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

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What is IROC?

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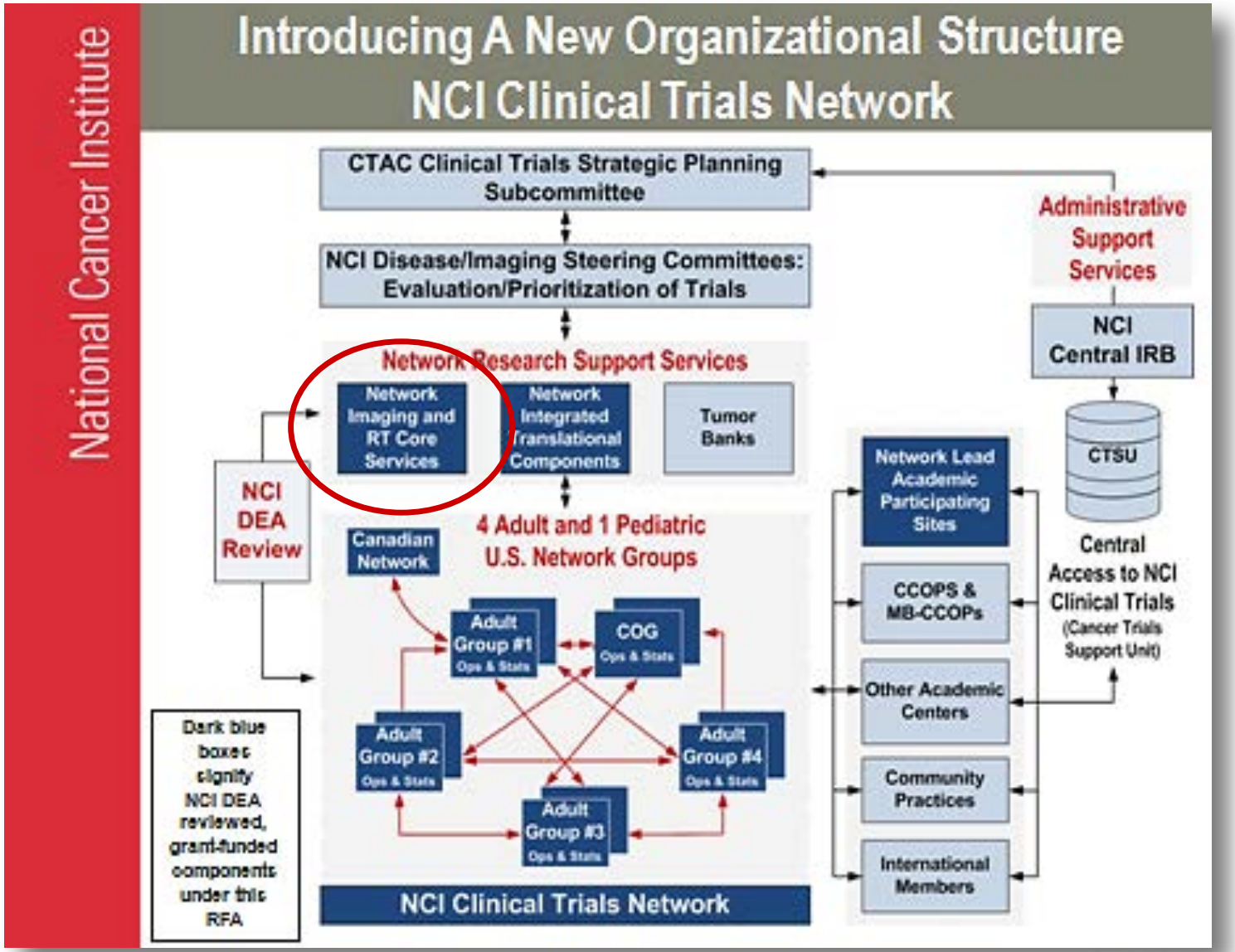

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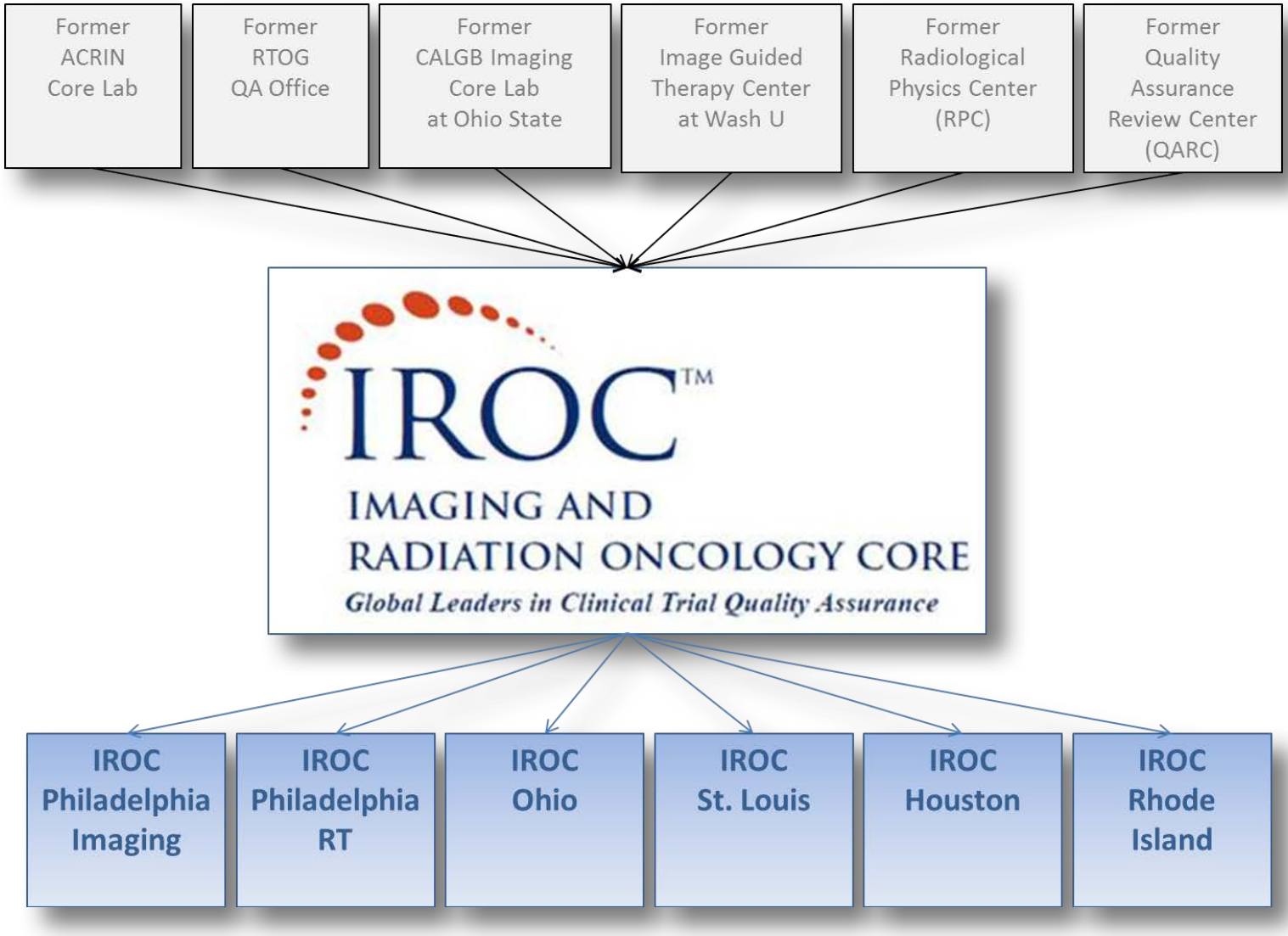

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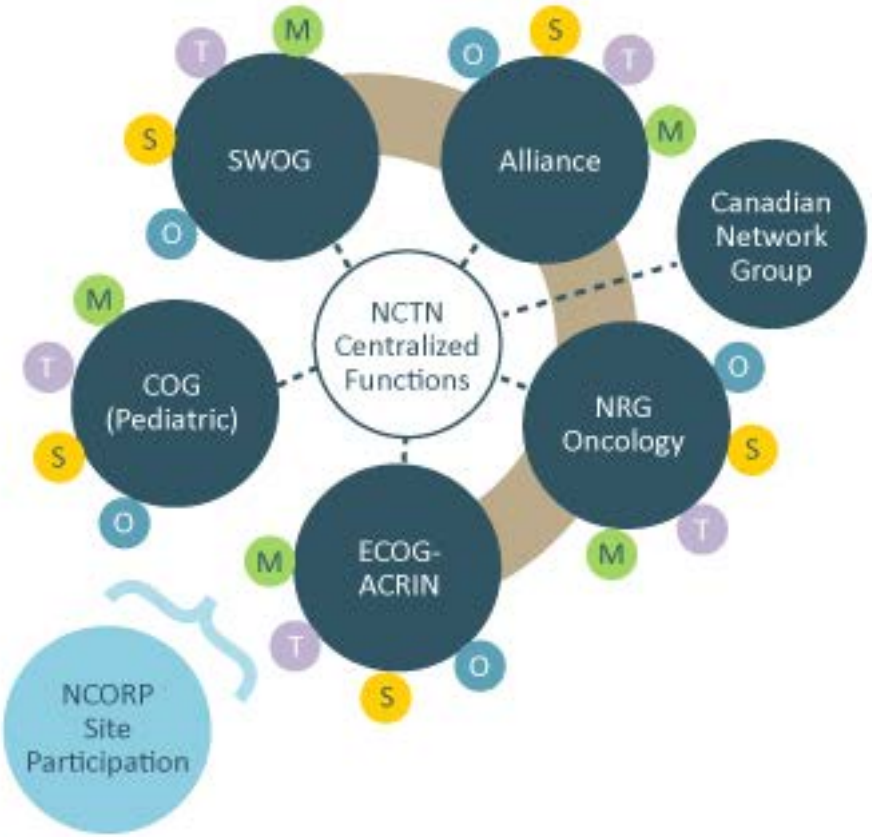
NCI National Clinical Trials Network Structure



LEGEND

- Centralized Functions:
  - Centralized Institutional Review Board
  - Cancer Trials Support Unit
  - Imaging and Radiation Oncology Core (IROC) Group
  - Common Data Management System Central Hosting
- 30 Lead Academic Participating Sites (LAPS)
- O — Operations
- S — Statistics & Data Management
- T — Tissue Banks
- M — Member Sites

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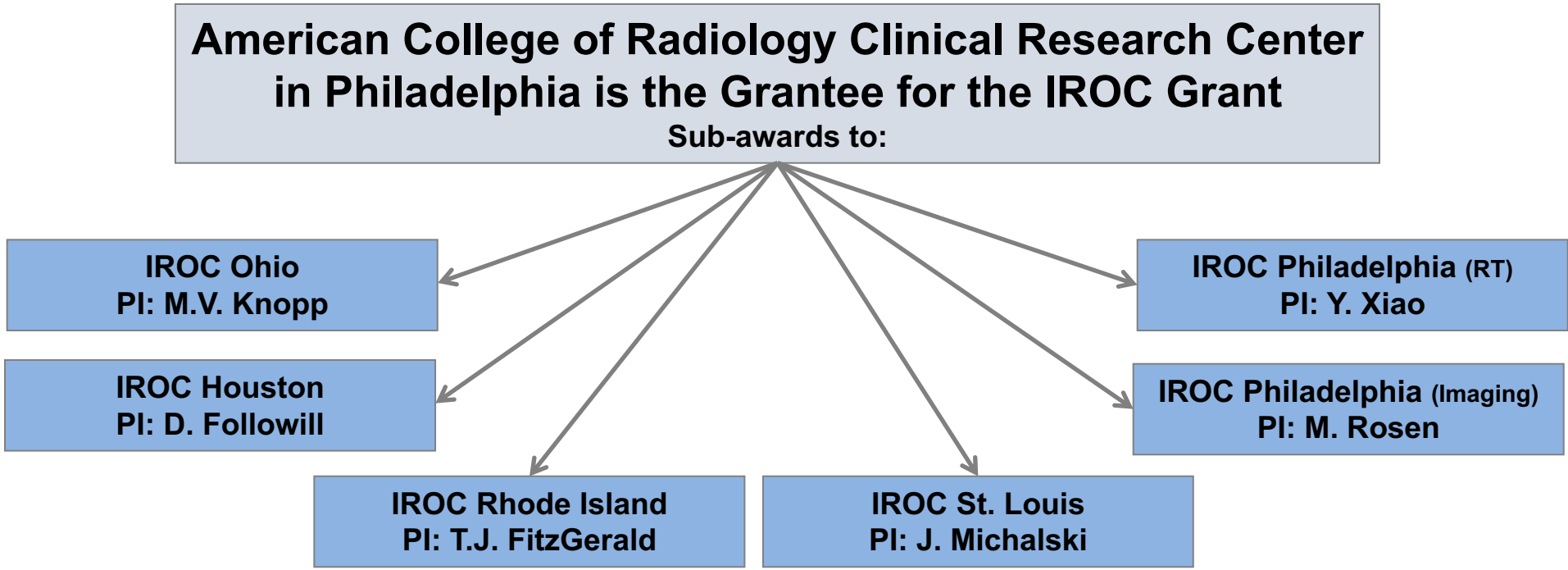
IROC's Structure



IROC Executive Committee

Co-Directors: D. Followill, Houston (RT) and M.V. Knopp, Ohio (Imaging)

IROC Admin: Rosen/O'Meara/Laurie

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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

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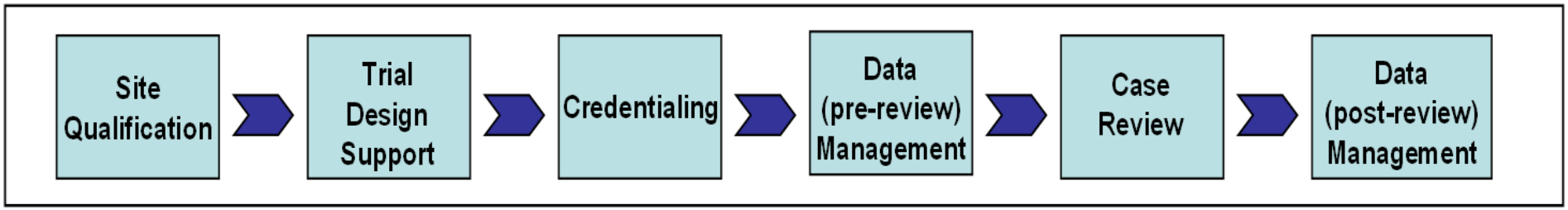
IROC's Core Services

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

NCTN Group	Radiation Oncology	Imaging
Alliance	Rhode Island	Ohio
COG	Rhode Island	Rhode Island
ECOG-ACRIN	Rhode Island	Philadelphia (DI)
NRG Oncology	Philadelphia (RT)	Philadelphia (DI)
SWOG	Rhode Island	Ohio

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.

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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.

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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

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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

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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.

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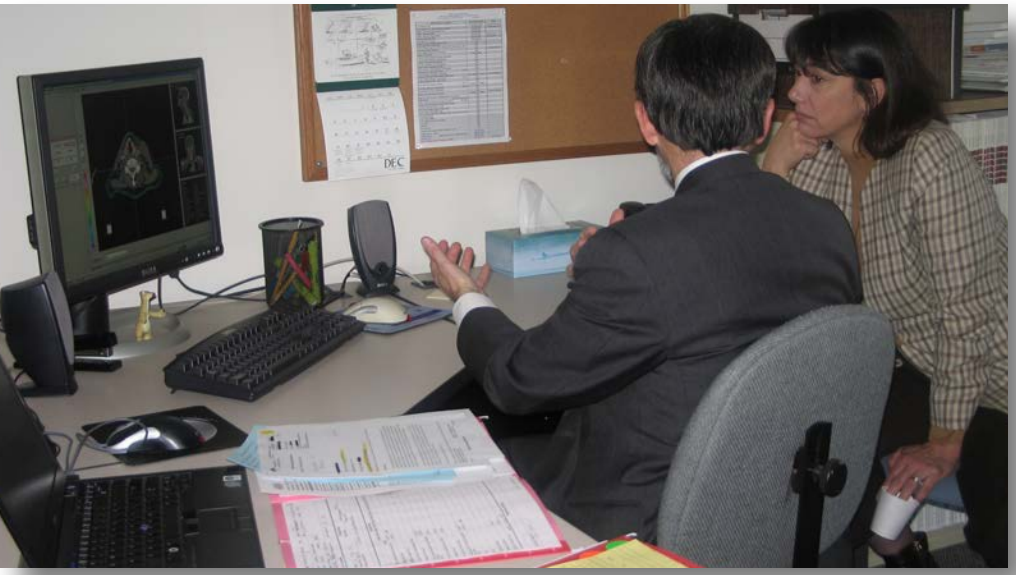


Data Status | DS 3C | Review Data | Clinical 1 | Clinical 2 | Mail | eMaterials | Intervention | Logs | Benchmark | Remote Rev. | Imaging

QARC Number: Case Number: Accession No.:

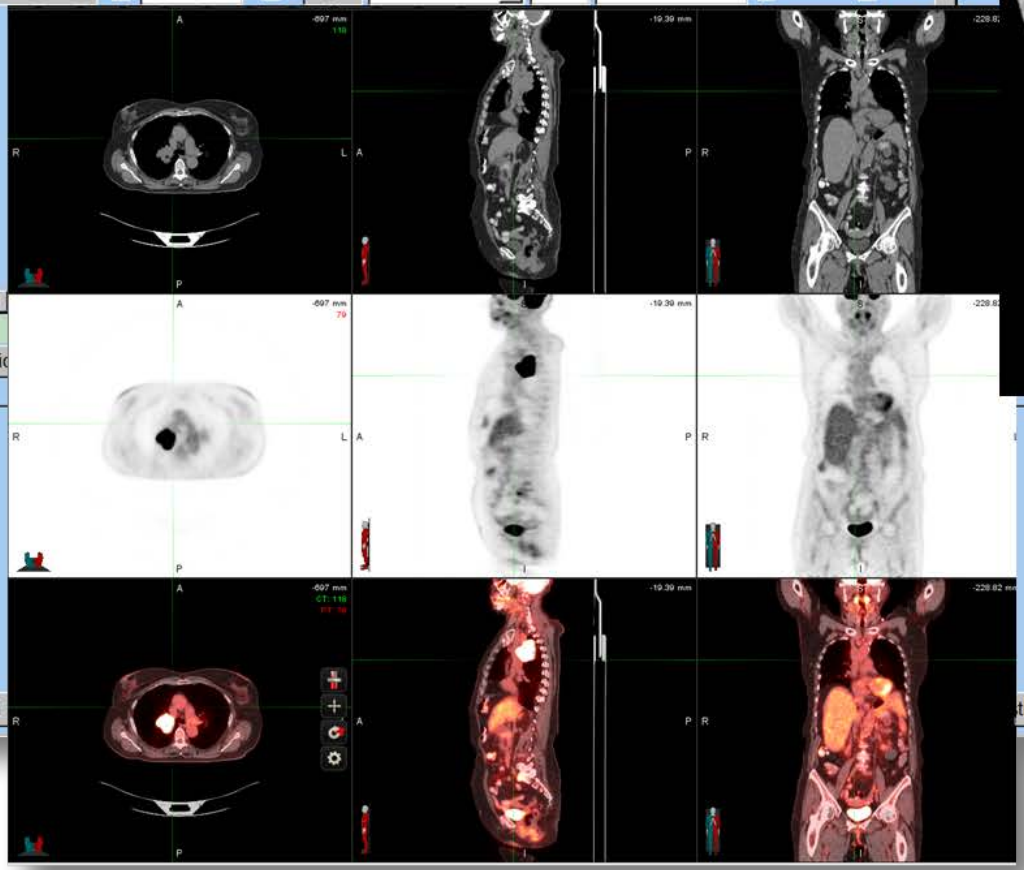
Diagnostic Comments:

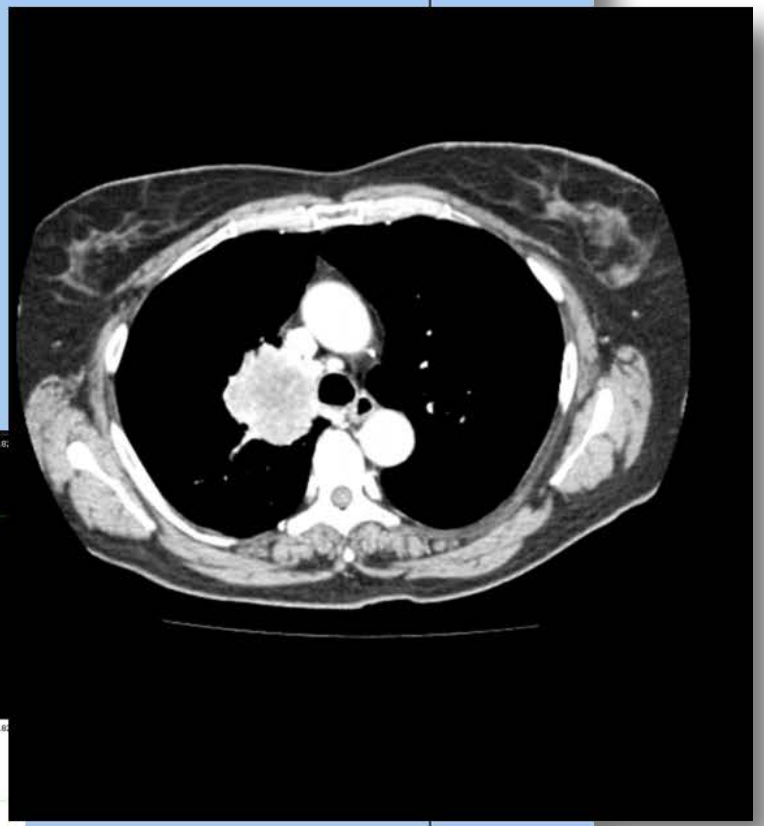
Note: Keep Event and Study Name Lengths within | guidelines | to insure proper fit in rpt qryDiagnostic Crosstab fields

Event	Order	Event Date	Interval Comments
C3610 Pre-Study	10		

Record: 1 of 2

Study	N/A	Study Date	Revwd	Order	eImage Type	CD	Comments	Form	Remote Review
Chest CT	☐	01/14/2015	☐	10	DICOM	1		☐	☑
PET	☐	01/07/2015	☐	20	DICOM	1		☐	☑
CT-2	☐		☐	30				☐	☐
CT-3	☐		☐	40				☐	☐

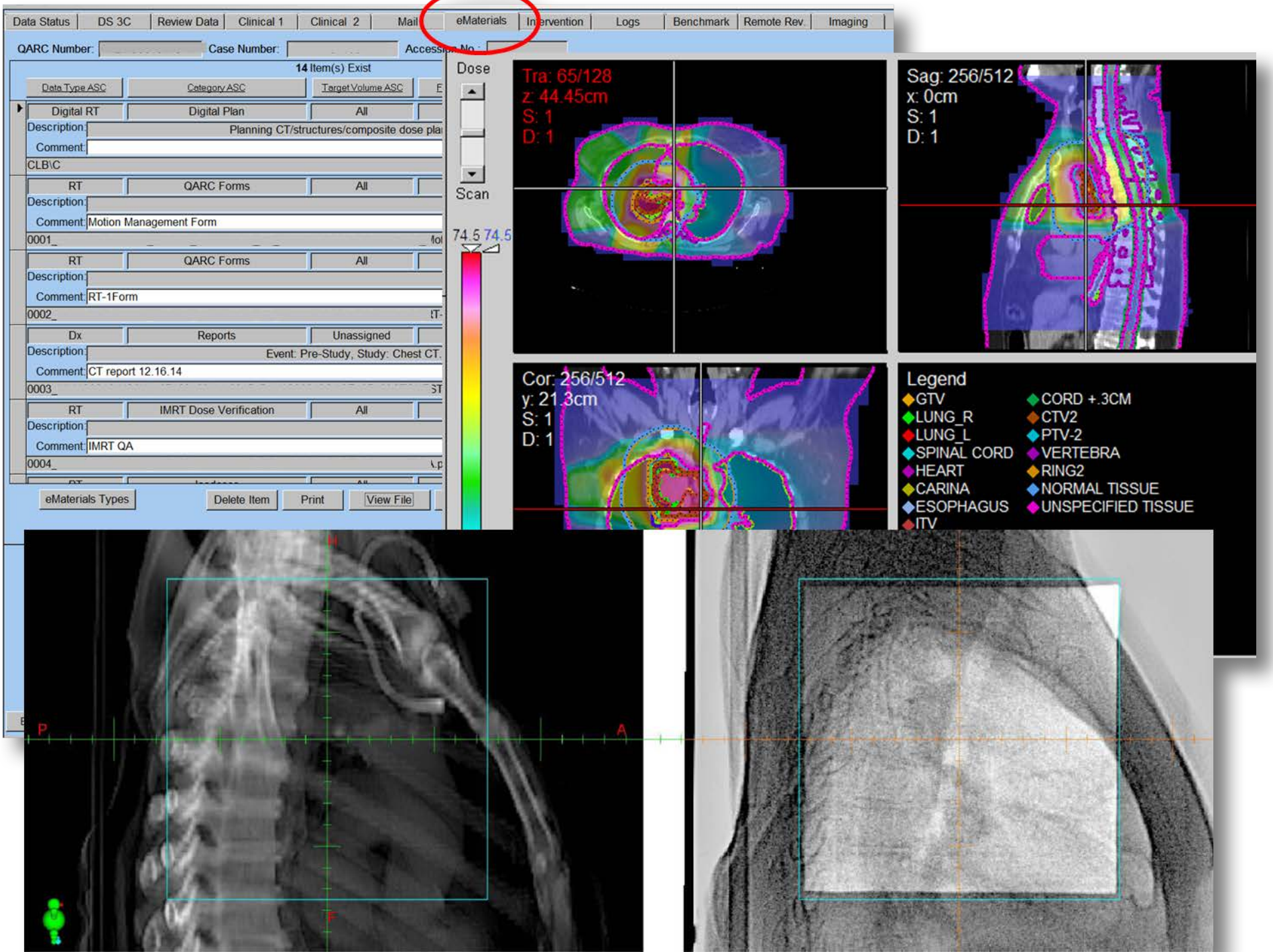




Record:

Diagnostic

Exit | tic Comments | Return


Data Status
DS 3C
Review Data
Clinical 1
Clinical 2
Mail
eMaterials
Intervention
Logs
Benchmark
Remote Rev.
Imaging
QARC Number:
Case Number:
14 Item(s) Exist
Data Type ASC
Category ASC
Target Volume ASC
Digital RT
Digital Plan
All
Description: Planning CT/structures/composite dose pla
Comment:
CLB\C
RT
QARC Forms
All
Description:
Comment: Motion Management Form
0001_
RT
QARC Forms
All
Description:
Comment: RT-1Form
0002_
Dx
Reports
Unassigned
Description: Event: Pre-Study, Study: Chest CT.
Comment: CT report 12.16.14
0003_
RT
IMRT Dose Verification
All
Description:
Comment: IMRT QA
0004_
eMaterials Types
Delete Item
Print
View File
Dose
Scan
74.5 74.5
Tra: 65/128
z: 44.45cm
S: 1
D: 1
Sag: 256/512
x: 0cm
S: 1
D: 1
Cor: 256/512
y: 21.3cm
S: 1
D: 1
Legend
GTV
LUNG_R
LUNG_L
SPINAL CORD
HEART
CARINA
ESOPHAGUS
ITV
CORD +.3CM
CTV2
PTV-2
VERTEBRA
RING2
NORMAL TISSUE
UNSPECIFIED TISSUE
H
P
A
F

Research Resource – Adults

Committee	#Protocols	#Patients	DICOM Diagnostic Studies	DICOM RT Treatment Plans
Breast	11	4745	5565	885
CNS	1	159	399	147
Lung	17	3306	8825	833
Lymphoma	7	783	2994	45
GI	24	3052	3230	942

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Research Resource – Pediatrics

Committee	#Protocols	#Patients	DICOM Diagnostic Studies	DICOM RT Treatment Plans
AALL	13	3,072	1,039	8
ACNS	22	3,111	16,651	1,546
AEWS	7	1,571	4,650	435
AHOD	10	2,812	29,908	596
ANBL	14	2,706	8,101	452
ARAR	3	414	2,299	77
AREN	5	7,250	11,045	896
ARST	10	2,123	6,275	958

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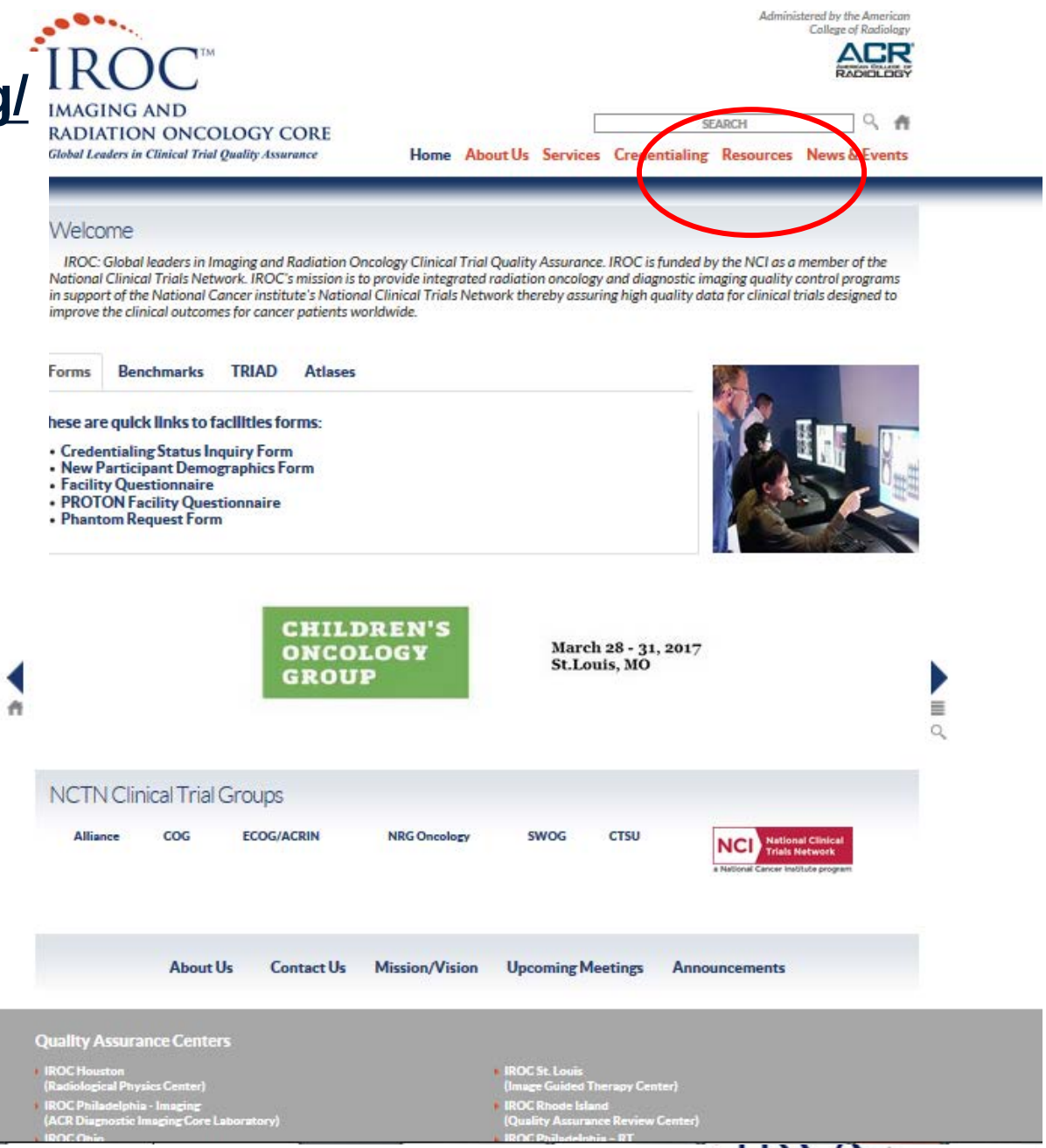
https://www.irocqa.org/

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.



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TRIAD

DDSI Form

Contouring Atlases

QA Publications

Contact Us

• Web Support

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

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 (x86) [meets exactly]
  - https://www.microsoft.com/en-us/download/details.aspx?id=8328
- Microsoft Visual C++ 2012 Redistributable (x86) [meets exactly]
  - https://www.microsoft.com/en-us/download/details.aspx?id=30679

*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:

TRIAD
ACR IMAGE AND INFORMATION EXCHANGE

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Importance of QA

International Journal of
Radiation Oncology
biology • physics

www.redjournal.org

Critical Review

Does Quality of Radiation Therapy Predict Outcomes of Multicenter Cooperative Group Trials? A Literature Review

Alysa Fairchild, MD, FRCPC,* William Straube, MSc,† Fran Laurie, BSc,‡ and David Followill, PhD§

*Department of Radiation Oncology, Cross Cancer Institute, Consortium, Imaged-Guided Therapy QA Center, St. Louis, M Island; and §Radiological Physics Center, University of Texa

Received Nov 17, 2012, and in revised form Mar 29, 2013. Accepte

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.

Dharmarajan, K.V., et.al. (2015). Radiotherapy quality assurance report from children's oncology group AHOD0031.International Journal of Radiation Oncology, Biology, Physics, 91(5):1065-1071.

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.

Published Ahead of Print on August 18, 2014 as 10.1200/JCO.2014.56.5838
The latest version is at http://jco.ascopubs.org/cgi/doi/10.1200/JCO.2014.56.5838

JOURNAL OF CLINICAL ONCOLOGY ORIGINAL REPORT

Radiation Field Design in the ACOSOG Z0011 (Alliance) Trial

Reshma Jagsi, Manjeet Chadha, Janaki Moni, Karla Ballman, Fran Laurie, Thomas A. Buchholz, Armando Giuliano, and Bruce G. Haffty

Reshma Jagsi, University of Michigan, Ann Arbor, MI; Manjeet Chadha, Beth Israel Medical Center, New York, NY; Janaki Moni, University of Massachusetts Medical School, Worcester, MA; Janaki Moni and Fran Laurie, Quality Assurance Review Center, Lincoln, RI; Karla Ballman, Alliance Statistics and Data Center, Mayo Clinic, Rochester, MN; Thomas A. Buchholz, MD Anderson Cancer Center, Houston, TX; Armando Giuliano, Cedars-Sinai Medical Center, Los Angeles, CA; and Bruce G. Haffty, Rutgers-Cancer Institute of New Jersey, New Brunswick, NJ.

ABSTRACT

Purpose
ACOSOG Z0011 established that axillary lymph node dissection (ALND) is unnecessary in patients with breast cancer with one to two positive sentinel lymph nodes (SLNs) who undergo lumpectomy, radiotherapy (RT), and systemic therapy. We sought to ascertain RT coverage of the regional nodes in that trial.

Methods
We evaluated case report forms completed 18 months after enrollment. From 2012 to 2013, we collected all available detailed RT records for central review.

Results
Among 605 patients with completed case report forms, 89% received whole-breast RT. Of these,

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**

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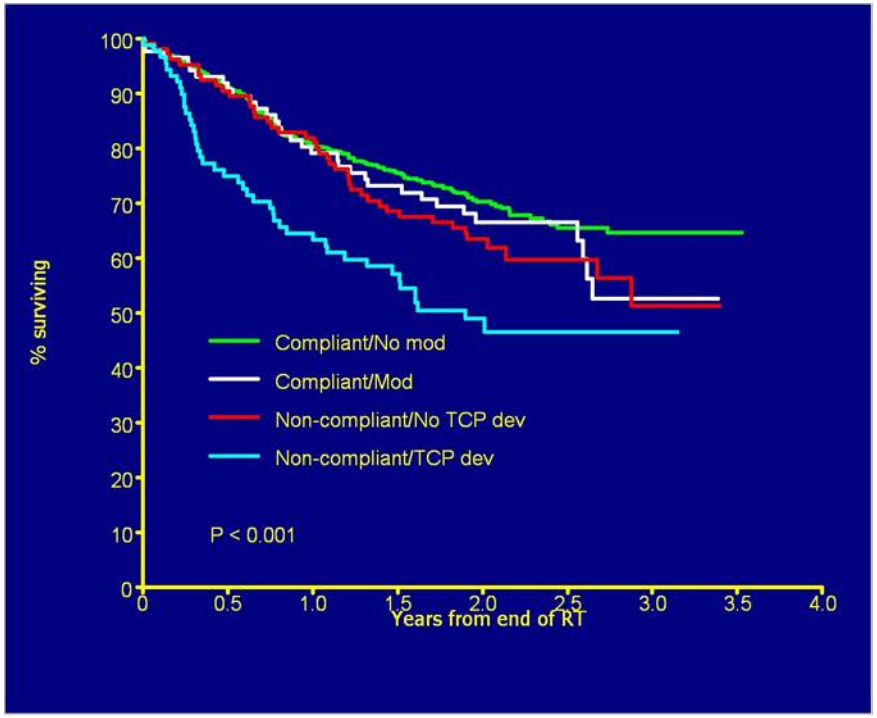
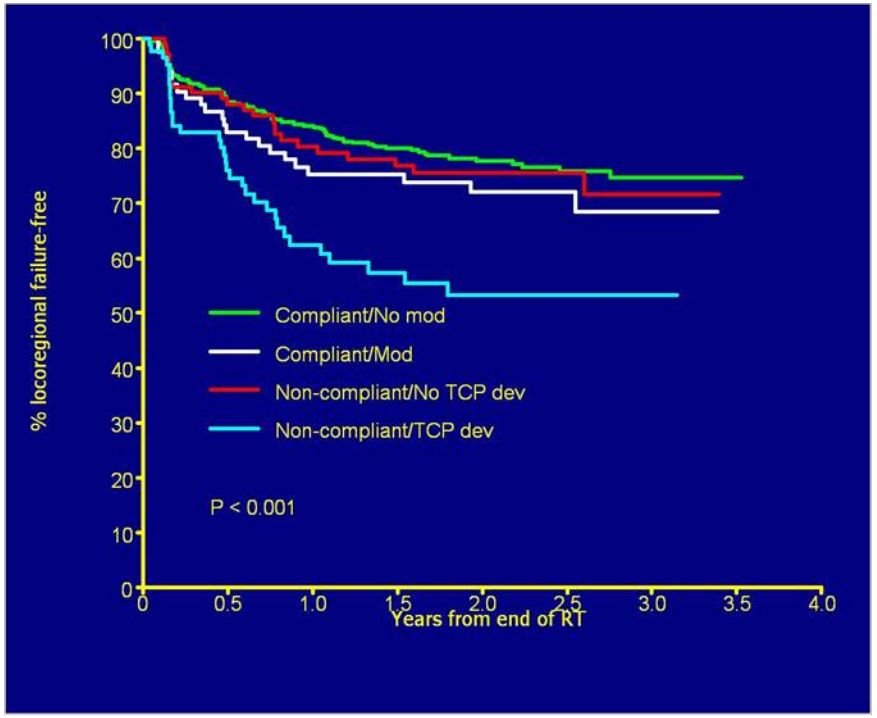
Critical impact of radiotherapy protocol compliance in the treatment of advanced HNSCC: Results from TROG 02.02



Overall survival by deviation status



Time to LRF by deviation status

Peters LJ, O'Sullivan B, Giralt J, Fitzgerald TJ, Trotti A, Bernier J, Bourhis J, Yuen K, Fisher R, Rischin D. **Critical impact of radiotherapy protocol compliance and quality in the treatment of advanced head and neck cancer: results from TROG 02.02.** *J Clin Oncol*. 2010 Jun 20;28(18):2996-3001.

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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

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