ACRIN 6678

FDG-PET/CT as a Predictive Marker of Tumor Response and Patient Outcome: Prospective Validation in Non-small Cell Lung Cancer

Study Overview
Protocol Investigators

**Protocol Investigator**

Wolfgang Weber, MD  
Department of Nuclear Medicine  
University of Freiberg  
Germany

**Protocol Co-Investigators**

Denise Aberle, MD  
Department of Radiology  
UCLA Medical Center

Barry Siegel, MD  
Division of Nuclear Medicine  
Mallinckrodt Institute of Radiology

**Protocol Co-Investigators**

Anthony Shields, MD, PhD  
Karmanos Cancer Institute

Ramaswamy Govindan, MD  
Washington University

Karen Reckamp, MD  
Department of Medicine  
City of Hope Medical Center

Steven Dubinett, MD  
Department of Medicine  
UCLA Medical Center

**Joel Karp, PhD**  
University of Pennsylvania  
Department of Radio Nuclear Medicine

**Protocol Statistician**

Constantine Gatsonis, PhD  
Center For Statistical Sciences  
Brown University
Protocol Overview

- Background
- Design
- Objectives
- Inclusion and Exclusion Criteria
- Participant Accrual
Single-institution studies suggest FDG-PET is useful for early monitoring of tumor response to therapy.

Validation is required in a multi-institutional trial prior to FDG-PET’s use as a new marker for tumor response for patient management.

Non-small cell lung cancer (NSCLC) was selected because:

- It is a common disease with a poor prognosis;
- It allows for correlation of FDG-PET/CT tumor response and patient survival;
- Almost universally demonstrates intense FDG uptake – facilitating the quantitative analysis.
Eligibility: Patients with advanced NSCLC: Groups A and B: Stage IIIB with malignant pleural effusion or Stage IV; Group C: Stages IIIA, IIIB or IV (therapy is not specified)

OPTION 1 / GROUP A:
- 2 FDG-PET/CT and 2 *volumetric CT scans prior to chemotherapy
  - at least 24 hours between the 2 PET/CT and 2 volumetric CT scans;
- 1 FDG-PET/CT and 1 *volumetric CT scan post-cycle 1 of chemotherapy;
- Follow-up CT scans every 6 weeks from initiation of chemotherapy for 18 weeks per standard of care;
- Observational clinical follow-up for 1 year.

OPTION 2 / GROUP B:
- 1 FDG-PET/CT and 1 *volumetric CT scan prior to chemotherapy;
- 1 FDG-PET/CT and 1 *volumetric CT scan post-cycle 1 of chemotherapy;
- OPTIONAL: 1 FDG-PET/CT and *1 volumetric CT scan post-cycle 2 of chemotherapy;
- Follow-up CT scans every 6 weeks from initiation of chemotherapy for 18 weeks per standard of care;
- Observational clinical follow-up for 1 year.
**Eligibility:** Patients with advanced NSCLC: Groups A and B: Stage IIIB with malignant pleural effusion or Stage IV; Group C: Stages IIIA, IIIB or IV (therapy is not specified)

**GROUP C Option:**

2 FDG-PET/CT scans prior to chemotherapy—at least 24 hours, but no more than 7 days, between the 2 scans.

* IMPORTANT NOTE FOR ALL GROUPS:

All volumetric CT scans are optional, but strongly encouraged. If a participant agrees to volumetric CT scanning, then 2 scans must be completed for inclusion of these imaging data in the study analysis.
- In Group B, at least 1 of these 2 scans must be pretreatment.
Study Hypotheses

1. Changes in tumor metabolism during chemotherapy provide early prediction of patient survival.
   - This primary study endpoint is evaluated in Groups A and B

2. Tumor glucose utilization can be measured by FDG-PET with high reproducibility.
   - This secondary study endpoint is evaluated in Groups A and C
1. To test whether a metabolic response (indicated by ≥ 25% decrease in peak tumor SUV post-cycle 1) provides early prediction of patient survival and best tumor response (Groups A and B).

2. To determine the test-retest reproducibility of quantitative assessment of tumor FDG uptake by SUVs (Group A and C).

3. To compare the predictive value of FDG-PET for one-year survival after 1 and 2 cycles of chemotherapy uptake (Group B).

4. To evaluate in an exploratory analysis changes in tumor volume during chemotherapy by multi-slice CT (Groups A and B).
Inclusion Criteria

1. Newly diagnosed histologically or cytologically proven NSCLC

2. Participant meets one of the following criteria:
   - (Groups A and B) Stage IIIB (with malignant pleural effusion) or stage IV; (Group C) Stages IIIA, IIIB or IV (therapy is not specified)
   - Recurrent or metastatic NSCLC – surgery or radiation therapy performed ≥ three (3) months prior to enrollment
     - Measurable lesion in the chest
   - Recurrent or metastatic NSCLC – received chemotherapy in the adjuvant setting or as part of combined modality therapy for locoregional disease ≥ three (3) months prior to diagnosis
     - Measurable lesion in the chest
     - If previously irradiated, lesion(s) must be outside the prior radiation port or, if within a prior radiation port, must demonstrate radiologic progression by RECIST criteria.
3. Participant has following minimum workup to confirm tumor stage:
   - Chest CT or MR – if necessary to confirm stage
   - History/physical examination within 6 weeks prior to registration;
   - CT or MR scan of the brain within 4 weeks prior to registration *if indicated* (Groups A and B only).

4. At least one measurable primary or other intrathoracic / supraclavicular lesion ≥ 2 cm, according to Response Evaluation Criteria in Solid Tumors (RECIST)

5. Performance status of 0 to 2 on the Eastern Cooperative Oncology Group (ECOG) scale (Groups A and B only).

6. Participant considered for cytotoxic chemotherapy regimen planned to be administered at 3 week intervals (Groups A and B only).
Inclusion Criteria cont.

7. Age 18 years or older

8. Using medically appropriate contraception if sexually active; women of childbearing potential must not be pregnant or breastfeeding

9. Able to give study-specific informed consent

10. Able to tolerate PET/CT imaging required by protocol, to be performed at an ACRIN-qualified facility
Exclusion Criteria

1. Small cell carcinoma histology

2. Pure bronchioloalveolar cell carcinoma histology

3. Thoracic radiotherapy, lung surgery or chemotherapy within three (3) months prior to inclusion in the study

4. Poorly controlled diabetes (defined as fasting glucose level > 150 mg/dl)

5. Prior malignancy (Exception: participants with basal cell or squamous cell carcinoma of the skin, or carcinoma in situ. If diagnosed with other cancer, participant has been disease free for more than 3 years)

6. Patients of reproductive potential, who are sexually active but unwilling and/or unable to use medically appropriate contraception, or women who are pregnant or breastfeeding
7. Intent to undergo chemoradiotherapy (Groups A and B)

8. Clinical or radiographic signs of post-obstructive pneumonia

9. Symptomatic brain metastases (Groups A and B)

10. Concurrent treatment is planned with any targeted or biologic therapy other than bevacizumab and/or cetuximab (Groups A and B)

11. Treatment planned with any targeted or biologic therapy alone, such as gefitinib and erlotinib, or failure of first-line treatment with such agents (Groups A and B)
Participant Accrual

- Targets
- Process
- Support
Enrollment Targets

- Groups A and B: 228 participants with at least 171 in Group B
- Groups A and C: 57 total combined participants

**Site** enrollment expectations: > 60 percent of what site reported on application.

**Trial** enrollment expectations: 7 to 10 patients per month
Participants interested in the trial will be consented to one of the three study arms depending upon their:

- eligibility evaluation,
- personal preference, and
- ability to adhere to the timing sequences for each arm.

The decision will be made by the referring physician, the study PI, and the research staff consenting the patient.
Primary medical oncologist coordinates enrollment within his or her practice and among clinicians specializing in lung cancer.
- pulmonologists, surgical oncologists, primary care physicians

Nuclear medicine physician and radiologist maintain communication with oncologist and oversee imaging.

Research associates coordinate participant communication and ensure timely imaging and follow-up.
Recruitment Materials

- Support letter – introduces trial to potential referring clinicians. Send with eligibility checklist and brochures.
- Protocol informational slide set – for use at tumor boards and other educational opportunities.
- Patient brochure – for distribution throughout hospital network. Spanish brochure can be made available.
- Consent flip chart – aid to discuss consent form
- Available at: www.acrin.org/6678_protocol.aspx
ACRIN 6678: *FDG-PET as a Predictive Marker of Tumor Response and Patient Outcome: Prospective Validation in Non-small Cell Lung Cancer* is the first multi-center clinical trial supported by the Biomarker Consortium which is a public-private partnership whose membership includes the National Institutes of Health, the US Food and Drug Administration, Centers for Medicare and Medicaid Services as well as industry and patient advocacy groups.
ACRIN 6678

FDG-PET/CT as a Predictive Marker of Tumor Response and Patient Outcome: Prospective Validation in Non-small Cell Lung Cancer

DATA MANAGEMENT TRAINING
Overview

• Online Data Management System
• Registration
• Data Collection
• Case Report Forms
• Data Management
Online Data Management System:

Navigating the ACRIN Website

http://www.acrin.org
Access to 6678 Protocol Page
Protocols specific accrual updates will be projected within the Enrollment column.

Clicking on the 6678 link automatically connects to the 6678 web page.
The Current Protocols screen for 6678 provides links to the Protocol, protocol specific contents, participating sites, protocol resources and PDF versions of all study specific data forms upon study activation.
#3

SUMMARY OF CHANGES

ACRIN Study:

The following changes are in effect:

Section 4.0:

“Outside CT and MRI studies will be accepted” has been changed to: “Either an outside CT or MRI study will be accepted”.

Section 7.5.3:

Last paragraph has been added:

“Registration is expected to be completed within 24 hours of imaging. If a patient is Registered more than 24 hours but less than 48 hours from the time of imaging, this will be considered a minor deficiency. Registration of a patient more than 48 hours following procedure, will be considered a major deficiency.”

Section 8.2.6:

Follow-up Form (FT):

“Q 3 months x 2 years” has been changed to: “q 3 months year 1 and q 6 months year 2”.

The word etc. had been added in the notation at the bottom of the chart.

Section 8.7.3:

Entire section has been added to protocol, including chart of reference.

Section 9.1:

“Every three months for 2 years” has been changed to: “During year 1 and every 6 months during year 2”.

Section 9.2.3:

This section has been deleted, as it is no longer being used as part of data collection.

If there are amendments made to a previously approved protocol version, the Summary of Changes link will detail the changes within the protocol by section.
Use the Data Forms link to access the paper version of the forms, form revision notices and form completion instructions.
Registration
Registration

• Standard demographic questions & protocol-specific questions
  – See protocol section 5.1 & 5.2 for Inclusion/Exclusion Criteria.
• Error messages boxes appear specific to:
  – Mandatory values
  – Validity Checks
  – Date Discrepancies
• Email confirmation upon successful registration.
• Participants may be registered to one of three groups depending on eligibility: Group A, B, or C.
Registration Reminders

• Q 16 (Calendar Base Date) & Q 17 (Randomization Date)
  – Cannot be prior to Q 4 (Consent Date)
• Q 25: Date of planned chemo tx must be within 1-30 days of registration (Groups A and B only).
• Q 28-33: Exam Dates
  – HX & PE, Chest/abdomen CT/MR, Brain CT/MR if applicable
  – ensure eligibility, per protocol section 5.1.
  – May be useful to have these dates ready before registering (to avoid timing out of system).
• Q 41: Pregnancy test within 7 days of registration (if applicable)
ACRIN 6678 Site Training

Access to all Protocol registration and data forms.
This site will allow users to register a patient or enter case form data directly on to active ACRIN studies 24 hours a day, seven days a week.

Select from the following Menu:

<table>
<thead>
<tr>
<th>ACTIVE</th>
<th>PRACTICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACRIN - Protocols</td>
<td>ACRIN - Pilot Testing</td>
</tr>
<tr>
<td>ACRIN 6666</td>
<td></td>
</tr>
</tbody>
</table>

Access to all active protocols and the pilot site

To obtain a username and password, complete the Username Request Form
Login ID and Password will be activated once all site participation documentation has been received at ACRIN Headquarters.

New research associates (RAs) must complete the ACRIN RA Tutorial prior to receiving a username and password.

Please Select your Institution and Group from the List Displayed

<table>
<thead>
<tr>
<th>Group</th>
<th>Inst No</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACRIN</td>
<td>4202</td>
<td>University of Pennsylvania Medical Center</td>
</tr>
<tr>
<td>ACRIN</td>
<td>9999</td>
<td>Test Institution</td>
</tr>
</tbody>
</table>

Select your Institution Number to proceed to the Main Menu.

Please note that the Institution Number is linked to your username and password.
Please enter the Study Number

Study Number: 6678

Register

Back To Main Menu Exit
### Eligibility Check List

**Instructions:** The eligibility checklist (A0) Part 1 must be completed prior to registration to determine and confirm study eligibility. At the time of enrollment, the participant is to review, sign and date the informed consent. The following questions will be asked at study registration. The date is submitted via the ACRIN website. Submit a paper form only in the event the website is down.

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

1. Name of Institutional person registering this case
2. Has the Eligibility Checklist been completed?
3. Is the Patient eligible for this study?
4. Date the study-specific Consent Form was signed? (mm-dd-yyyy) (Must be prior to study entry)
5. Patient’s Initials (last, first) (L, F)
6. Verifying Physician (Site PI)
7. Participant’s ID Number (optional: 999999 may be coded)
8. Date of Birth [mm-dd-yyyy (must be – or > than 18 years)]
9. Ethnicity
   1. Hispanic or Latino
   2. Not Hispanic or Latino
   3. Unknown
10. Gender
    1. Male
    2. Female
11. Participant’s country of residence (if other, complete Q18)
    1. United States
    2. Canada
    3. Other

### ACRIN 6678 Site Training
Hello,

This message is Confirmation of New Case Registration for the American College of Radiology Study# 6678 Case# 13. Please find the attached A0 & Patient Calendar HTML File.

Thanks,
ACR

Note:
This information E-mail is Auto generated by the Clinical Server On Tue Feb 13 12:24:00 EST 2007 (Eastern Standard Time). Replies will not be checked on this server, so please send your Queries to HQ directly for prompt response.

DISCLAIMER:
This message contains privileged confidential information which is not to be disclosed. If you are not the intended recipient of this message please contact websupport@phila.acr.org and destroy this message as well as all existing copies and attachments.
A participant specific calendar is generated for each registered case. The calendar identifies the randomization group and all data forms/images/reports due for submission.
Data Collection
Select the Data Collection to view forms expected for submission through the ACRIN website.
Select the appropriate form to begin data entry
## View Patient Calendar

**Study No 6678**  
**Institution 9999 - Test Institution**  
**Case No 10**  
**Patient Name DAD**

<table>
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<tr>
<th>FormCd</th>
<th>Description</th>
<th>Visit Seq Desc</th>
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<th>Assd Date</th>
<th>Recvd Date</th>
<th>Lock Status</th>
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<td></td>
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<td>00/00/0000</td>
<td>00/00/0000</td>
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<td>03/12/2007</td>
<td>00/00/0000</td>
<td>00/00/0000</td>
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<td>00/00/0000</td>
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Data Collection

• Upon web submission of the form
  – the received date is updated
  – the form is removed from the Data Collection screen
  – updated within the View Patient Calendar screen
Case Report Forms
I1: Initial Evaluation Form

- Records date of initial diagnosis of NSCLC and stage.
- Documents prior treatment
  - Surgery
  - Radiotherapy
  - Chemotherapy
- Blood glucose level
  - Within 4 weeks prior to registration
  - Can be serum test or finger stick
ACRIN 6678 Site Training
Additional Forms

- PET/CT Local Technical Assessment Forms
- PET/CT Local Interpretation Forms
- Chemotherapy Forms
- Follow-up Forms
- Off Study Form (O1)
- End of Study Form (DS)
- Adverse Event Form (AE)
Adverse Event Reporting

• For this trial:
  – ACRIN will collect and report AE’s considered possibly, probably, or definitely related to the trial.
  – Grades 3, 4, 5 that occur during study participation and up to 30 days after the last study procedure.

• Refer to Protocol Section 12.0
  – When and How to Report
**ACRIN Adverse Event Form**

All questions regarding Adverse Events should be directed to ACRIN. All Adverse Events (AEs) and Serious Adverse Events (SAEs) as defined in the protocol require routine reporting via web entry of the AE CRF. In addition, SAEs meeting the criteria for expedited reporting, as specified in the protocol, require (a) telephone report to both NCI and ACRIN within 24 hours of knowledge, (b) AdEERS report completed and submitted as specified in the protocol, and (c) completed AE case report form with investigator’s signature submitted to ACRIN via web and filed in the participant chart.

<table>
<thead>
<tr>
<th>AE Description</th>
<th>AE Short Name</th>
<th>CTCAE v3.0</th>
<th>Attribution</th>
<th>Action Taken</th>
<th>Outcome</th>
<th>Date of AE Onset and Resolution</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1 = Mild</td>
<td>1 = Unrelated</td>
<td>1 = None</td>
<td>1 = Recovered</td>
<td>(mm-dd-yyyy); check box “on-going” if the AE is ongoing at the time of report</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = Moderate</td>
<td>2 = Unlikely</td>
<td>2 = Medication Therapy</td>
<td>2 = Improved</td>
<td>On-going</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = Severe</td>
<td>3 = Possible</td>
<td>3 = Procedure</td>
<td>3 = Ongoing</td>
<td>On-going</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 = Life threatening or disabling</td>
<td>4 = Probable</td>
<td>4 = Hospitalization</td>
<td>4 = Death</td>
<td>On-going</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 = Definite</td>
<td>5 = Definite</td>
<td>5 = Other</td>
<td>5 = Unknown</td>
<td>On-going</td>
</tr>
</tbody>
</table>

**Comments:** For each comment, identify the AE number from above (1-3):

If there are more than 3 AEs for a visit, check this box and use another form.

**Investigator Signature:**

**Date Form Completed (mm-dd-yyyy):**

---

ACRIN 6678 Site Training
Data Management
Data Corrections

• Data corrections **cannot** be made through the web.

• Corrections must be noted on the original CRF or the Summary Data Form.
Data Corrections

• Copy is sent to ACRIN via fax or mail
  – Label all pages with study #, form type, case #.

• Follow Good Clinical Practice (GCP)
  – Single strike mark through incorrect data
  – Indicate the correct data
  – Initial, date
# Example of Good Clinical Practices: Form Completion

### ACRIN Study 6671

**MRI Lymph Node Evaluation Central Read:**

All Sequences Review

If this is a revised or corrected form, please check: [ ]

---

### T1.

1. **Reader ID:**
   - CT12345

2. **Date of exam:**
   - 03.01.2010
   - CT03/26/2010

---

### T2.

**Pelvic Lymph Nodes**

**Right Obturator Lymph Node (0-92):**

1. **Total number of LN visible:**
   - (Enter 0 if no LN visible, proceed to next region)
   - Maximum of 5 positive LN to report in Q3a)

2. **Ferrumoxtran-10 evidence of LN metastasis:**
   - (Choose one option)
     - Definite benign
     - Most likely benign
     - Probably benign
     - Probably malignant
     - Most likely malignant
     - Definitely malignant
   - 02

3. **Number of positive LNs:**
   - 3
   - CT03/26/2010

   - **LN with the lowest short axis**
     - Short axis [0.3 mm] Long axis [0.3 mm]

   - **LN with the highest short axis**
     - Short axis [0.5 mm] Long axis [0.5 mm]

   - **Smallest positive focus**
     - Short axis [0.2 mm] Long axis [0.2 mm]

   - **Largest positive focus**
     - Short axis [0.3 mm] Long axis [0.3 mm]

---

### MR Image Quality

3. **T2 Weighted Sequence:**
   - 1. Adequate (Continue to T2)
   - 2. Suboptimal (Complete C3a)

3a. **Reason study is suboptimal:**
   - [ ] Inadequate FOV
   - [ ] Artifacts
   - [ ] Motion from breathing or patient's motion
   - [ ] Indeterminate

---

### Reporting

#### LN 1

- Type of involvement:
  - [ ] > 50% replacement
  - [ ] < 50% replacement

#### LN 2

- Type of involvement:
  - [ ] > 50% replacement
  - [ ] < 50% replacement

#### LN 3

- Type of involvement:
  - [ ] > 50% replacement
  - [ ] < 50% replacement

#### LN 4

- Type of involvement:
  - [ ] > 50% replacement
  - [ ] < 50% replacement

#### LN 5

- Type of involvement:
  - [ ] > 50% replacement
  - [ ] < 50% replacement

---

3f. **Are there any positive LNs anterior/posterior to the obturator nerve?**

- (Choose one)
  - [ ] No (Continue to Q4)
  - [ ] Yes (Complete C3g)

3g. **Indicate position relative to the obturator nerve:**

- [ ] Anterior
- [ ] Posterior
- [ ] Both

---

4. **Number of negative LNs:**

4a. **LN with the lowest short axis**

- Short axis [0.1 mm] Long axis [0.1 mm]

4b. **LN with the highest short axis**

- Short axis [0.2 mm] Long axis [0.2 mm]

---

*Copyright 2010*
**EXAMPLE OF “BAD” CLINICAL PRACTICES**

**ACRIN 6671**
MRI Lymph Node Evaluation Central Read: All Sequences Review

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

**T1.**

1. Reader ID
2. Date of exam: 05/13/2009

**MR Image Quality**

3. **T2** Weighted Sequence
   - Suboptimal (Complete Q3b)

3a. Reason study is suboptimal
   - Inadequate FOV
   - Artifacts
   - Motion from breathing or patient’s motion
   - Indeterminate

**T2.**

**Pelvic Lymph Nodes**

1. Total number of LNs visible
   - Enter 0 if no LN visible, proceed to next region
   - Maximum of 5 positive LNs to report in Q3a

2. Fenomoxtran-10 evidence of LN metastasis (choose one option)
   - Definitely benign
   - Most likely benign
   - Probably benign
   - Probably malignant
   - Most likely malignant
   - Definitely malignant

3. Number of positive LNs:
   - LN with the lowest short axis
     - Short axis [ ] mm Long axis [ ] mm
   - LN with the highest short axis
     - Short axis [ ] mm Long axis [ ] mm
   - Smallest positive focus
     - Short axis [ ] mm Long axis [ ] mm
   - Largest positive focus
     - Short axis [ ] mm Long axis [ ] mm

3f. Are there any positive LNs anterior/posterior to the obturator nerve?

3g. Indicate position relative to the obturator nerve
   - Anterior
   - Posterior
   - Both

4. Number of negative LNs:
   - LN with the lowest short axis
     - Short axis [ ] mm Long axis [ ] mm
   - LN with the highest short axis
     - Short axis [ ] mm Long axis [ ] mm
Data Queries

• Generated when:
  – Inconsistencies exist
  – Confirmation of data entered is necessary
  – Mandatory data fields are incomplete

• Request for Study Information-Z1Form
  – E-mailed to site RA
  – Protocol, case, form, question specific
  – Due Date is the date query is mailed
  – Respond in timely manner
  – Reminder letters
    • 2 weeks from due date
    • 4 weeks from due date
    • 8 weeks from due date (final)
Z1: Request for Additional Information

Additional Information Request Z1
Institution #: 4202
Institution Name: University of Pennsylvania

Request Sent By: Laura Hill, ACRIN Data Management

DATE: 3/27/07
STUDY #: 5678

Q#: form specific question number(s)
Query: ACRIN description of data in need of clarification
Resolution: Site provided description of data clarification

<table>
<thead>
<tr>
<th>Case #</th>
<th>Form</th>
<th>Due Date</th>
<th>Q #</th>
<th>Query*</th>
<th>Resolution**</th>
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ACRIN Z1.4-1-04
Forms Due Reports

- Site case management tool
- Request for outstanding data
- Encourage prompt submission of data, reports, and images
- Affords an opportunity to resolve discrepancies between the Institution's records and the Data Management Center
- A listing of each item that has not been received by a specified deadline
- Sent to the PI and RA of record for a protocol
- Time specific
# Forms Due Report

**AMERICAN COLLEGE OF RADIOLOGY IMAGING NETWORK**

**FORMS DUE REPORT**

**REPORTING PERIOD:** from 01/01/1999 through 12/31/2002

**GROUP:** 26  American College of Radiology Imaging Network

**INST:** [Redacted]

**STUDY:** 6651  CERVIX

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<th>Patient Status</th>
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</table>
Use the Site Operations Tool to view outstanding or projected forms on calendars across a study or case.
Communication with Sites
Communication with Sites

• Protocol specific conference calls
• Telephone
• Email
• Training
General Communication Memo

• Communication memo submitted to the Data Management Center.
• Used to communicate info not previously reported in forms.
ACRIN
GENERAL COMMUNICATION MEMO/REPLY TO FORMS DUE REQUEST

INSTRUCTIONS: Use this memo
• To communicate the unavailability of a required calendar item.
• To inform us that a participant has expired and you are awaiting details.
• To communicate information about the case that cannot be reported on a form. Note: A narrative will not be accepted in lieu of a form.

Use a separate form for each case.

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

From Institution #/Name: ___________________________ Forms Due Request Date __________
ACRIN Protocol # ____________ Case # ____________ Participant Initials/ID _______________

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<th>Assessment/Imaging Date Recorded on Form by Institution</th>
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_________________________ ___________________________ 04/04
Research Associate Date
Laura Hill
Research Associate
lhill@acr.org
Phone: 215-717-2767

*Fax : 215-717-0936
Imaging Requirements
Group A - Imaging Exams

- Two (2) FDG-PET/CT scans prior to chemotherapy – at least 24 hours between the 2 scans

- Two (2) *volumetric CT scans prior to chemotherapy – at least 24 hours between the 2 scans (Optional)

- One (1) FDG-PET/CT scan post-cycle 1 of chemotherapy

- Follow-up diagnostic CT scans every 6 weeks for 18 weeks per standard of care

* Volumetric CT scans are optional
Group B - Imaging Exams

- One (1) FDG-PET/CT and (1) volumetric CT scan prior to chemotherapy
- One (1) FDG-PET/CT and (1) *volumetric CT scan post-cycle 1 of chemotherapy
- OPTIONAL: One (1) FDG-PET/CT scan post-cycle 2 of chemotherapy
- Follow-up diagnostic CT scans every 6 weeks for 18 weeks per standard of care

* Volumetric CT scans are optional
Group C - Imaging Exams

- Two (2) FDG-PET/CT scans prior to chemotherapy – at least 24 hours between the 2 scans

- Two (2) *volumetric CT scans prior to chemotherapy – at least 24 hours between the 2 scans (Optional)

* Volumetric CT scans are optional
Imaging Exams

- PET/CT (submit the attenuated corrected emission PET, non-attenuated emission PET, and the non-contrast CT scan used for attenuation correction)

- Volumetric CT (breath held, full inspiration)

- Group A and B: Diagnostic CT for RECIST (breath held, full inspiration, contrast per standard of care)

- PET/CT or CT images produced for volumetric may be prospectively reconstructed for RECIST measurements if the participant does not receive IV contrast.

- If the participant receives IV contrast, PET/CT or CT images produced for volumetric must be done pre contrast; A second, post contrast scan will be used for RECIST measurements
Blinding of Treating Physicians to Local Read

• Treating physicians will be blinded to the results of the CT and FDG-PET/CT scans completed post-cycle 1. Only potentially life threatening CT findings or other serious complications, such as impending fractures will be reported after cycle 1. For ethical reasons, treating physicians will not be blinded to the results of the later FDG-PET/CT scan (post-cycle 2), since tumor response is routinely assessed at this time.
Questions to consider:

• If the participant is to get iodinated contrast, can your PET/CT department inject iodinated contrast?

• Can your PET/CT scanner perform a CT scan using the volumetric parameters?
If you answer **YES** to **both** of the questions on the prior slide, you may use your PET/CT scanner for all imaging.
If you answer **NO** to either of these questions, you will need to use a **Dedicated CT Scanner** for the diagnostic CT scans.
ACRIN 6678 Site Training

Can CT scanner on PET/CT obtain ≤1.5mm slices?
- Yes
  - Perform volumetric NC-CT on PET/CT scanner. Recon at 1-1.5mm and 3mm
  - Will patient receive iodine contrast for “routine” CT study?
    - No
      - Use 3mm reconstruction of volumetric NC-CT for RECIST read
    - Yes
      - Perform CE-CT Recon at 1-1.5mm and 3mm
  - Does PET center have ability to give iodine contrast with power injector?
    - Yes
      - Perform CE-CT Recon at 1-1.5mm and 3mm
    - No
      - Use 3mm reconstruction of volumetric NC-CT for RECIST read

- No
  - Perform volumetric NC-CT on separate CT scanner. Recon at 1-1.5mm and 3mm
  - Will patient receive iodine contrast for “routine” CT study?
    - No
      - Use 3mm reconstruction of volumetric NC-CT for RECIST read
    - Yes
      - Perform CE-CT Recon at 1-1.5mm and 3mm
      - Use 3mm reconstruction of CE-CT for RECIST read

PET CENTER

CT CENTER
Image Submission
Sites have two options for submitting the CT and MR exams to ACRIN’s image archive:

- Using ACRIN’s electronic image transfer application (TRIAD)
- Express mailing images on a CD-ROM or DVD
TRIAD Software for Secure File Transfer Protocol (sFTP) Submission

• The preferred image transfer method is via TRIAD

• TRIAD anonymizes, encrypts, and performs a lossless compression of the images

• TRIAD transfers images securely to the ACRIN image archive in Philadelphia.

• ACRIN IT staff will contact you to set up the software at your site
Media Delivery Instructions

Please affix a label to the CD/DVD jacket that includes: study name, site name, site number, subject number, date of scan(s), image time point, and type of imaging. Do not apply adhesive labels directly to the CD.

Complete the ITW (see “Image Transmittal Worksheet Instructions”) and include with the media shipment.

Mail the images and ITW to:
American College of Radiology Imaging Network
PET Core Laboratory
Attn: ACRIN 6678
1818 Market Street, 16th floor
Philadelphia, PA 19103
ACRIN 6678 Image Transmittal Worksheet

Imaging Transmittal Worksheet
Captures Timepoint/Scan Date Information
MUST be completed, in its entirety, for ALL imaging submissions

Email to imagearchive@phila.acr.org
Or FAX to 215-923-1737
Kesha Smith, RT (R)(MR)(M)
Imaging Technologist
Phone: 215-940-8810
Fax: 215-923-1737
E-mail: ksmith@acr-arrs.org

Adam Opanowski, CNMT, RT (N)
Imaging Technologist
Phone: 215-940-8890
Fax: 215-923-1737
aopanowski@phila.acr.org