IROC
Imaging and Radiation Oncology
Quality Assurance for the NCTN

Fran Laurie
IROC Rhode Island
May 11, 2017
Presentation Objectives

- What is IROC
- Understand IROC’s organization
- Learn about the services IROC provides to the NCTN
- How/When to interact with IROC
- Why is QA important
What is IROC?
Introducing A New Organizational Structure
NCI Clinical Trials Network

CTAC Clinical Trials Strategic Planning Subcommittee

NCI Disease/Imaging Steering Committees: Evaluation/Prioritization of Trials

Administrative Support Services
- NCI Central IRB

Network Research Support Services
- Network Imaging and RT Core Services
- Network Integrated Translational Components
- Tumor Banks

NCI DEA Review

4 Adult and 1 Pediatric U.S. Network Groups

Canadian Network
- Adult Group #1: Ops & Stats
- Adult Group #2: Ops & Stats

Network Lead Academic Participating Sites
- CCOPS & MB-CCOPs

Other Academic Centers
- Community Practices
- International Members

CTSU

Central Access to NCI Clinical Trials (Cancer Trials Support Unit)

Dark blue boxes signify NCI DEA reviewed, grant-funded components under this RFA

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

IMAGING AND RADIATION ONCOLOGY CORE
Global Leaders in Clinical Trial Quality Assurance
IROC’s Structure

American College of Radiology Clinical Research Center in Philadelphia is the Grantee for the IROC Grant

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: Y. Xiao

- IROC Philadelphia (Imaging)
  PI: M. Rosen

- IROC St. Louis
  PI: J. Michalski

IROC Executive Committee
Co-Directors: D. Followill, Houston (RT) and M.V. Knopp, Ohio (Imaging)
IROC Admin: Rosen/O’Meara/Laurie
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’s Core Services

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

2. Trial Design Support/Assistance
   (Key contact QA centers, protocol review, templates)

3. Credentialing
   (Tiered system to minimize institution effort)

4. Data Management
   (Data collection, pre-review, post-review for analysis)

5. Case Review
   (Pre-, on-, post-treatment reviews, facilitate review logistics)
# Key Contact QA Centers

<table>
<thead>
<tr>
<th>NCTN Group</th>
<th>Radiation Oncology</th>
<th>Imaging</th>
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<tbody>
<tr>
<td>Alliance</td>
<td>Rhode Island</td>
<td>Ohio</td>
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IROC Houston is the primary contact center for all RT credentialing activities and questions.

IROC Houston maintains the database for radiation and imaging facilities and provides this information to CTEP for the IROC Roster.
Site Qualification and Credentialing

- Site Qualification requirements must be completed for sites to be eligible to participate.
  - Enrollment to protocols with RT components requires that the treating RT facilities participate with the IROC Houston monitoring program.

- Credentialing requirements may be protocol specific or may be modality/technique specific.
  - IROC is working to harmonize these requirements across the NCTN Groups to eliminate redundant requirements.
Trial Design Support/Assistance

- Review new protocols and amendments
- Ensure that the RT and Imaging guidelines are technically achievable, clearly written and in agreement with NCI guidelines
- Check that QA and data submission requirements are current and appropriate
Data Management

- Data collection
- Data management
- Case evaluation
- Feedback to participating sites
- Submit review data to Statistical Center for study analysis
- Report performance data to IPEC
- Data archiving
Case Review

- **Diagnostic Imaging Central Reviews**
  - Confirm eligibility and staging
  - Confirm response
  - Confirm progression/relapse
  - Correlate patterns of failure
  - Can be performed in real-time to direct patient treatment or retrospective to confirm local patient management and reporting
  - Can be performed on-site or remotely using secure VPN connections

- **RT Reviews**
  - Interventional reviews (pre-treatment or early on-treatment) to assure that patient’s treatment plan is per protocol requirements. Possible to modify planning to protocol compliance
  - Post treatment reviews performed to confirm patient’s treatment was delivered per protocol. RT details from this review are transferred for protocol analysis.
### Diagnostic Comments

Note: Keep Event and Study Name Lengths within guidelines to ensure proper fit in report.

<table>
<thead>
<tr>
<th>Event</th>
<th>Order</th>
<th>Event Date</th>
<th>Interval Comments</th>
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<td>CT-3</td>
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**Study**
- Chest CT
  - Date: 01/14/2015
  - Order: 10
  - N/A: No
  - Study Date Rev\#d: No
  - Image Type: DICOM
  - Diff: 1
  - Comments: None

**Ev**
- Event: C3610 Pre-Study
- Order: 10
- Event Date: 01/14/2015
- Interval Comments: None

**Image**
- 3D rendering of a chest CT scan.
## Research Resource – Adults

<table>
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<tr>
<th>Committee</th>
<th>#Protocols</th>
<th>#Patients</th>
<th>DICOM Diagnostic Studies</th>
<th>DICOM RT Treatment Plans</th>
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## Research Resource – Pediatrics

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TRIAD

- Developed by the American College of Radiology (ACR)
- Customized for use with NCTN trials and integrated with Rave
- Sophisticated anonymization ability to de-identify PHI in DICOM
- Is being phased in across all NCTN Groups to transfer Diagnostic Imaging and Digital Radiotherapy Data. First COG Trial identified – ANBL1531.
TRIAD

TRIAD (Transfer of Images and Data) is a Web-based application that provides secure, efficient, and robust transmission of medical images and related electronic data. Developed and maintained by the American College of Radiology (ACR) with a focus on user-friendliness, TRIAD supports the exchange of electronic images and data for the multi-center clinical trials and other clinical research projects. Also, TRIAD has been accepted for use by the ACR's accreditation programs and National Radiology Data Registry.

A new TRIAD website was recently launched. Visit http://triadhelp.acr.org to learn more about how this tool supports imaging and radiation quality assurance for the NCI National Clinical Trials Network.

Quick Links to TRIAD Resources

TRIAD Fact Sheet
CTEP-IAM Account Registration Link
TRIAD Installation and User Guide

IMPORTANT Message for TRIAD users:

In mid-March 2017, a new version of the ACR TRIAD software v4.9 will be released. This version of the software will require the following prerequisites:

- Microsoft .NET Framework 4.5.2 or later
- Microsoft Visual C++ 2010 Redistributable (x64) (meets exactly)
- Microsoft Visual C++ 2012 Redistributable (x64) (meets exactly)

*Note: Other versions of Visual C++ can be on the workstation. However, Visual C++ 2010 and Visual C++ 2012 must be on the workstation in order for TRIAD to run.

Prior to the release date, we strongly suggest checking your system to make sure that these required components are installed. All users currently running TRIAD will be prompted to upgrade to the latest release version 4.9.

Administrative privileges are required to install or upgrade these components.

Questions?

Contact TRIAD-Support:
Conclusion: Current reports suggest protocol-compliant RT tends to decrease failure rates & increase overall survival, and likely contributes to the ability of the collected data to answer the central trial question.


This paper sets the standard for the clinical trial research testing the value of RT, and demonstrates that the time, money, effort of doing an extensive RT QA review is mandatory if the overall study results are to be believed. Also it shows the importance of physician education so to improve performance and decrease protocol deviations, with improved protocol compliance.
Z0011 was an important clinical trial that demonstrated limited axillary surgery was efficacious and tangential RT was appropriate in patients with limited nodal involvement. The protocol included guidelines for the tangential adjuvant RT but there was no central review of the dose and volume during the trial. After the primary paper was published, efforts were made by Reshma Jagsi and QARC colleagues to review the RT information.

These data demonstrated a number of study patients were treated with regional RT and some patients received no RT at all. This further complicates strategies for future studies as the role of limited regional RT in breast cancer care remains ambiguous. If imaging and RT information had been acquired on-study, including relapse imaging, defining axillary volume for current NCTN studies would be based on more secure evidence.
Tirapazamine, Cisplatin, and Radiation Versus Cisplatin and Radiation for Advanced Squamous Cell Carcinoma of the Head and Neck (TROG 02.02, HeadSTART): A Phase III Trial of the Trans-Tasman Radiation Oncology Group

Objectives

• To analyze the impact of protocol non-compliance and poor radiotherapy quality on the outcome of treatment in patients with loco-regionally advanced squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx or larynx
• International phase III registration trial TROG 02.02 “HeadSTART” designed to test the efficacy of adding the hypoxic cell cytotoxin tirapazamine (TPZ) to cisplatin-based chemoradiotherapy
• 853 eligible patients from 81 sites in 16 countries enrolled Sep 02 - Apr 05
• Median potential FU 2.3 yrs (range 20 days -3.7 yrs)

Results

• In contrast to the randomized Phase II trial TROG 02.02 showed essentially no differences between the arms in any of the key endpoints: Overall survival, Disease-free survival and Freedom from locoregional failure
• Major impact of radiotherapy quality which compromised interpretation of the results
Critical impact of radiotherapy protocol compliance in the treatment of advanced HNSCC: Results from TROG 02.02

Overall survival by deviation status

Time to LRF by deviation status

IROC Contact Information

- RT Credentialing questions IROC-Credentialing@mdanderson.org
- NRG
  - Oncology RT questions IROCPHILA-RT@acr.org
  - Diagnostic Imaging questions IROCPHILA-DI@acr.org
- Alliance
  - Diagnostic Imaging questions help@irocohio.org
  - RT questions IROCRI@QARC.org & Additional Information at: WWW.QARC.org
- ECOG-ACRIN
  - Diagnostic Imaging questions IROCPHILA-DI@acr.org
  - RT questions IROCRI@QARC.org
- SWOG
  - Diagnostic Imaging questions help@irocohio.org
  - RT questions IROCRI@QARC.org

TRIAD Support for issues installing and utilizing the TRIAD Software
  T: 703.390.9858 or,
  E: Triad-Support@acr.org