IROC
Imaging and Radiation Oncology
Quality Assurance for the NCTN

Fran Laurie
IROC Rhode Island
November 6, 2015
Presentation Objectives

- What is IROC
- Understand IROC’s organization and services
- How to interact with IROC
- How are cases reviewed
- Why is QA important
- TRIAD
Introducing A New Organizational Structure
NCI Clinical Trials Network

CTAC Clinical Trials Strategic Planning Subcommittee

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

Network Research Support Services

Network Imaging and RT Core Services

Network Integrated translational Components

Tumor Banks

Administrative Support Services

NCI Central IRB

4 Adult and 1 Pediatric U.S. Network Groups

Canadian Network

Adult Group #1

COG Ops & Stats

Adult Group #2

Adult Group #3

Adult Group #4

NCI Clinical Trials Network

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

Administered by NCI

ALLIANCE
FOR CLINICAL TRIALS IN ONCOLOGY

IROC
IMAGING AND RADIATION ONCOLOGY CORE
Global Leaders in Clinical Trial Quality Assurance
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 St. Louis
PI: J. Michalski

IROC Philadelphia (RT)
PI: J. Galvin

IROC Philadelphia (Imaging)
PI: M. Rosen

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

IROC™
IMAGING AND RADIATION ONCOLOGY CORE
Global Leaders in Clinical Trial Quality. Assurance
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>
</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>ECOG-ACRIN</td>
<td>Rhode Island</td>
<td>Philadelphia (DI)</td>
</tr>
<tr>
<td>NRG Oncology</td>
<td>Philadelphia (RT)</td>
<td>Philadelphia (DI)</td>
</tr>
<tr>
<td>SWOG</td>
<td>Rhode Island</td>
<td>Ohio</td>
</tr>
</tbody>
</table>

IROC Houston is the key contact center for all RT credentialing questions.
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.
Credentialing

A011202 --- A RANDOMIZED PHASE III TRIAL EVALUATING THE ROLE OF AXILLARY LYMPH NODE DISSECTION IN BREAST CANCER PATIENTS (cT1-3 N1) WHO HAVE POSITIVE SENTINEL LYMPH NODE DISEASE AFTER NEOADJUVANT CHEMOTHERAPY

A021101 --- NEOADJUVANT FOLFIRINOX AND CHEMORADIATION FOLLOWED BY DEFINITIVE SURGERY AND POSTOPERATIVE GEMCITABINE FOR PATIENTS WITH BORDERLINE RESECTABLE PANCREATIC ADENOCARCINOMA: AN INTERGROUP SINGLE-ARM PILOT STUDY -- Closed(1.5.2015)

A021302 --- IMPACT OF EARLY FDG-PET DIRECTED INTERVENTION ON PREOPERATIVE THERAPY FOR LOCALLY ADVANCED GASTRIC CANCER: A RANDOM ASSIGNMENT PHASE II STUDY

A071102 --- A PHASE II/III RANDOMIZED TRIAL OF VELIPARIB OR PLACEBO IN COMBINATION WITH ADJUVANT TEMOZOLOMIDE IN NEWLY DIAGNOSED GLIOBLASTOMA WITH MGMT PROMOTER HYPERMETHYLATION

http://rpc.mdanderson.org/RPC/home.htm
6.3 Imaging credentialing and submission

6.3.1 Institutional credentialing procedures for imaging

Prior to the enrollment of patients, institutions that have not previously been credentialed for any other Alliance trials must be credentialed to participate in the trial by the Alliance Imaging Core Laboratory (ICL) at The Ohio State University Medical Center. If the site has previously been credentialed by the ICL to participate in imaging studies, the ICL will provide a brief A031201 protocol refresher prior to the site enrolling patients for this trial.

Institutions should contact the Alliance ICL directly to complete credentialing or a refresher for A031201. See Section 6.3.3 for the Alliance ICL contact information.

6.3.2 Individual training for bone scan interpretation

Bone imaging will be interpreted in accordance with modified PCWG2 progression criteria, as described in Section 13. For the purposes of determining progression, the following individuals will perform bone imaging interpretation (in order of preference), and will undergo training in correctly identifying bone scan progression using modified PCWG2 criteria. These individuals are:

- A reference radiologist designated by the participating institution or;
- The local PI or designated local investigator or;
- In the absence of either a reference radiologist or local investigator, the Alliance Imaging Core will perform the interpretation.
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
Alliance for Clinical Trials in Oncology

Checklists

- AG11202 Checklist
- AG21302 Checklist
- CALGB 30610 Checklist
- CALGB 31102 Checklist
- CALGB 50901 Checklist
- CALGB 70906 Checklist
- CALGB 80903 Checklist
- N1048 Checklist
- Z11102 Checklist

Alliance Protocol Data Manager
IROC Rhode Island
Building B, Suite 201
640 George Washington Highway
Lincoln, RI 02865-4207
Phone: (401) 753-7600
Alliance@QARC.org
Checklist for Submission of Radiation Oncology Quality Assurance Materials

<table>
<thead>
<tr>
<th>Patient Initials:</th>
<th>Registration #:</th>
<th>RT Start Date:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sender’s Name:</th>
<th>Phone #:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Email:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Radiation Oncologist:</th>
<th>Email:</th>
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</table>

Please enclose a copy of this Checklist together with the RT materials you submit. All materials must be labeled with the protocol and assigned registration number.

Digital treatment plan, screenshots of other RT data and diagnostic imaging may be submitted via sFTP or on CD. For data sent via sFTP, a notification email should be sent to sFTP@qarc.org with the protocol # and registration # in the subject line. Please refer to IROC Rhode Island website for instructions on sending digital data (www.qarc.org).

Data not sent via sFTP may be sent via email to datasubmission@qarc.org with the protocol # and registration # in the subject line. Data may also be sent via courier to the address below.

The following materials must be submitted prior to the start of radiotherapy for pre-treatment review:

<table>
<thead>
<tr>
<th>DATE SUBMITTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative &amp; pathology reports for lumpectomy/mastectomy procedure</td>
</tr>
<tr>
<td>Copy of digital RT Treatment Plan (DiconRT or RTOG format)</td>
</tr>
<tr>
<td>Treatment planning system summary report that includes the MU calc, beam parameters, calculation algorithm, and volume of interest dose statistics</td>
</tr>
<tr>
<td>DRRs of each treatment field (3D) or orthogonal isocenter images (IMRT)</td>
</tr>
<tr>
<td>Prescription sheet for the ENTIRE treatment</td>
</tr>
<tr>
<td>RT-1 Dosimetry Form <a href="http://www.qarc.org/forms/ROC_RT-1DosimetrySummaryForm.pdf">www.qarc.org/forms/ROC_RT-1DosimetrySummaryForm.pdf</a></td>
</tr>
<tr>
<td>Motion Management Reporting Form (if applicable) <a href="http://www.qarc.org/forms/ROC_MotionManagementForm.pdf">www.qarc.org/forms/ROC_MotionManagementForm.pdf</a></td>
</tr>
<tr>
<td>Explanation if recommended doses to organs at risk are exceeded</td>
</tr>
</tbody>
</table>

Final Review materials must be submitted within 1 week of the completion of radiation:

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed RT Daily Treatment Chart, including prescription, daily and cumulative doses</td>
</tr>
<tr>
<td>RT-2 Total Dose Record <a href="http://www.qarc.org/forms/ROC_RT2RadiotherapyTotalDoseRecord.pdf">www.qarc.org/forms/ROC_RT2RadiotherapyTotalDoseRecord.pdf</a></td>
</tr>
<tr>
<td>Documentation listed above showing modifications from the original submission (if not previously submitted).</td>
</tr>
</tbody>
</table>

Please contact study CRA by email (alliance@qarc.org) or phone: (401) 753-7600 for clarification as necessary. Thank you for your ongoing co-operation.
<table>
<thead>
<tr>
<th>Number</th>
<th>Target Volume</th>
<th>On TX</th>
<th>#Rev</th>
<th>Review</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PTV1</td>
<td>Y</td>
<td>-</td>
<td>A</td>
<td>F</td>
<td></td>
</tr>
<tr>
<td>1T1</td>
<td>PTV2</td>
<td>E</td>
<td>-</td>
<td>A</td>
<td>F</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Brain</td>
<td>X</td>
<td>-</td>
<td>A</td>
<td>F</td>
<td></td>
</tr>
</tbody>
</table>

Comments: Mtg: Final Review Pending

Performance Evaluation: [ ] [ ] [ ] RT Status: C

IMRT: Y

Brachy: 

All Credentials Met: Y

Date: 3/28/2015

User: 

Chart Page  Print Options  DX Status: C
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.
DR T. J. Fitzgerald, MD
Director
TJF/krt
IROC RI (QARC)
640 George Washington Highway

From: ktoole@qarc.org
Sent: Tuesday, February 17, 2015
To: , MD
Cc:
Subject:

Dear Doctor,

We have reviewed the on treatment data submitted for your patient, who has been entered on Alliance Protocol 30610.

I appreciate receiving the imaging and radiation therapy treatment objects which appear to meet study guidelines. There is trace uptake in both R and L region 10 of uncertain significance. The SUV of both is less than liver (3.13 using the MIM viewer), however neither appears to meet size criteria for disease. Your participation in this study is appreciated.

We look forward to receiving the RT-2 form and daily RT treatment chart once RT is complete.

Sincerely Yours,
T.J. Fitzgerald, MD
Director
TJF/krt
IROC RI (QARC)
640 George Washington Highway
# PATIENT RT REVIEW DATA SUMMARY

<table>
<thead>
<tr>
<th>Target Volume</th>
<th>Average Fraction Dose</th>
<th>Protocol Dose</th>
<th>Dose Variation</th>
<th>Total Dose</th>
<th>Protocol Total Dose</th>
<th>Total Dose Variation</th>
<th>Volume Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esophagus</td>
<td>180 cGy</td>
<td>180 cGy</td>
<td>0 %</td>
<td>5040 cGy</td>
<td>5040 cGy</td>
<td>0 %</td>
<td>Appropriate</td>
</tr>
</tbody>
</table>

## Reference Points

<table>
<thead>
<tr>
<th>Reference Point</th>
<th>Reference Point Name</th>
<th>Dose Received</th>
<th>Protocol Dose</th>
<th>Percent Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Cord</td>
<td>4182 cGy</td>
<td>0-4500 cGy</td>
<td>0 %</td>
</tr>
<tr>
<td>B</td>
<td>Stomach</td>
<td>5365 cGy</td>
<td>0-5400 cGy</td>
<td>0 %</td>
</tr>
</tbody>
</table>

## QARC Comments

Volumes and doses are appropriate.

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Thank you for submitting this data to us and for participating in this study. We are available to discuss this review with you.

T.J. Fitzgerald, MD
Director

Phone: 404-1753-7600 Fax: 404-1753-7601
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

TRIAD: TRansfer of Image And Data

- 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
- Will be used in all NCTN trials to transfer Diagnostic Imaging and Digital Radiotherapy Data
- Currently being phased into Alliance Trials
  - As new Trials are activated will be set up to allow use of TRIAD.
  - First trial is A071401.
- Access to TRIAD is controlled by User roles on the Site’s roster
https://www.irocqa.org/
Welcome

Welcome to the Imaging and Radiation Oncology Core (IROC) website. Our overarching goal is to provide easy access to information about IROC’s quality assurance (QA) services and processes for individuals at sites participating in NCI-sponsored trials.

We welcome your comments and suggestions. Please contact us!

National Clinical Trials Network

IROC has been awarded a grant by the National Cancer Institute (NCI) as a member of the NCI National Clinical Trials Network (NCTN).

Contact Us

View Our Services

Why Is QA Important?

Quality Assurance Centers

- ACR Diagnostic Imaging Core Laboratory
  IROC Philadelphia - Imaging
- Imaging Core Laboratory
  IROC Ohio
- Image Guided Therapy Center
  IROC St. Louis
- Quality Assurance Review Center
  IROC Rhode Island
- ACR Radiation Oncology Core Laboratory
  IROC Philadelphia - RT
- Radiological Physics Center
  IROC Houston

Announcements

IROC launches its website to support the continuum of imaging and radiotherapy quality assurance services for the National Cancer Institute’s National Clinical Trials Network.

read more...
https://www.irocqa.org/
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 adopted for use by the ACR's accreditation programs and National Radiology Data Registry.

A new TRIAD website has 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