abbvie

ABT-888, M14-360
RADIATION THERAPY QUALITY ASSURANCE MANUAL

Version 1 | 13 December 2016

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OVERVIEW

All radiation therapy (RT) sites are to have RT facility approval and modality credentialing before the first subject is enrolled into M14-360 at site. This includes approval of the RT facility's capabilities for planning and treatment as well as its quality assurance (QA) procedures (facility approval) and its ability to deliver the study RT modality safely and accurately (credentialing). Institutions may be granted a waiver for modality credentialing based on participation in certain cooperative group run lung cancer trials. After approval/credentialing or acknowledgement of being granted a waiver, all RT sites are to submit each enrolled subject's treatment plan within 3 business days of starting RT treatment. The Quality Assurance Review Center (QARC) will centrally review the treatment plan(s) and provide the site with quick feedback for future cases.

The requirements for RT facility approval, modality credentialing and submission of subject treatment plans are outlined below.

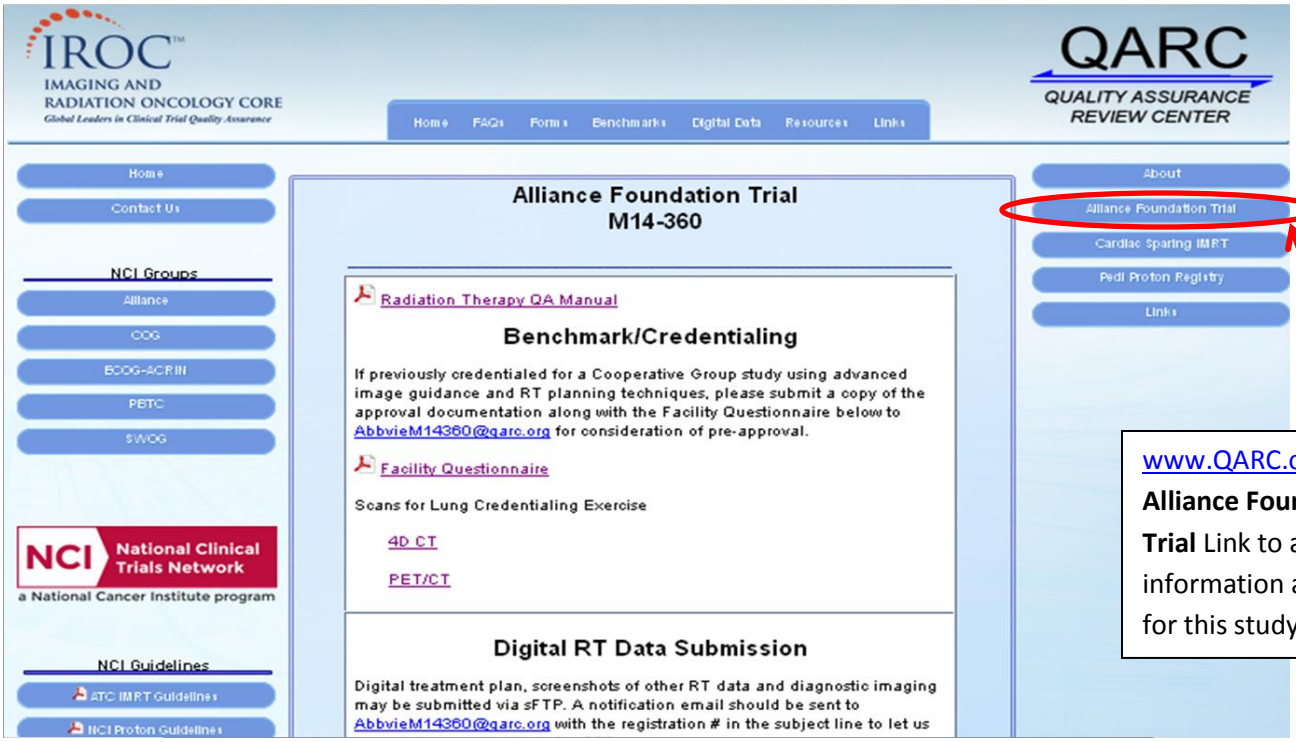
RADIATION THERAPY FACILITY APPROVAL & MODALITY CREDENTIALING

Overview

All sites delivering RT for subjects enrolled in this study must complete the following from the Quality Assurance Center:

- RT Facility Questionnaire
- Modality credentialing

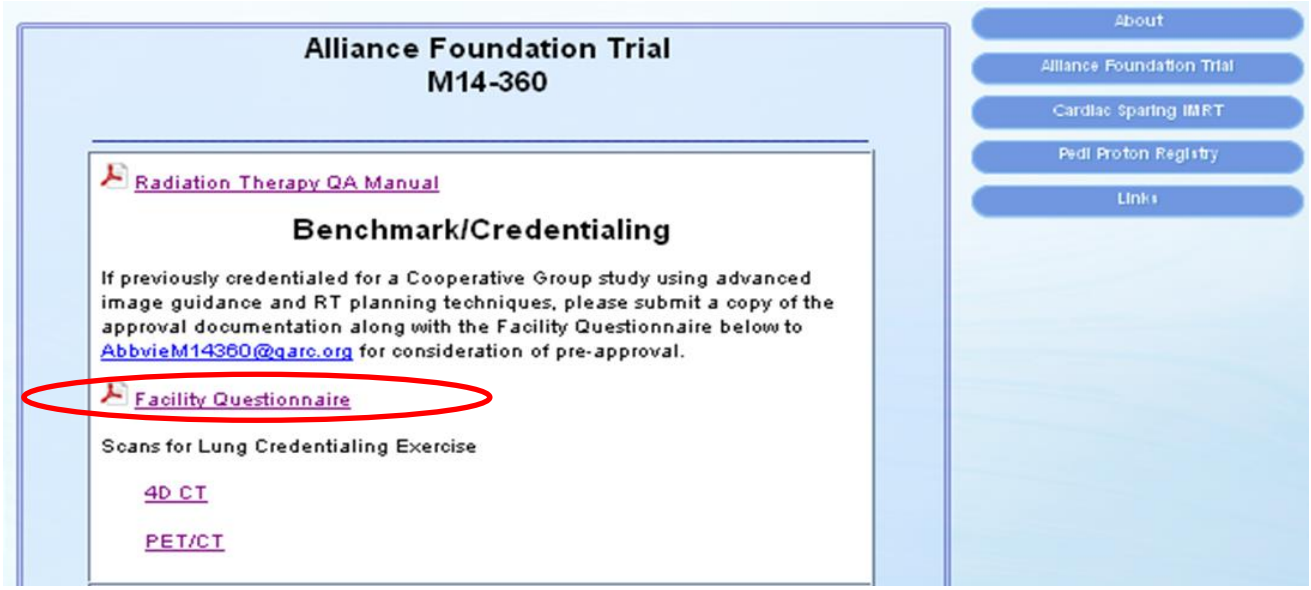
All information and forms for this trial are available on the QARC website at www.QARC.org under the Alliance Foundation Trial link.



www.QARC.org **Alliance Foundation Trial** Link to all information and forms for this study

RT Facility Questionnaire

Every site must fill out a Facility Questionnaire to provide information on personnel involved with the study, including contact information. The Facility Questionnaire is available on the QARC website at www.QARC.org under the Alliance Foundation Trial link.

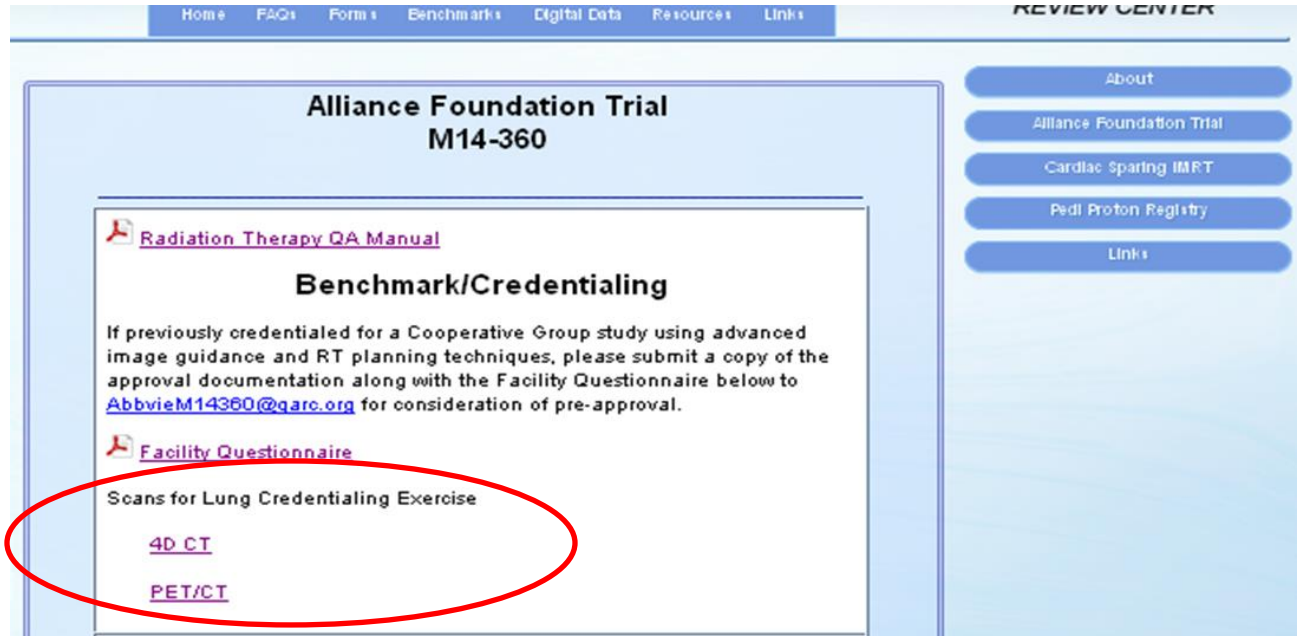


Modality Credentialing

To participate in the M14-360 study, facilities must demonstrate that they have the expertise and the tools required to treat subjects in compliance with the protocol.

Institutions that have participated in a cooperative group (EORTC, TROG, NCIC, RTOG, NRG, or Alliance) lung cancer trial utilizing respiratory motion assessment and management as well as daily image-guidance may be granted a waiver of the modality credentialing requirement for this study. Proof of participation in one or more of these studies is to be emailed to AbbvieM14360@QARC.org and the site's AbbVie monitor for assessment.

Sites not approved through the waiver process must complete modality credentialing, which consists of planning a benchmark case according to the M14-360 protocol guidelines and submitting the plan for review. The following instructions are provided for completing the benchmark process.



Methods:

QARC will provide a protocol compliant CT-Sim dataset of a patient to be used as a benchmark case. The images are in DICOM format and are to be downloaded from the QARC website, www.QARC.org. An unfused PET/CT dataset is included for aid in determining the extent of disease as well as a multi-phase 4DCT. Sites that do not use 4DCT in planning should follow the 4DCT instructions in the protocol for the purpose of this benchmark case.

The CT scan shall be entered into the RT facility's treatment planning system, and the treatment shall be planned as one would for a subject participating in M14-360. The target volumes, including gross disease and nodal volumes, shall be drawn on the CT scan by a radiation oncologist who will be treating subjects on this study.

The Dose Technique that you plan to use for subjects enrolled in the study will be used for the benchmark treatment plan. Sites that have been credentialed to treat with IMRT may also use 3D conformal planning techniques. Sites that have only been credentialed to treat with 3D conformal may not treat with IMRT without also successfully completing the IMRT credentialing.

Critical structure dose limits and dose uniformity requirements, as specified in the protocol, will apply to the benchmark case.

- **3D conformal planning:**
  If your facility will treat your subjects on this study using 3D conformal planning techniques, the benchmark case shall be planned and calculated using 3D techniques. Treatment fields shall be designed to satisfy the dose constraints in the protocol. The total plan dose shall be calculated and submitted.
- **IMRT planning:**
  If your facility will use IMRT for treating subjects on this study, the benchmark case shall be planned using IMRT. The total dose shall be calculated and submitted.
  An independent verification of the IMRT dosimetry must also be performed for this benchmark case. The independent verification may be done with portal dosimetry or other commercial device available for performing IMRT QA. It is usually required that the independent verification be a measurement and not just a secondary calculation of the monitor units. A summary of the results of the independent verification of the delivered dose is to be submitted with the benchmark treatment plan.

Summary of Steps:

- Complete the drawing of the target volumes as described in the protocol.
- Complete a treatment plan as described in the protocol for the planning technique you will be using. If you have been credentialed to treat with IMRT, you may also treat with 3D conformal techniques. If you have only been credentialed to treat with 3D conformal techniques, you may not treat with IMRT.
- Submit all treatment planning data listed below.

Institutions are required to submit this Lung Benchmark in digital format as DICOM RT. Digital data shall include planning CT, structure, dose, and plan files. The data is to be submitted electronically via QARC's secure File Transfer Portal (sFTP) server. Any items listed below that are not part of the digital plan may be included with the transmission of the digital data via sFTP or submitted separately as digital files to AbbvieM14360@QARC.org.

The following items are to be submitted for review:

1. Treatment Planning System Output

   - RT treatment plans including CT, structures, dose and plan files. These items are included in the digital plan. **Note that only the image series that was used for planning needs to be submitted. Please do not submit the entire 4DCT.**
   - Dose volume histograms (DVH) for the composite treatment plan for all target volumes and required organs at risk. When using IMRT, a DVH shall be submitted for a category of tissue called "unspecified tissue." This is defined as tissue contained within the skin, but which is not

otherwise identified by containment within any other structure. DVHs are included in the digital plan.

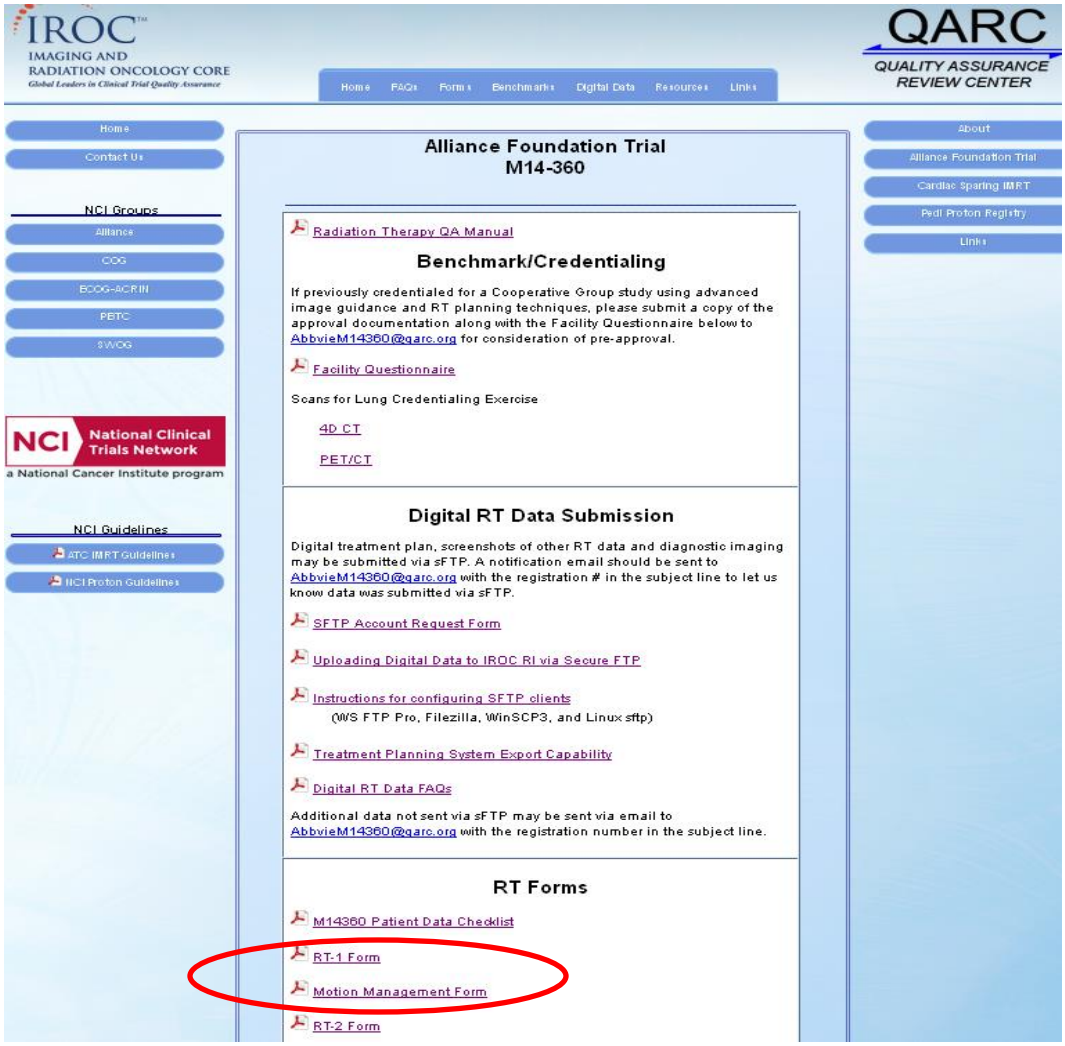
- Digitally reconstructed radiographs (DRR) for each treatment field, showing the collimator and beam aperture. Submission of DRRs is not required for IMRT.
- Treatment planning system summary report that includes the monitor unit calculations, beam parameters, calculation algorithm, and volume of interest dose statistics.

2. Supportive Data

   - Documentation of an independent check of the calculated dose if IMRT is used.

3. Forms (available at www.qarc.org under the Alliance Foundation Trial link)

   - RT-1 Dosimetry Summary Form
   - Motion Management Reporting Form



Benchmark Case Submissions:

The process for submission of the benchmark case is the same as the process for submission of subject treatment plans. Please see submission instructions found at the end of this manual under 'Submission of Digital Data'.

RADIATION THERAPY QUALITY ASSURANCE

Overview

Submission of all subject treatment plans as DICOM RT is required. Subject treatment plans are to be submitted electronically via QARC's secure FTP (sFTP) server within 3 business days of a subject starting RT treatment. The digital data must include treatment planning CT scan, structures, plan and dose files. Within one week of the completion of a subject's RT, sites must submit the additional data listed below for final assessment. Any items listed below that are not part of the digital plan may be included with the transmission of the digital data via sFTP or submitted separately as digital files to AbbvieM14360@QARC.org.

Each RT site must request a SFTP account prior to enrolling their first subject. See instructions below for how to submit data via SFTP.

RT Treatment Plan

The following items are to be submitted within 3 days of the start of radiotherapy for on-treatment review:

1. Treatment Planning System Output

    - RT treatment plans including CT, structures, dose and plan files. These items are included in the digital plan. **Note that only the image series that was used for planning needs to be submitted. Please do not submit the entire 4DCT.**
    - Dose volume histograms (DVH) for the composite treatment plan for all target volumes and required organs at risk. When using IMRT, a DVH shall be submitted for a category of tissue called "unspecified tissue." This is defined as tissue contained within the skin, but which is not otherwise identified by containment within any other structure. DVHs are included in the digital plan.
    - Digitally reconstructed radiographs (DRR) for each treatment field, showing the collimator and beam aperture. Submission of DRRs is not required for IMRT.
    - Treatment planning system summary report that includes the monitor unit calculations, beam parameters, calculation algorithm, and volume of interest dose statistics.

2. Supportive Data

    - Contrast enhanced CT or PET imaging used to define the target volume.
    - Prescription sheet for entire treatment.

3. Forms (available at www.qarc.org under the Alliance Foundation Trial link)

- RT-1 Dosimetry Summary Form
- Motion Management Reporting Form

Final Assessment (Process)

The following items are to be submitted within 1 week of each subject's completion of radiotherapy:

- RT-2 Radiotherapy Total Dose Record Form
- A copy of the subject's RT record including the prescription and the daily and cumulative doses to all required areas.
- Documentation showing any modifications from the original submission.

Questions regarding the dose calculations or documentation should be directed to the Protocol Dosimetrist at QARC:

- Phone: (401) 753-7600
- Email: AbbvieM14360@QARC.org

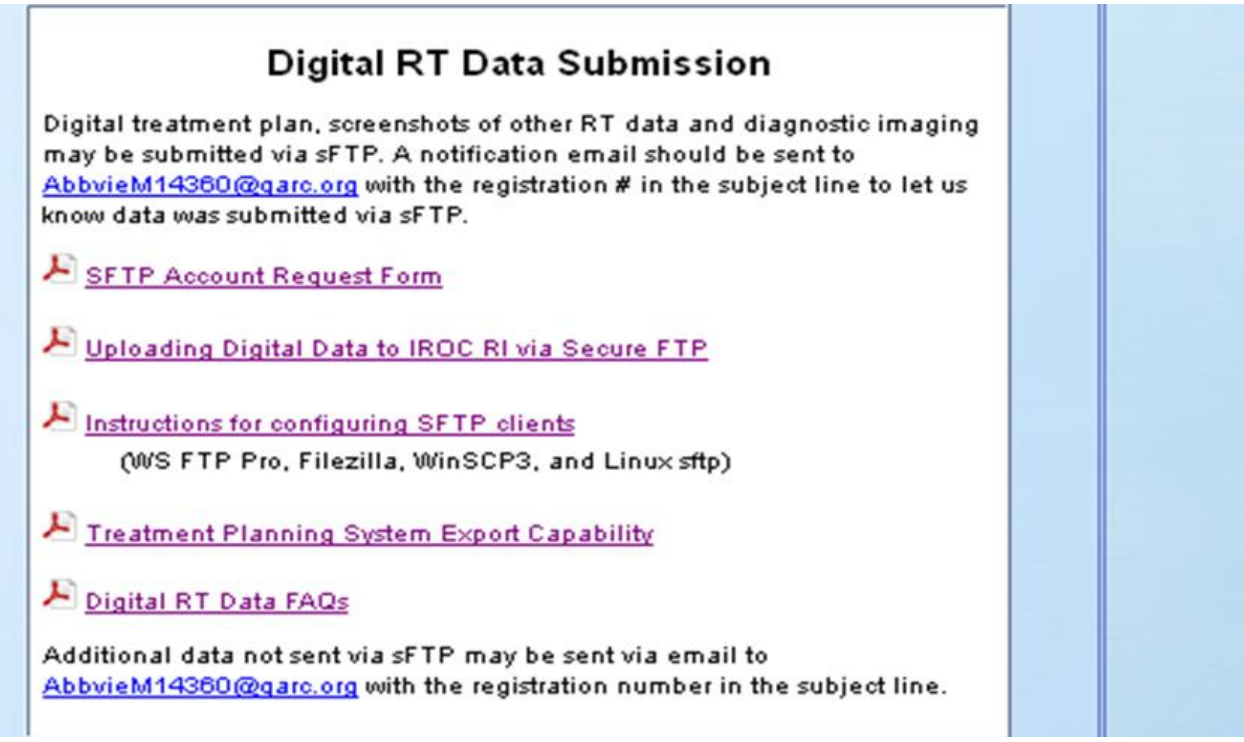
SUBMISSION OF DIGITAL DATA

Overview

Submission of digital data related to RT QA will be by SFTP. In order to submit data via SFTP to QARC, institutions must obtain an SFTP account for QARC and configure an SFTP client on a local computer. Instructions for obtaining an SFTP account and for configuring a variety of SFTP clients are on the QARC website at www.qarc.org under the Alliance Foundation Trial link.

Request a sFTP Account

1. Access www.qarc.org
2. Select Alliance Foundation Trial link
3. Select 'SFTP Account Request Form' in the Digital RT Data Submission section
4. Complete request form and submit to QARC (IROC RI) by emailing to AbbvieM14360@QARC.org.
5. Within 3 days of submission, QARC will provide an account username and temporary password for access to the SFTP server.



Digital RT Data Submission

Digital treatment plan, screenshots of other RT data and diagnostic imaging may be submitted via sFTP. A notification email should be sent to AbbvieM14360@qarc.org with the registration # in the subject line to let us know data was submitted via sFTP.

SFTP Account Request Form

Uploading Digital Data to IROC RI via Secure FTP

Instructions for configuring SFTP clients
(WS FTP Pro, Filezilla, WinSCP3, and Linux sftp)

Treatment Planning System Export Capability

Digital RT Data FAQs

Additional data not sent via sFTP may be sent via email to AbbvieM14360@qarc.org with the registration number in the subject line.

Configure a sFTP Client

The Quality Assurance Review Center has tested several SFTP client programs for submitting digital data to QARC. Procedures for configuring each of these programs to submit data to QARC are available on the QARC website, under the Alliance Foundation Trial link, labeled “Instructions for configuring SFTP clients.”

Submit Data

1. Connect to the QARC SFTP server (sftp.qarc.org).
2. Change to the "incoming" directory (cd incoming).
3. Create a new subdirectory within the incoming directory with the subject’s protocol registration/case number.
4. Send an email to AbbvieM14360@QARC.org to indicate that you have uploaded protocol data. Please identify the protocol, and registration/case number for the submission as well as your contact information. If you are uploading a benchmark submission, please indicate that in your email.

Contact QARC at AbbvieM14360@QARC.org if you are unable to access the SFTP server or are having problems uploading digital data.

For additional guidance, please reference the FAQs (frequently asked questions) for "Uploading Digital Data to QARC via Secure FTP" and for "Digital RT Data." FAQs may be found on the QARC website under the Alliance Foundation Trial link.