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THE SWOG
RADIATION THERAPY QUALITY ASSURANCE COMMITTEE

A. RADIATION THERAPY (RT) QUALITY ASSURANCE (QA)

One of the requisites of the National Cancer Institute (NCI) National Clinical Trials Network (NCTN) is that Network Groups must have a radiation therapy quality assurance (RT QA) program in place. SWOG has had a RT QA program in place since February 2003 when it arranged to have the Quality Assurance Review Center (QARC) provide RT QA services for all SWOG studies with radiation therapy components. In 2014, with the creation of the NCTN, RT QA services provided by QARC were moved under the Imaging and Radiation Oncology Core (IROC). The IROC grant supports four QA Centers providing radiation and diagnostic imaging quality assurance services. The four QA Center are IROC Rhode Island (formerly QARC), IROC Houston (formerly the Radiological Physics Center-RPC), IROC Ohio and IROC Philadelphia. IROC Rhode Island works closely with all of the IROC Centers, but especially IROC Houston and IROC Ohio which are providing other aspects of the overall QA program for SWOG. IROC works with SWOG to tailor its RT QA program based on the needs of each clinical trial and as new radiation modalities and technologies are adopted into clinical research. The components of this program are described below.

B. RADIATION THERAPY QA PROGRAM COMPONENTS

I. Protocol Development

The conduct of a quality multi-institutional trial relies substantially on the quality of the protocol document. QARC reviews the protocol to assure that the scientific question asked in the study can be achieved with the RT proposed. QARC ensures that the radiation section is consistent with all sections throughout the document. QARC helps Study Chairs write the radiation section in a clear, concise, and technically achievable manner to ensure the implementation of a uniform delivery of radiation across institutions. It is critical that protocols allowing technologies, such as Intensity Modulated Radiation Therapy (IMRT) or proton therapy, follow stringent guidelines directed by the NCI. QARC provides the appropriate language and list of materials to be submitted for QA documentation. QARC assists Study Chairs in writing guidelines that can be compatible with a wide variety of capabilities while maintaining a standard to ensure uniformity.

II. Site Participation, Qualification and Credentialing

Across the NCTN, IROC Houston provides site qualification and credentialing services. Radiation therapy facilities wanting to participate in NCTN cancer clinical trials led by SWOG or any of the Network Groups must agree to participate in IROC Houston's QA program. For site qualification, facilities must complete a facility questionnaire, found on the IROC Houston website (http://irochouston.mdanderson.org), and comply with annual OSLD Monitoring described below for all of their megavoltage therapy machines. Proton centers must comply with the National Cancer Institute (NCI) guidelines

(http://irochouston.mdanderson.org) for use of proton therapy in NCI-supported clinical trials prior to enrolling a participant.

In addition to site qualification requirements, many SWOG studies have protocol-specific credentialing requirements for participation. These requirements may include phantom irradiations, benchmarks, or questionnaires specific to the technology being used or mode of treatment. All protocol-specific credentialing requirements will be outlined in the protocol and can also be found in the IROC Houston website (http://irochouston.mdanderson.org).

III. Protocol Specific Radiation Requirements (PSR)

As noted, certain protocols may have site credentialing requirements that will be checked before a site is able to participate. For these trials, IROC has worked with the Clinical Trial Support Unit (CTSU) to streamline the checking of credentials to ensure only credentialed sites are participating. Systems have been built to share the IROC Houston credentialing information with the CTSU. A simple explanation of the process is that enrolling sites are able to associate the RT facility or multiple facilities they intend to use for participants on a NCTN trial using the Provider Association application on the CTSU website. The RT facility completes the Credentialing Status Inquiry form on IROC Houston's website to indicate their intended participation in a specific trial. When the enrolling site registers a new participant they enter the RT Facility (RTF) # where the participant will receive radiation therapy and the system verifies that appropriate credentials are met. More information regarding credentialing and registration requirements is available in protocols.

IV. Data Management and Case Evaluation

Data Acquisition

Once a protocol is activated and as participants are enrolled, IROC RI is notified by the CTSU of each enrollment. The participant is entered into the QARC database and the expected RT date is determined. QARC has adopted a pro-active approach to data collection. At the time each participant is due to begin radiotherapy, a notice is sent to the Clinical Research Associate (CRA) as a reminder that data should be submitted for the Rapid Review (required by protocol) or at the completion of treatment. Data that are not received will be requested through an interim report to the CRA and the responsible radiation oncologist at each institution.

Data required for the RT QA review will be outlined in each protocol. These data are submitted to IROC RI electronically. TRIAD is the method the NCTN has adopted for transmission of DICOM, DICOM RT and Non-DICOM files to IROC QA Centers. Information about TRIAD and how to implement it at your institution is available at: https://triadinstall.acr.org/triadclient/

Case Evaluations

All participants entered on SWOG studies with RT components undergo an evaluation to determine whether or not the participant's treatment is in accordance with the protocol guidelines. Some studies require an early review performed prior to or early in the participant's radiation treatment. This early interventional review is known as a Rapid Review. Studies requiring Rapid Review will also include a Final Review.

Rapid Review

The Rapid Review is an important function that IROC RI performs for SWOG. This review may be conducted within the first few days of the initiation of therapy or may be required prior to the participant beginning radiation treatment. Data including the staging information, diagnostic imaging, the treatment plans including target volumes and dosimetry arrive at IROC RI within the time specified by the protocol guidelines. These are assessed by the CRA at IROC RI to determine that all of the necessary information is included. The dosimetry staff at IROC RI reviews the treatment plan to ensure that it meets the protocol requirements. IROC RI Radiation Oncologists will perform a clinical review of the material to ensure that the treatment volumes and treatment plan meet the protocol requirements. When the submitted data meet the protocol requirements, an email is sent to the treating physician to either inform them that the planned treatment is according to protocol or state that the planned treatment does not meet the protocol requirements and what modifications would be needed for compliance. A second review while the participant is still under treatment may be required to ensure that the plan has been modified appropriately.

The Rapid Review data will be reviewed by a radiation oncologist and a medical physicist or dosimetrist within 48 hours of receipt at IROC RI. An evaluation will include, but not necessarily be limited to, the following:

- Review of the treatment volumes
- Review of the treatment planning and/or Diagnostic Imaging Data
- Review of the computed treatment plans as specified in the protocol, including prescription target dose and doses to organs at risk (OAR)

If there is an indication suggestion of protocol non-compliance either variation acceptable (minor) or deviation unacceptable (major) IROC RI will email the radiation oncologist at the participating institution.

The aim of the Rapid Review is to ensure that all participants are treated according to the protocol guidelines in a uniform manner to validate protocol analysis.

Final Review

Once the participant has completed treatment, summary data of the complete course is submitted to IROC RI. These data include copies of the treatment chart, treatment plans, isodoses and dose calculations for subsequent volumes treated after the initial review, e.g., boosts. The complete course of therapy is reviewed by IROC RI's dosimetry staff. The fraction dose, the total dose, number of fractions, elapsed time, patient position, modality and specified doses for uniformity or normal tissue concerns are compared to the requirements of the protocol.

The IROC RI dosimetrist reviewing the case determines if there have been any changes in the participant's treatment after an approval had been determined in the rapid review. If there have been any changes, or if the data were not submitted timely for the rapid review, or if the protocol did not require a rapid review as is the case in trials with short course RT, the target volumes as well as the dosimetry are reviewed in this final review. The Final Review verifies that the prescribed treatment was carried out to completion and details of the treatment compliance to the protocol requirements are evaluated and captured in the IROC RI database. Upon completion, a final summary is sent to the responsible radiation oncologist detailing the evaluation of their participant. A copy of this summary is sent to the Primary Study Chair and the RT Study Chair.

Participation of the RT Study Chair(s)

The responsible Study Chair(s) is able to participate in both the rapid review and the final review. This can be arranged in a number of ways with IROC RI. On occasion the Study Chair may choose to do the rapid reviews, but it is much more common that they participate in final reviews. A VPN account for access to the IROC RI database is established and the Study chair is able to log in and review cases assigned to them. Alternatively, sessions can be established with the CRA and dosimetry staff at IROC RI for the Study Chair(s) to participate in a review session either remotely with a web conference or on-stie at IROC RI.

Data Transfer/Institutional Performance

Details of the RT delivered to each protocol participant and the agreement of the treatment to the protocol requirements are stored in the IROC RI database. These treatment data are transferred to SWOG for use in the study analysis. Additionally, data to determine an institution's compliance with the data submission guidelines and the protocol requirements are used by SWOG to assess institutional performance.