ ___ . ___ ___ Gy [24]

6. Status [25]

- O 1 Completed as Planned
- O 2 Treatment not completed
- O 88 Other, specify _____ [26]

Part II. Concurrent Chemotherapy

1. Type of Concurrent Chemotherapy [27]

- O 1 Cisplatin
- O 2 Carboplatin
- O 88 Other, specify _____ [28]

2. Start date _____-_____-_____ (mm-dd-yyyy) [29]

☐ Unknown [30]

3. End date _____-_____-_____ (mm-dd-yyyy) [31]

☐ Unknown [32]

4. Number of Full Weekly Cycles ____ ____ [33]

5. Number of Reduced Weekly Cycles ____ ____ [34]

Part III. Additional Treatment

1. Did the participant receive any additional treatment not recorded on this form? [35]

- O 1 No (initial and date form)
- O 2 Yes (provide details in comments)

Comments: _____

_____

_____

_____

_____

_____ [36]

_____ [37]

Initials of person(s) completing this form

_____ - _____ - _____ [38]

Date form completed (mm-dd-yyyy)

V4

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer
Visit 4 Evaluation

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

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT 4

INSTRUCTIONS: This form is to be completed during visit 4, 3 months after completion of chemoradiotherapy, to collect the visit details as described in the protocol. Dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via web at www.acrin.org.

1. Was Visit 4 conducted? [1]

O 1 No (complete Q1a, then initial and date form)
O 2 Yes (continue to Q2)

1a. Reason visit 4 not done

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Scheduling problem [2]
- ☐ Participant refusal [3]
- ☐ Participant withdrew consent [4]
- ☐ Participant death (please complete DS form) [5]
- ☐ Other, [6] specify _____ [7]
- ☐ Unknown [8]

2. Date of Visit 4: _____ - _____ - _____ (mm-dd-yyyy) [9]

Part I. Disease Status

Provide the patients disease status as of this visit referencing the FDG PET/CT, additional imaging, and/or other clinical follow-up.

1. Participants disease status at this visit [10]

O 1 No evidence of disease
O 2 Evidence of disease (complete PF form)
O 99 Unknown

Part II. Blood Specimen Collection

Complete the following questions pertaining to the whole blood sample consent and, if applicable, collection

1. Did the participant consent to blood sampling for future correlative studies? [11]

O 1 No (continue to Part III)
O 2 Yes

2. Were blood samples collected? [12]

O 1 No (provide reason in Q2a, then skip to Part III)
O 2 Yes (continue to Q2b)

2a. Reason blood samples not collected

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Patient withdrew blood sample consent [13]
- ☐ Medical reasons [14]
- ☐ Administrative reasons [15]
- ☐ Time constraints [16]
- ☐ Other, [17] specify _____ [18]
- ☐ Unknown [19]

2b. Date blood samples collected:

_____ - _____ - _____ (mm-dd-yyyy) [20]

3. Have the blood samples been sent to Washington University? [21]

O 1 No (complete Q3a, then skip to Part III)
O 2 Yes (continue to Q3c)

3a. Reason(s) samples not sent

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Samples lost [22]
- ☐ Sample damaged [23]
- ☐ Administrative reasons [24]
- ☐ Sample will be sent on future date (please provide tentative date in Q3b) [25]
- ☐ Other, [26] specify _____ [27]
- ☐ Unknown [28]

3b. Tentative date samples will be sent:

_____ - _____ - _____ (mm-dd-yyyy) [29]

3c. Date samples sent :

_____ - _____ - _____ (mm-dd-yyyy) [30]

V4

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer
Visit 4 Evaluation

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

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT 4

Part III. Visit 4 Study Procedures

Complete the following questions regarding the routine clinical follow-up conducted as part of this visit. **Protocol defined clinical follow-up at this visit are: medical history, physical examination, and clinical lab tests**. ***Details of this clinical follow-up should be recorded in source.***

1. Please check routine clinical follow-up assessed

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Physical exam [31]
- ☐ Laboratory test [32]
- ☐ Medical history [33]
- ☐ Concomitant medication [34]
- ☐ CT [35]
- ☐ PET [36]
- ☐ FDG PET/CT [37]
- ☐ Other imaging, [38] specify

_____ [39]

- ☐ Other, [40] specify

_____ [41]

1a. If protocol defined Visit 4 procedures (medical history, physical examination, and clinical lab tests) were not assessed, provide reason

(Please mark all that apply ☐ = 1 not marked; ☑ = 2 marked)

- ☐ Participant Refusal [42]
- ☐ Time constraints [43]
- ☐ Not clinically indicated per treating physician [44]
- ☐ Other, [45] specify

_____ [46]

- ☐ Unknown [47]

Comments: _____

_____

_____

_____ [48]

_____ [49]
Initials of person(s) completing this form

_____-_____-_____ [50]
Date Form Completed (mm-dd-yyyy)

TD

ACRIN 6682

^{64}Cu-ATSM in Cervical Cancer

FDG-PET Imaging-Related Drug History

ACRIN Study 6682 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

1. Clinical trial time point: [1] O Registration / eligibility Visit (baseline) O Visit 4 (3 months post TX)

2. Is the participant a known diabetic? [2] O No O Yes, *complete Q2a*

2a. Were any drugs taken by the participant or administered to the participant on the day of PET study for control of blood glucose level? [3]

O No O Yes, check drug(s) used O Unknown

- ☐ A sulfonylurea, [4] drug name _____ [5] given ____ ____ [6] hours before FDG
- ☐ Metformin [7] given ____ ____ [8] hours before FDG
- ☐ Other oral agent (s) [9] drug name _____ [10] given ____ ____ [11] hours before FDG
  drug name _____ [12] given ____ ____ [13] hours before FDG
- ☐ Short-acting insulin [14] given, ____ ____ [15] hours before FDG, given (check one) [16] O Intravenously O Subcutaneously O Inhaled
  Record 99 if hours unknown
- ☐ Intermediate or long-acting insulin [17] given ____ ____ [18] hours before FDG
- ☐ Insulin Pump [19] *(check one)* [20] O On during FDG injection and uptake period
  O Off during FDG injection and uptake period, off ____ ____ [21] hours before FDG
- ☐ Other injectable agent [22] specify _____ [23] given ____ ____ [24] hours before FDG
  Record 99 if hours unknown
- ☐ Unknown [25]

3. Were any drugs administered as part of the PET imaging procedure? [26] *In addition to any listed in Q2a*

O No O Yes, check drug(s) used: O Unknown

- ☐ A benzodiazepine to decrease brown fat FDG uptake, [27] drug name _____ [28]
- ☐ A beta-blocker to decrease brown fat FDG uptake, [29] drug name _____ [30]
- ☐ A diuretic to decrease urinary tract activity, [31] drug name _____ [32]
- ☐ Sedation or anesthesia [33]
- ☐ Other drug(s), [34] drug name (s) _____ [35]
- ☐ Unknown [36]

4. Is the participant currently being treated with corticosteroids? [37] O No O Yes O Unknown

Taken ____ ____ [38] hours before FDG

5. Has the participant received a bone marrow stimulating agent in the last 2 months? [39] O No O Yes, *complete Q5a* O Unknown

5a. Agent Name: _____ [40]

Given approximately ____ ____ days ago [41]

☐ Unknown [42]

_____ [43]
Initials of Person(s) Completing this Form

__-__-__ [44]
Date form completed (mm-dd-yyyy)

TA

ACRIN 6682

^{64}Cu-ATSM PET/CT in Cervical Cancer
PET/CT Technical Assessment Form

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

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: This form is to be completed, by the Technologist for each timepoint specified in the protocol. All images are to be transmitted to ACRIN as detailed in the study protocol. All times must be reported in military format (i.e., 2:45pm = 1445 hours).

1. Study time point [1]

- O 1 Baseline FDG-PET/CT (complete Part I and Part III)
- O 2 Visit 1 - ^{64}Cu-ATSM (complete Part II and Part III)
- O 3 Visit 4 - post-treatment FDG-PET/CT (complete Part I and Part III)

Part I. FDG scan (Baseline Visit and Visit 3 only)

1. Was blood glucose testing done? [2]

- O 1 No (complete Q1a and Q2, then skip to Part III)
- O 2 Yes (continue to Q2)

1a. If no, provide reason *(check all that apply)*

- ☐ Imaging not completed [3]
- ☐ Participant refusal [4]
- ☐ Unknown [5]
- ☐ Other, [6] specify: _____ [7]

2. Duration of participant fasting pre-PET/CT imaging: [8]

☐☐ **Hours**
(up to time of FDG injection; if unknown record 99)

3. Blood glucose before injection of FDG

☐☐☐.☐ mg/dL [9]
☐ Unknown [10]

4. Time blood sample was obtained for glucose measurement

(military time) ☐☐:☐☐ [11]

5. ^{18}F-FDG Source [82]

- O Purchase, *provide;*
  Name of licensed pharmacy:
  _____ [83]
- O Synthesized, *provide:*
  Method:
  _____ [84]

Pyrogen test result [85]

- O Passed
- O Failed
- O Not done

Radiochemical purity test result:

☐☐.☐ % [86]

Part II. ^{64}Cu-ATSM scan (Visit 1 only)

1. ^{64}Cu-ATSM underwent quality control and passed? [87]

- O 1 No
- O 2 Yes

If ^{64}Cu-ATSM fails any part of the quality control (or if quality control is not completed), the radiopharmaceutical should NOT be injected into the participant. Complete rest of form as instructed in Part III. Q1.

Part III. All Scans

1. Was PET/CT imaging completed? [19]

- O No, radiotracer not given and imaging not done (Q1a and Q2 required, then initial and date form)
- O No, radiotracer given, imaging not started (Q1a-Q10 required, complete Q11 if applicable)
- O No, radiotracer given, imaging not completed (Q1a-Q17 required, complete Q18-27 as applicable)
- O Yes, radiotracer given and imaging completed (Q2-Q27 required)

1a. *If PET/CT Imaging not completed, provide reason *(check all that apply)*:

- ☐ ^{64}Cu-ATSM did not pass QC [20]
- ☐ Scheduling problem [21]
- ☐ Equipment failure [22]
- ☐ Participant refusal [23]
- ☐ Medical reason [24]
- ☐ Injection site complications [25]
- ☐ Claustrophobia [26]
- ☐ Blood glucose level [27]
- ☐ Participant withdrew consent [28]
- ☐ Progressive disease [29]
- ☐ Participant death [30]
- ☐ Other, [31] specify: _____ [32]
- ☐ Unknown [33]

2. Date of PET/CT imaging (appointment):

_____ - _____ - _____(mm-dd-yyyy) [34]
☐ Participant missed imaging appointment [88]

TA

ACRIN 6682

^{64}Cu-ATSM PET/CT in Cervical Cancer
PET/CT Technical Assessment Form

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

3. Subject weight (measured on day of scan) [35]

___.___ kg

☐ Unknown [36]

4. Subject height (measured on day of scan) [80]

___ cm

☐ Unknown [81]

5. Full activity in syringe before injection

___.___ **mCi** [37]

5a. Time of assay of full syringe before injection

(military time) ___:___ [38]

☐ Unknown [39]

6. Time of injection (military time)

___:___ [40]

☐ Unknown [41]

7. Residual activity in syringe after injection

___.___ **mCi** [42]

7a. Time of assay of residual activity after injection

(military time) ___:___ [43]

☐ Unknown [44]

8. Net Administered activity ___.___ **mCi** [45]

9. Location of injection site [46]

- O 1 Right antecubital
- O 2 Right wrist
- O 3 Left antecubital
- O 4 Left wrist
- O 5 Right foot
- O 6 Left foot
- O 88 Other, specify: _____ [47]
- O 99 Unknown

10. Any radiotracer infiltration at injection site noted? [48]

- O 1 None
- O 2 Minor (estimated to be less than 20% of dose)
- O 3 Severe (estimated to be more than 20% of dose)

11. Was Foley catheter in place for study? [49]

- O 1 No (complete Q12-Q13)
- O 2 Yes (skip to Q14)

12. Patient voided immediately pre-imaging? [50]

- O 1 No
- O 2 Yes
- O 99 Unknown

13. Patient voided immediately post-imaging? [51]

- O 1 No
- O 2 Yes
- O 99 Unknown

Scanner

14. Has the scanner used for <u>this study</u> been qualified by ACRIN? [52]

- O 1 No, specify reason: _____ [53] (complete Q15)
- O 2 Yes, provide ACRIN Scanner ID# (skip to Q16)

_____ [54]

15. PET/CT Scanner used for this exam:

Manufacturer _____ [55]

Manufacturer model name/or number

_____ [56]

16. Date of last PET/CT Scanner SUV calibration/validation:

_____ - _____ - _____(mm-dd-yyyy) [57]

17. Daily scanner QC run on date of study? [58]

- O 1 No
- O 2 Yes

TA

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer
PET/CT Technical Assessment Form

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Image Acquisition

Transmission Scan

18. CT transmission scan:

18a. Was Oral contrast used? [59]
- O 1 No (skip to Q18c)
- O 2 Yes, specify type [60]
  - O 1 Positive contrast
  - O 2 Negative contrast

18b. Amount of Oral contrast ingested [61]

|_|_|_|_| ml

☐ Unknown [62]

18c. Was IV contrast used? [63]
- O 1 No (skip to Q19)
- O 2 Yes

18d. Amount of IV contrast injected [64]

|_|_|_| ml

☐ Unknown [65]

18e. Time IV contrast injection [66]

|_|_|:|_|_| (military time)

☐ Unknown [67]

19. kVp |_|_|_| [68]

20. mAs |_|_|_| [69]

21. Slice Thickness of reconstructed images

|_|.|_|_| mm [70]

PET Emission Scan

22. Emission acquisition mode [71]
- O 1 2D
- O 2 3D

23. |_|_| **Number of bed positions scanned** [72]

PET Emission Scan

24. Emission scan start time: (military time) |_|_|:|_|_| [73]

25. Emission scan stop time: (military time) |_|_|:|_|_| [74]

26. Pixel Size of Reconstructed images |_|.|_|_| **mm** [75]

27. Thickness of Reconstructed images |_|.|_|_| **mm** [76]

Comments: _____

_____

_____

_____ [77]

_____ [78]
Initials of person(s) completing this form

_____ - _____ - _____ [79]
Date form completed (mm-dd-yyyy)

PT

ACRIN 6682

^{64}CU-ATSM in Cervical Cancer PET/CT Local Reader Form

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: This PT form is to be completed by the study Radiologist/Nuclear Medicine Physician for all scans. All dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN at www.acrin.org.

This PET/CT Reader corresponds to: [1]

- O 1 Baseline FDG-PET/CT (complete Part I and Part II)
- O 2 Visit 1 Cu-ATSM PET/CT (complete Part I and Part III)
- O 3 Visit 4 FDG-PET/CT (complete Part I and Part II)

Part I. All Scans

1. Image quality [2]

- O 1 Uninterpretable (complete Q1a, then initial and date form)
- O 2 Adequate (continue to Q2)

1a. Reason *(check all that apply):*

- ☐ Missing images [3]
- ☐ Noisy images [4]
- ☐ Patient motion [5]
- ☐ Artifact [6]
- ☐ Non-diagnostic [7]
- ☐ Other, [9] specify _____ [10]

2. Date of Imaging _____-_____-_____ *(mm-dd-yyyy)* [11]

3. Date of PET/CT Interpretation _____-_____-_____ *(mm-dd-yyyy)* [12]

4. Reader ID |__|__|__|__|__|__|__|__| [13]

PT

ACRIN 6682

^{64}CU-ATSM in Cervical Cancer PET/CT Local Reader Form

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

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part II. FDG-PET/CT

Site	Uptake Scale 0 Not imaged; cannot evaluate 1 Definitely not tumor 2 Probably not tumor 3 Indeterminate 4 Probably tumor 5 Definitely tumor
Primary Tumor	[14]
Pelvic Lymph Nodes	[15]
Common Iliac Lymph Nodes	[16]
Para-aortic Lymph Nodes	[17]
Mediastinal Lymph Nodes	[18]
Supraclavicular Lymph Nodes	[19]
Other, specify _____ _____ [20]	[21]
Other, specify _____ _____ [22]	[23]
Other, specify _____ _____ [24]	[25]

Part III. ^{64}Cu-ATSM PET/CT

1. Was the primary tumor included in the field of view? [26]

O 1 No (please complete Q1a)
O 2 Yes (initial and date form)

1a. Please provide reason *(check all that apply)*:

☐ Image not adequate (as described in part I Q1a) [27]

☐ Other, [28] specify _____ [29]

Comments: _____

_____

_____ [30]

_____ _____-_____-_____ [32]

Radiologist/Nuclear Medicine physician Responsible for this Data — Date form completed

_____ [33]

Initials of Person(s) completing this form

F1

ACRIN 6682
^{64}Cu-ATSM PET/CT in Cervical Cancer Follow-up Evaluation

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

ACRIN Study 6682
PLACE LABEL HERE

Institution _____ **Institution No.** _____
Participant Initials _____ **Case No.** _____

INSTRUCTIONS: This form is completed every 3 months for 2 years after Visit 4, then every 6 months for the 3rd year. All dates are recorded as mm-dd-yyyy. The completed form is submitted to ACRIN via the web, www.acrin.org. Please refer to the form completion instructions for further instructions.

1. Timepoint for this follow-up [1]

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

2. Participant's vital status at the time of this follow-up [2]

O 1 Alive
Date confirmed: _____-_____-_____ *mm-dd-yyyy* [3]
O 2 Dead
O 99 Unknown, *check reason then initial and date form* [4]
O Participant lost
O Other, specify _____ [5]

3. Please indicate method vital status was obtained
Check all that apply

☐ Last visit with treating physician [6]
☐ PET imaging [7]
☐ Other imaging, [8] specify _____ [9]
☐ Other source, [10] specify _____ [11]

4. Disease status at this assessment [12]

O 1 No evidence of disease (Skip to Q5)
O 2 Evidence of disease (Continue to Q4a)
O 99 Unknown (Skip to Q7)

4a. Did the participant develop a confirmed 1st progression and/or new distant metastatic disease since the last F1 was submitted? [13]

Progression is defined as persistence, recurrence, and/or new lesion. Progression should only be reported when it is 1st established. Any future progression ***with the exception of 1st report of distant metastasis*** *should not be reported.*

O 1 No
O 2 Yes (Complete PF form)
O 99 Unknown

5. Date the disease status was determined [14]

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

6. Please indicate method disease status was obtained
Check all that apply

☐ Last visit with treating physician [15]
☐ PET imaging [16]
☐ Other imaging, [17] specify _____ [18]
☐ Other source, [19] specify _____ [20]

7. Did the participant receive any radiation therapy related to cervical cancer (not previously reported) [21]

O 1 No (Skip to Q8)
O 2 Yes (Continue to Q7a. If > 1 course, record details in comments)
O 99 Unknown (Skip to Q8)

7a. Anatomic location of radiation therapy

_____ [22]

7b. Start date of radiation therapy

_____-_____-_____ *mm-dd-yyyy* [23]
☐ Unknown [24]

7c. Stop date of radiation therapy

_____-_____-_____ *mm-dd-yyyy* [25]
☐ Unknown [26] or ☐ Ongoing [27]

8. Did the participant have any surgery related to cervical cancer (not previously reported) [28]

O 1 No (Skip to Q9)
O 2 Yes (Continue to Q8a. If > 1 surgery, record details in comments)
O 99 Unknown (Skip to Q9)

8a. Anatomic location of surgery

_____ [29]

8b. Date of surgery

_____-_____-_____ *mm-dd-yyyy* [30]
☐ Unknown [31]

9. Did the participant receive any chemotherapy related to cervical cancer (not previously reported) [32]

O 1 No (Initial and date form)
O 2 Yes (Continue to Q9a. If > 1 course, record details in comments)
O 99 Unknown (initial and date form)

9a. Type of chemotherapy

_____ [33]

9b. Start date of chemotherapy

_____-_____-_____ *mm-dd-yyyy* [34]
☐ Unknown [35]

9c. Stop date of chemotherapy

_____-_____-_____ *mm-dd-yyyy* [36]
☐ Unknown [37] or ☐ Ongoing [38]

Comments: _____

_____

_____ [39, 40]

_____ [41]
Initials of person(s) completing the form

_____-_____-_____ [42]
Date form completed *mm-dd-yyyy*

IM

ACRIN 6682

^{64}Cu-ATSM in Cervical Cancer Immunohistochemical Analysis

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: The immunostain results will be interpreted by the Research Imuunohistochemical Laboratory at Washington University in a blinded fashion as described in section 11.0 of the protocol. This form is submitted to ACRIN via fax or mail.

1. Number of slides received: _____ [29]

☐ No slides received, [30] reason:

_____ [31]

2. Was tissue analysis for tumor hypoxic markers completed? [1]

O 1 No (Complete Q2a, then initial and date form)
O 2 Yes (Complete Table below)

2a. Reason not completed [2]

O 1 Slides never received from site
O 2 Limited size of biopsy specimen
O 3 Slides lost
O 88 Other, specify _____ [3]
O 99 Unknown

3. Number of Slides Analyzed _____ _____ [28]

Hypoxic Marker	**Percentage of Tumor Cells Staining Score** 0 = <1% tumor cells 1 = 1%–33% tumor cells 2 = 34%–66% tumor cells 3 = >66% tumor cells	**Staining Intensity Score** 0 = no staining 1 = weak staining 2 = moderate to strong staining	**Composite Score** = % tumor cells staining (Column 2) X staining intensity (Column 3) **Range 0-6**
VEGF	[4]	[5]	[6]
GLUT-1	[7]	[8]	[9]
CA-IX	[10]	[11]	[12]
OPN	[13]	[14]	[15]
Other, specify _____ [16]	[17]	[18]	[19]
Other, specify _____ [20]	[21]	[22]	[23]

Comments: _____

_____ [24]

_____ [25]
Initials of person(s) completing this form

_____-_____-_____ [26]
Date form completed

_____
Blinded Investigator signature

DS

ACRIN 6682
End of Study Form
Cu-ATSM PET/CT in Cervical Cancer

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: For each registered participant, please submit this form within two (2) weeks of study completion or premature discontinuation, including death.

1. Did the participant complete the trial? [1]

O 1 No (continue to Q2)
O 2 Yes (continue to Q4, then initial and date form)

2. Date of discontinuation: _____-_____-_____ *(mm/dd/yyyy)* [2]

2a. Primary reason for premature discontinuation: *(check only one)* [3]

O 1 Adverse events/side effect/complications (also specify on the Adverse Event form)
O 2 Participant explicitly withdraws from further study participation
O 3 Protocol violation
O 4 Did not meet eligibility criteria
O 5 Lost to follow-up (unable to obtain contact with the participant during the prescribed protocol intervals)
O 6 Unsatisfactory therapeutic effect
O 7 Abnormal laboratory value(s)
O 8 Investigator decision (specify reason below)
O 9 Participant death (complete Q3)
O 10 Site regulatory violation (specify reason below)
O 88 Other (specify reason below)

Specify reason: _____ [4]

3. Date of death _____-_____-_____ *(mm/dd/yyyy)* [5]

3a. Cause of death [6]

O 1 Disease Progression
O 88 Other _____ *(specify cause of death)* [7]

4. Was the data assessed, reviewed, and approved by the investigator? [12]

O 1 No
O 2 Yes

COMMENTS: _____

_____

_____ [8]

_____ [9]
Initials of person(s) completing the form

_____-_____-_____ [10]
Date form completed (mm-dd-yyyy)

PR

ACRIN 6682

^{64} Cu-ATSM PET/CT in Cervical Cancer Protocol Variation Form

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

ACRIN Study 6682 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 Imaging-related deviation (complete 1b)
- O 3 Study activity performed prior to participant signing study consent form
- O 4 Blood sample taken prior to participant signing biomarker consent form
- O 5 Cervical biopsy slides not obtained/sent/analyzed per protocol
- O 6 Blood sample not obtained/sent per protocol
- O 7 Visit or follow-up procedures not performed per protocol (specify visit in Q6)
- O 8 Baseline FDG-PET/CT not performed within 4 weeks of enrollment
- O 9 Visit performed outside of protocol specified time frame (specify visit in Q6)
- O 10 Chemoradiotherapy not per protocol
- O 11 Case enrolled under expired IRB approval/FWA
- O 88 Other, specify: _____ [2]

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

I. Cu-ATSM [3]

- O 1 PET instrument not credentialed prior to performing scan
- O 2 PET scan done at an non-ACRIN qualified institution
- O 3 PET images lost/unavailable
- O 4 Cu-ATSM preparation, apyrogenicity, and/or radiochemical purity not done per protocol **(NOTE: IND violation)**
- O 5 Time between injection and start of scan is unknown
- O 6 Time between Cu-ATSM injection and start of scan ≥ 40 or < 30 minutes
- O 7 Injected dose <18 mCi or >25 mCi
- O 8 Cu-ATSM PET/CT emission scan duration not 30 minutes
- O 9 Body weight is incorrect or unknown
- O 10 Misregistration of the tumor between PET and CT by more than 3 slices
- O 11 CT acquisition parameters not per protocol
- O 88 Other, specify: _____ [4]

II. FDG [5]

- O 1 PET instrument not credentialed prior to performing scan
- O 2 PET scan done at an non-ACRIN qualified institution
- O 3 PET images lost/unavailable
- O 4 Time between injection and start of scan is unknown
- O 5 Blood glucose testing not done
- O 6 Body weight is incorrect or unknown
- O 7 Scan not performed according to ACRIN SOP
- O 88 Other, specify: _____ [6]

PR

ACRIN 6682

^{64} Cu-ATSM PET/CT in Cervical Cancer Protocol Variation Form

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

ACRIN Study 6682 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

2. Date the protocol deviation occurred: ____ - ____ - **20**____ (mm-dd-yyyy) [7]

3. Date the protocol deviation was discovered: ____ - ____ - **20**____ (mm-dd-yyyy) [8]

4. Describe the protocol deviation:

_____ [9]

_____ [10]

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

_____ [11]

_____ [12]

6. Please provide the time point this Study Deviation applies to: [13]

- O 1 Study Enrollment Visit
- O 2 Visit 1 (14 days from baseline Visit 1)
- O 3 Visit 2 (within 4 weeks from baseline Visit 1)
- O 4 Visit 3 (4 weeks post completion of chemoradiotherapy)
- O 5 Visit 4 (3 months post completion of chemoradiotherapy)
- O 6 Follow-up Time Point, specify (check only one): [14]

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

_____ [15]
Initials of person responsible for data (RA, study staff)

____ - ____ - **20**____ (mm-dd-yyyy) [16]
Date Form Completed

_____
Investigator Signature

PF

ACRIN 6682

^{64}Cu-ATSM PET/CT in Cervical Cancer Disease Progression

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

DISEASE PROGRESSION

INSTRUCTIONS: This form should be completed to capture 1st progression of disease and/or any new distant metastatic disease. Please specify in each table whether each listed site has progression based upon persistent disease, progression based upon recurrence of disease, progression based upon a new lesion, no progression, or unknown if the site has not been evaluated for disease. If there is a 1st progression and/or a new distant metastatic disease at a site not listed, please enter the site into the appropriate table under 'other, specify'. For each site with progression (persistent, recurrence, or new lesion) please provide the method of evaluation and the date the progression was documented. **If more than one method of evaluation was used, please provide the most definitive method that determined the progression.**. **The date documented should be recorded as the date the method of evaluation was performed**. Dates are recorded as mm-dd-yyyy. This form is to be submitted to ACRIN via web at www.acrin.org.

1. Indicate disease status [1]

- O 1 1st report of any progression (complete table 1)
- O 2 New distant metastatic disease not previously reported (complete table 2)
- O 3 Both of the above (complete table 1 and 2)

Table 1. 1st Report of Any Progression

Site	Status of Disease at Site 1 = Progression - Persistent 2 = Progression - Recurrence 3 = Progression - New Lesion 4 = No progression 99 = Unknown	Method of Evaluation 1 = Pathology, 2 = CT Scan, 3 = MRI Scan, 4 = PET Scan, 5 = Ultrasound, 6 = Bone Scan, 7 = Physical Exam, 88 = Other (specify in comments)	Date Documented *(mm-dd-yyyy)*
Cervix	[2]	[3]	[4]
Pelvic Lymph Nodes	[5]	[6]	[7]
Common Iliac Lymph Nodes	[8]	[9]	[10]
Para-aortic Lymph Nodes	[11]	[12]	[13]
Supraclavicular Lymph Nodes	[14]	[15]	[16]
Other pelvic organ, specify: _____ [17]	[18]	[19]	[20]
Other, specify _____ [21]	[22]	[23]	[24]
Other, specify _____ [25]	[26]	[27]	[28]

PF

ACRIN 6682

^{64}Cu-ATSM PET/CT in Cervical Cancer Disease Progression

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

ACRIN Study **6682**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

DISEASE PROGRESSION, contd.

Table 2. New Distant Metastatic Disease Not Previously Reported

Site	Status of Disease at Site 1 = New Lesion 2 = No progression 99 = Unknown	Method of Evaluation 1 = Pathology, 2 = CT Scan, 3 = MRI Scan, 4 = PET Scan, 5 = Ultrasound, 6 = Bone Scan, 7 = Physical Exam, 88 = Other (specify in comments)	Date Documented *(mm-dd-yyyy)*
Supraciavicular Lymph Nodes	___ [29]	___ [30]	___-___-___ [31]
Other Non Pelvic/Non Abdominal Lymph Nodes specify _____ [32]	___ [33]	___ [34]	___-___-___ [35]
Liver	___ [36]	___ [37]	___-___-___ [38]
Lung	___ [39]	___ [40]	___-___-___ [41]
Bone	___ [42]	___ [43]	___-___-___ [44]
Other, specify _____ [45]	___ [46]	___ [47]	___-___-___ [48]
Other, specify _____ [49]	___ [50]	___ [51]	___-___-___ [52]

COMMENTS: _____

_____

_____ [53]

_____ [54]
Initials of person(s) completing the form

___ - ___ - ___ [55]
Date form completed (mm-dd-yyyy)

AE

ACRIN Adverse Event Form
ACRIN 6682
Cu-ATSM PET/CT in Cervical Cancer

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

ACRIN Study 6682 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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)*

MH

ACRIN 6682

^{4}Cu-ATSM PET/CT in Cervical Cancer

Supplemental Baseline Medical History Form

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

ACRIN Study 6682

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

SUPPLEMENTAL BASELINE ABNORMALITIES

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

☐ None[1]

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

Sequence # [2]	Condition / Event [3]	Online CTCAE/MedDRA Term [4]	Grade (1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatning or disabling, 99 = Unknown) [6]
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99
___			O 1 O 2 O 3 O 4 O 99

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

CO

ACRIN 6682

^{64}Cu-ATSM in Cervical Cancer

Supplemental Concomitant Medications

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

ACRIN Study 6682

PLACE LABEL HERE

Institution ______________ **Institution No.** ______________

Participant Initials ______________ **Case No.** ______________

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 subsequent Supplemental CO form.*****