



ACRIN 6678
FDG-PET/CT Tumor Response
Protocol Deviation Form

ACRIN Study 6678 Case #
PLACE LABEL HERE

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

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

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]

- Inclusion/exclusion criteria not met at time of registration/randomization
- Imaging-related deviation *(complete Q1a)*
- Study activity performed prior to participant signing study consent form
- Participant received protocol imaging for opposite randomization group
- Required pregnancy test not performed prior to scan
- Required blood glucose test not performed prior to administration of FDG
- PET/CT scan not performed according to protocol specific intervals
- PET interpretation guidelines not followed
- Treating physician not blinded to the results of PET/CT completed post-chemo cycle 1
- Chemotherapy cycle commences prior to a required scan for that time point
- Chemotherapy regimen not administered per protocol
- Participant following other treatment preference
- Other, specify: _____ ^[2]

1a. Image Deviation: *(Select only one)*

i. PET Imaging Deviation ^[3]

- PET scan performed at a non-ACRIN qualified institution
- PET scan performed on a non-ACRIN qualified scanner
- PET scan performed on a different scanner from the Baseline PET Imaging
- PET Images lost or unavailable
- PET Scan not per protocol
- Other, specify: _____ ^[4]

ii. Volumetric CT Imaging Deviation ^[5]

- CT scan performed at a non-ACRIN qualified institution
- CT scan performed on a non-ACRIN qualified scanner
- CT Images lost or unavailable
- CT Scan Image quality inadequate for volumetric measurement
- Volumetric CT Scan not performed
- Other, specify: _____ ^[6]

iii. RECIST CT Imaging Deviation ^[7]

- CT images lost or unavailable
- CT scan Image quality inadequate for RECIST assessment
- RECIST CT Scan not performed
- Other, specify: _____ ^[8]



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2. Date the protocol deviation occurred: _____ - _____ - **20**_____ (mm-dd-yyyy) [9]

3. Date the protocol deviation was discovered: _____ - _____ - **20**_____ (mm-dd-yyyy) [10]

4. Describe the protocol deviation:

_____ [11]

_____ [12]

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

_____ [13]

_____ [14]

6. Timepoint this deviation applies to: (select only one) [15]

- Visit A1** (pre-chemo: within 14 days after registration)
- Visit A2 / B1** (pre-chemo: within 1-7 days before the start of chemo cycle 1)
- Visit A3 / B2** (post-chemo cycle 1: within 3 days before the start of chemo cycle 2)
- Visit B3** (post-chemo cycle 2: within 3 days before the start of chemo cycle 3)
- Other, specify: _____ [16]

_____ [17]
Person responsible for data (RA, study staff)

_____ - _____ - **20**_____ (mm-dd-yyyy)
Date Form Completed [18]

_____ [19]
Investigator Signature