RTOG 1106 (A3) Section 12: Data Collection

12.0 DATA COLLECTION

Data should be submitted to:

RTOG Headquarters*
1818 Market Street, Suite 1600
Philadelphia, PA 19103

***If a data form is available for web entry, it must be submitted electronically.**

Patients will be identified by initials only (first middle last); if there is no middle initial, a hyphen will be used (first-last). Last names with apostrophes will be identified by the first letter of the last name.

12.1 Summary of Data Submission (12/5/12)

Item	Due
Demographic Form **(A5)** Initial Evaluation Form **(I1)**	2 weeks after registration
Radiotherapy Form **(T1)** Complete Daily Treatment Record –copy of the RT treatment chart **(T5)**	Within 1 week of end of RT
Concurrent Treatment Form **(TF)**	1 week after the completion of concurrent treatment
Mid-Course PET/CT Form **(FS)**	Within 1 week of completing the mid-course PET/CT scan
Consolidation Treatment Form **(SF)**	1 week after the completion of consolidation treatment
Follow-up Form **(F1)**	At 1 month after the end of treatment, then every 3 months for the first year, every 6 months for years 2-3, then annually

The following forms will be submitted to ACRIN for each FDG-PET/CT scan completed:

Item	Due
FDG PET/CT Technical Assessment Form **(TA)**	Within 2 weeks of scan date
FDG PET/CT Imaging-Related Drug History **(TD)**	Within 2 weeks of scan date
FDG Administration Treatment Exposure Form **(EX)**	Within 2 weeks of scan date
Image Transmittal Worksheet **(ITW)**	Within 2 weeks of scan date*

The TA, TD, and EX forms can be submitted through the ACRIN data center (www.acrin.org).

* The Image Transmittal Worksheet (ITW) must be submitted along with the images for all follow-up CT's done within 2 years (see section 11.2.3), as well as for the baseline and during treatment FDG-PET/CT.

- 3 month follow-up
- 6 month follow-up
- 9 month follow-up
- 12 month follow-up
- 18 month follow-up
- 24 month follow-up

A completed, signed Image Transmittal Worksheet (ITW) MUST be submitted to ACRIN for each time-point. The Image Transmittal worksheet can be found on the ACRIN web site for this study under Protocol Summary Table at http://www.acrin.org/6697_protocol.aspx. The completed ITW can be faxed to (215) 923-1737.

12.2 Summary of Dosimetry Digital Data Submission (Submit to ITC; see Section 12.2.1) **(8/19/13)**

Item	**Due**
Preliminary Dosimetry Information (DD)	
Digital Data Submission – Treatment Planning Data submitted to ITC via SFTP account exported from treatment planning system. **Digital data must be submitted in DICOM format.**	
Arm 1: RT Planning Data • Primary CT1 dataset, GTV, CTV, PTV, and all critical normal structures • Contrast CT dataset, if used to aid in target delineation • PET1 (FDG) and PET2 (FDG) datasets (PET2 dataset should be submitted within 1 week of scan) • Digital RT Plan and RT Dose files	Within 1 week of start of RT
• RTOG 1106 Datasheet (available at http://atc.wustl.edu/protocols/rtog/1106/1106.html • Digital Data Submission Information Form **(DDSI)** – Submitted online (Form located on ATC web site, http://atc.wustl.edu/forms/DDSI/ddsi.html	Within 1 week of scan dates
Note: For F-MISO- PET/CT submissions, see Appendix V for instructions	
Arm 2: Initial Planning Data • Primary CT1 dataset, GTV, CTV, PTV, and all critical normal structures • Contrast CT dataset, if used to aid in target delineation • PET1 (FDG) dataset • JPG screen capture of CT1/PET1 fusion with transversal, sagittal, coronal view through the center of the target volume RTOG 1106 Datasheet (available at http://atc.wustl.edu/protocols/rtog/1106/1106.html • Digital Data Submission Information Form **(DDSI)** – Submitted online (Form located on ATC web site, http://atc.wustl.edu/forms/DDSI/ddsi.html)	Within 1 week of start of RT or, prior to start of RT if pre-treatment review is required **Note: For Pre-Treatment Review cases, Initial Planning Data must be submitted, reviewed, and approved prior to the start of initial RT. See Section 6.0 for further details**
Arm 2: Adaptive Planning Data Treatment Plan includes the following in DICOM format:	Within 1 week of start of Adaptive RT or, prior to start of Adaptive RT if pre-treatment review is required

- Primary CT1 dataset, GTV, CTV, PTV and all required critical normal structures
- Adaptive CT2 dataset
- Adaptive Contrast CT dataset, if used to aid in target delineation
- PET2 (FDG) dataset
- Digital RT Plan and RT Dose files (Adaptive only)
- JPG screen capture of CT1/PET2 fusion with transversal, sagittal, coronal view through the center of the target volume
- JPG screen capture of CT1/CT2 fusion with transversal, sagittal, coronal view through the center of the target volume
- ***Updated*** RTOG 1106 Datasheet (available at http://atc.wustl.edu/protocols/rtog/1106/1106.html
- the same form submitted for initial plan
- Digital Data Submission Information Form **(DDSI)** – Submitted online (Form located on ATC web site, http://atc.wustl.edu/forms/DDSI/ddsi.html)

Note: For Pre-Treatment Review cases, Adaptive Planning Data must be submitted, reviewed, and approved prior to the start of adaptive RT See Section 6.0 for further details.

Note: For F-MISO- PET/CT submissions, see Appendix V for instructions

NOTE: Sites must notify ITC via e-mail (itc@wustl.edu) after each digital data submission. The e-mail must include study and case numbers or, if the data is phantom, "Benchmark" or "other".

Final Dosimetry Information — Within 1 week of end of RT

Radiotherapy Form **(T1)**
Daily Treatment Record – copy of RT treatment chart **(T5)**
Modified digital patient data as required through consultation with Image-Guided Therapy QA Center

12.2.1 Digital Data Submission to ITC

Digital data submission may be accomplished using media or the Internet.
For network submission: The SFTP account assigned to the submitting institution by the ITC shall be used, and e-mail identifying the data set(s) being submitted shall be sent to:

itc@wustl.edu
Image-Guided Therapy Center (ITC)
4511 Forest Park, Suite 200
St. Louis, MO 63108
314-747-5415
FAX 314-747-5423

12.3 Summary of Form Data Submission for Sites with Patients Participating in FMISO-PET/CT Imaging

Note: **See Appendix V for details of FMISO-PET/CT imaging submission.**

12.3.1 General

All ACRIN data forms will be entered through ACRIN's Data Center. The web address is www.acrin.org.

12.3.2 Clinical Data Submission

- Upon successful registration to RTOG of participants consented to the FMISO-PET/CT, an ACRIN case-specific calendar will be generated. This calendar lists all forms and designated reports required by protocol along with form due dates at ACRIN's Data Management Center (DMC). The calendars are available 24 hours a day on the ACRIN web site and will be updated as the study proceeds to reflect data that have been received, due dates for queries about unclear data, deadlines for follow-up reports of adverse events, or changes in the protocol that change the data being collected or the timeframe. The research associate may use the calendar as a case management tool for data submission and follow-up scheduling. The investigative site is required to submit data according to protocol as detailed on each participant's ACRIN calendar.
- The user selects the link to the appropriate form and enters data directly into the web-based form. As information is entered into the web form application, various logic checks will be performed. These logic checks look for data that are missing, out of range, or in the wrong format (e.g. character data in a field requiring numeric responses). Such errors will be detected as soon as the user attempts to either submit the form or move to the next data element. The user will not be able to finalize form transmission to the DMC until all data entered pass these logic checks. Forms that are not completed in one sitting can still be submitted and completed at a later date. The form will remain available on the web until the "Complete Form" button is depressed.
- Once data entry of a form is complete, and the summary form is reviewed for completeness and accuracy, the investigator or the research staff presses the "Complete Form" button on the form summary screen and the data is transferred into the clinical database. No further direct revision of the submitted data is allowed after this point. E-mail confirmation of web data entry is automatically generated and sent to the site investigator or research associate listing all of the data generated and just submitted. Should a problem occur during transmission and the e-mail confirmation of data submission is not received, the investigator or research associate should contact the DMC for resolution of the submission.
- If technical problems prevent access to the Data Center web site, sites will be unable to enter data. The site RA or investigator should notify the DMC if a problem with the Data Center is encountered. All sites will be notified through an ACRIN broadcast message when access to the web data entry is unavailable and the estimated time when access will be restored.. The investigative site should wait until access is restored to submit data.

12.3.3 Data Security

The registration and data collection system has a built-in security feature that encrypts all data for transmission in both directions, preventing unauthorized access to confidential participant information. Access to the system is controlled by a sequence of identification codes and passwords.

12.3.4 Electronic Data Management

Data received from the web-based forms are electronically stamped with the date and time of receipt by the ACRIN server; the data are then entered into the database. A protocol-specific validation program is used to perform more extensive data checks for accuracy and completeness. Complementary validation programs are initiated at the Biostatistics and Data Management Center (BDMC) that are more comprehensive than those built into the web-based data entry screens. The BDMC will run thorough cross-form validations, frequency distributions to look for unexpected patterns in data, and other summaries needed for study monitoring. The validation program generates a log of errors which is managed by the DMC Data Manager (DM). The program is frequently updated to incorporate exceptions to rules so that subsequent validity checks minimize the time DMC spends resolving problems. All communication with the participating sites is handled by the DMC.

If missing or problematic data is detected, the DM sends an Additional Information Request (Z1 query letter) to the site RA or investigator specifying the problem and requesting clarification. The DM updates the participant's data submission calendar with the Z1 due date to notify the site RA or investigator of when a response is expected. The calendar will be updated upon receipt of the query response.

12.3.5 Missing and Delinquent Data Submission

In addition to providing the investigator a data collection calendar for each case, the DMC periodically prompts institutions for timely submission of data through the use of a Forms Due Report. This report lists data items (e.g. forms, reports, and images) that are delinquent. It is distributed at regular intervals via the electronic mail system to both the RA and the investigator at each site. In addition to prompting clinicians to submit overdue data, the Forms Due Report helps to reconcile the DMC's case file with that of the RA and/or investigator. Future Forms Due Reports may be sent on an as-needed basis in addition to past due reports. The site investigator or RA may use the Forms Due and Future Due Reports as a case management tool. At any time, sites may run their own Forms Due Reports using the Site Operations Tool on the ACRIN web site.

12.3.6 Data Quality Assurance

The Biostatistics Center (BC) at Brown University will maintain a study database at its site for monitoring data quality and for performing analyses. These data are drawn directly from the permanent database at the DMC. The transfer of data between the DMC and the BC have been validated through a series of checks consisting of roundtrip data verification in which data are sent back and forth to verify that the sent data are equivalent to the received data. These checks are repeated at random intervals during the course of a given study. Any discrepancies and other data quality issues will be referred to the DMC for resolution, since only the DMC can correct the data file. No changes to the data will be made at the BC.

Data will be monitored to assess compliance with the protocol and to look for unforeseen trends that may be indicative of procedural differences among clinical sites. If patterns are discovered in the data that appear to arise from causes specific to an institution, the DMC will contact the site to resolve the problem. The ACRIN Protocol Development and Regulatory Compliance (PDRC) Department will be involved in this process as needed. If the BDMC and PDRC cannot reconcile the problem with the site, it will be brought to the ACRIN Quality Assurance (QA) Committee for further discussion and resolution.