Imaging and Radiation Oncology Core Cooperative: QA Center Organization and Core Services

David Followill, Ph.D.
AAPM Summer Meeting
Austin, TX
July 22, 2014
Clinical Trial Groups

Current
RTOG
NSABP
GOG
NCCTG
CALGB
ACOSOG
ECOG
ACRIN
SWOG
COG

March 1, 2014
NRG Oncology
Alliance
ECOG/ACRIN
SWOG
COG
IROC’s Definition
Who Are WE?

The Imaging and Radiation Oncology Core Cooperative better known as IROC:

- Is a New Clinical Trial Quality Assurance Organization comprised of 6 QA Centers with multiple PIs. Began operation on March 1, 2014

- IROC RT and Imaging Centers have an extensive and impressive amount of experience, knowledge and infrastructure to aid in the improvement of clinical outcomes for cancer patents.
IROC’s Mission

Provide integrated radiation oncology and diagnostic imaging quality control programs in support of the NCI’s NCTN Network thereby assuring high quality data for clinical trials designed to improve the clinical outcomes for cancer patients worldwide.
IROC Principal Investigators

David S. Followill, PhD, IROC Co-director
and principal investigator for radiation oncology
and chief of outreach physics in the Department of
Radiation Physics at the University of Texas MD
Anderson Cancer Center in Houston

Michael V. Knopp, MD, PhD, IROC Co-director
and principal investigator for imaging
and the director of the Wright Center of Innovation in
Biomedical Imaging at Ohio State University in
Columbus, Ohio
**ACR IROC Grant**
Co-Directors: D. Followill, Houston (RT) and M.V. Knopp, Ohio (Imaging)
ACR rep: Steve king
Sub-awards to:

- **IROC Ohio**
  PI: M.V. Knopp

- **IROC Houston**
  PI: D. Followill

- **IROC Rhode Island**
  PI: T.J. FitzGerald

- **IROC Philadelphia (RT)**
  PI: J. Galvin

- **IROC Philadelphia (Imaging)**
  PI: M. Rosen

- **IROC St. Louis**
  PI: J. Michalski
IROC's NCTN RT Core Services

Principal supervisors of a core service

Site Qualification
Followill/Galvin

Trial Design Support
Galvin/Fitzgerald

Credentialing
Molineu/Xiao

Data (Pre-rev.) Mgmt
Straube/Ulin

Case Review
Leif/O'Meara/Laurie

Data (Post-rev.) Mgmt
Laurie/O'Meara

Houston QA Center

All IROC QA Centers

Houston-Phil. (RT) QA Centers

Phi (RT), Rhode Is., St Louis QA Centers

Phi (RT), Rhode Is., Houston QA Centers

Phi (RT), Rhode Is.

NCTN Participating Sites

IROC
IMAGING AND RADIATION ONCOLOGY CORE

Global Leaders in Clinical Trial Quality Assurance
IROC’s Five General Core Services

1. **Site Qualification** *(Houston)*
   (FQs, ongoing QA (OSLD, visits), proton approval, resources)

2. **Trial Design Support/Assistance** *(All IROC QA Ctrs)*
   (protocol review, templates, help desk, key contact QA centers)

3. **Credentialing** *(Houston, Philly (RT))*
   (tiered system to minimize institution effort)

4. **Data Management** *(Houston, Philly(RT), Rhode Is.)*
   (pre-review, use of TRIAD, post-review for analysis)

5. **Case Review** *(Houston, Philly(RT), Rhode Is.)*
   (Pre-, On-, Post-Treatment, facilitate review logistics for clinical reviews)
## RT Credentialing Requirements

<table>
<thead>
<tr>
<th>Facility Questionnaire</th>
<th>X</th>
<th>X</th>
<th>X</th>
<th>The IROC Houston electronic facility questionnaire (FQ) should be completed or updated with the most recent information about your institution. To access this FQ, email <a href="mailto:irochouston@mdanderson.org">irochouston@mdanderson.org</a> to receive your FQ link.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Credentialing Status Inquiry Form</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>To determine whether your institution needs to complete any further credentialing requirements, please complete the “Credentialing Status Inquiry Form” found under credentialing on the IROC Houston QA Center website (<a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a>)</td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Benchmark Cases</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Phantom Irradiation</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>A liver phantom study provided by the IROC Houston QA Center must be successfully completed. Instructions for requesting and irradiating the phantom are found on the IROC Houston web site (<a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a>). Note that only the most sophisticated technique needs to be credentialed, e.g., if credentialed for IMRT, 3DCRT may be used. VMAT, Tomotherapy, Cyberknife and proton treatment delivery modalities must be credentialed individually.</td>
</tr>
<tr>
<td>IGRT Verification Study</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>The institution must submit a sample of verification images showing their ability to reproducibly register daily IGRT information with a planning CT dataset (i.e., the GTV falls within the CT simulation defined PTV). The patient (“as if patient”) used for this study must have a target (or mock target) in the liver. The information submitted must include 2 IGRT datasets (from 2 treatment fractions) for a single patient and must employ the method(s) that will be used for respiratory control for patients entered from a particular institution (e.g. abdominal compression, breath hold, etc...). This information with a spreadsheet (the spreadsheet is available on the IROC Houston web site, <a href="http://irochouston.mdanderson.org">http://irochouston.mdanderson.org</a></td>
</tr>
<tr>
<td>Pre-Treatment Review</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>The first patient to be enrolled from each institution will be planned per NRG-GI001 specifications and submitted via TRIAD for evaluation by the IROC Houston QA Center and the trial PI or designee. Feedback will be given to the institution within 3 business days regarding any concerns prior to the patient being treated. Any required treatment plan modifications must be resubmitted for evaluation prior to treatment.</td>
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</tbody>
</table>

### Knowledge Assessment

- **SBRT**
- **IMRT**
- **Proton**

### Benchmark Cases

- **SBRT**
- **IMRT**
- **Proton**

### Phantom Irradiation

- **SBRT**
- **IMRT**
- **Proton**

### IGRT Verification Study

- **SBRT**
- **IMRT**
- **Proton**

### Pre-Treatment Review

- **SBRT**
- **IMRT**
- **Proton**

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**Credentialing Notification Issued to:**

IROC Houston QA Center will notify the institution and NRG Headquarters that all desired credentialing requirements have been met.
# IROC QA Centers Key Support
*(IROC Support Contacts for NCTN Groups)*

<table>
<thead>
<tr>
<th>NCTN GROUP</th>
<th>RADIATION ONCOLOGY</th>
<th>IMAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alliance</td>
<td>Rhode Island</td>
<td>Ohio</td>
</tr>
<tr>
<td>COG</td>
<td>Rhode Island</td>
<td>Rhode Island</td>
</tr>
<tr>
<td>ECON-ACRIN</td>
<td>Rhode Island</td>
<td>Philadelphia (I)</td>
</tr>
<tr>
<td>NRG Oncology</td>
<td>Philadelphia (RT)</td>
<td>Philadelphia (I)</td>
</tr>
<tr>
<td>SWOG</td>
<td>Rhode Island</td>
<td>Ohio</td>
</tr>
</tbody>
</table>
Data Transfer

2012

Inst

QARC
ITC
Study Group
OSU
ACR
ACRIN

2014-2015

Inst

RAVE
CRF
RT&I data
OSU
ACR
QARC
ACRIN

IROC Cloud

2017

Inst

CRF
CRF & DICOM

RAVE

NCTN DICOM (RT) Archive

Study Group

Philly
Ohio
Columbus
TRIAD

What is TRIAD

TRIAD™ is the American College of Radiology’s (ACR’s) image and data exchange platform. TRIAD is a standards based open architecture platform that supports HIPAA security rules relevant to Clinical Trials. It automatically de-identifies the DICOM headers and cleans the PHI from the DICOM images before submission via the internet. Access to the application is role-based and controlled by username and password.
Accessing TRIAD

- Integrated with CTSU log in using CTEP-IAM username and password
- Any staff who will be submitting RT digital data MUST be listed on the site roster as TRIAD SITE USER
- The Lead RA must update their roster with the staff members that need to submit via TRIAD on the CTSU website
- NON- RTOG sites need to update their rosters directly through the CTSU helpdesk
- After March 1\textsuperscript{st} RT data for all NSABP, GOG and RTOG (NRG) trials will be submitted via TRIAD
Where to find information on TRIAD
(www.irocqa.org)
Summary

• The NCI NCTN Reorganization is how IROC started.
• IROC RT QA centers have decades of experience, knowledge and infrastructure.
• Protocol review as early as possible is critical to establishing appropriate QA procedures.
• Patient case reviews require IROC and Groups to work together.
• RT and Imaging are working closely together
• Be Patient, this is new to us as well!
Thank You

Questions