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

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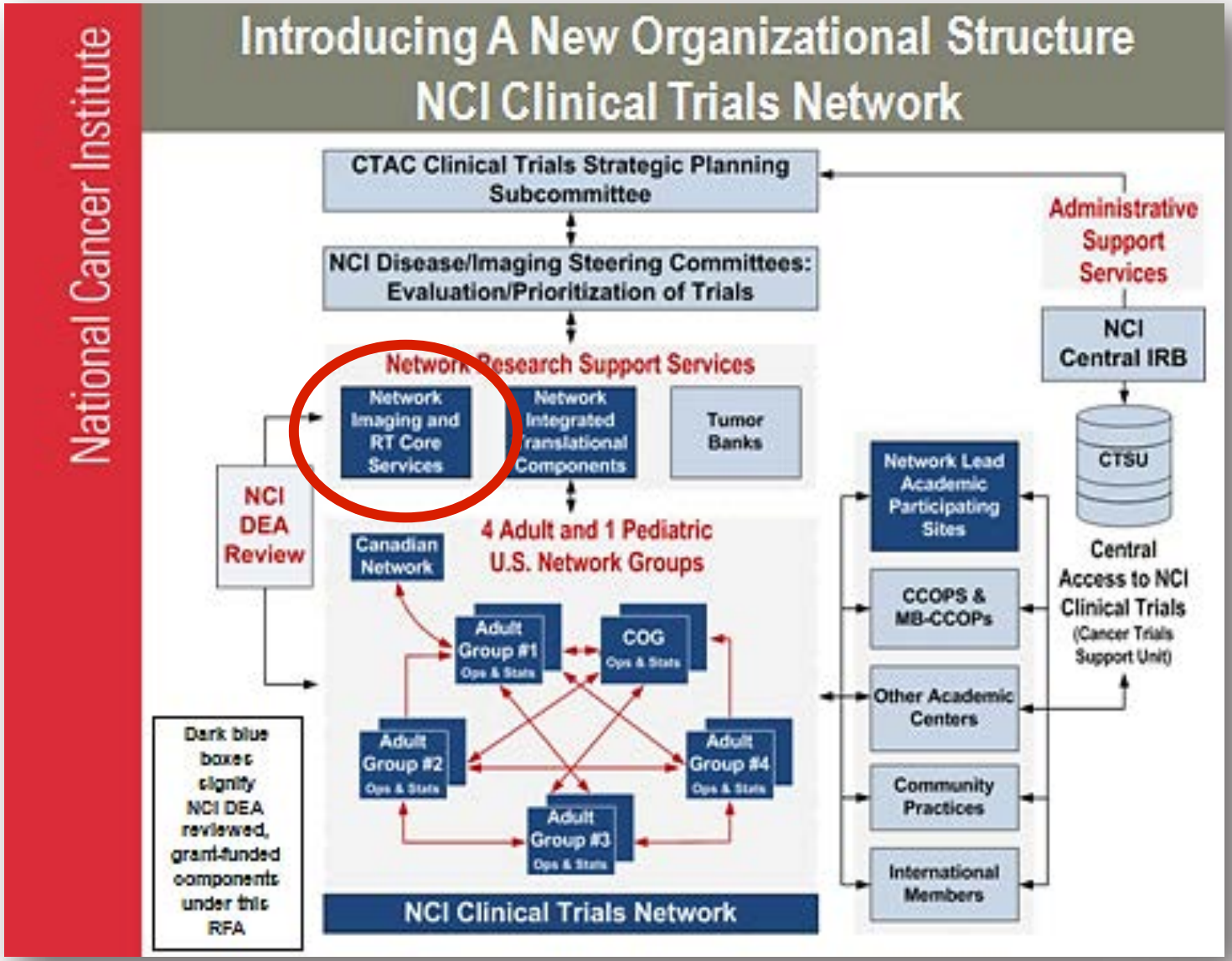

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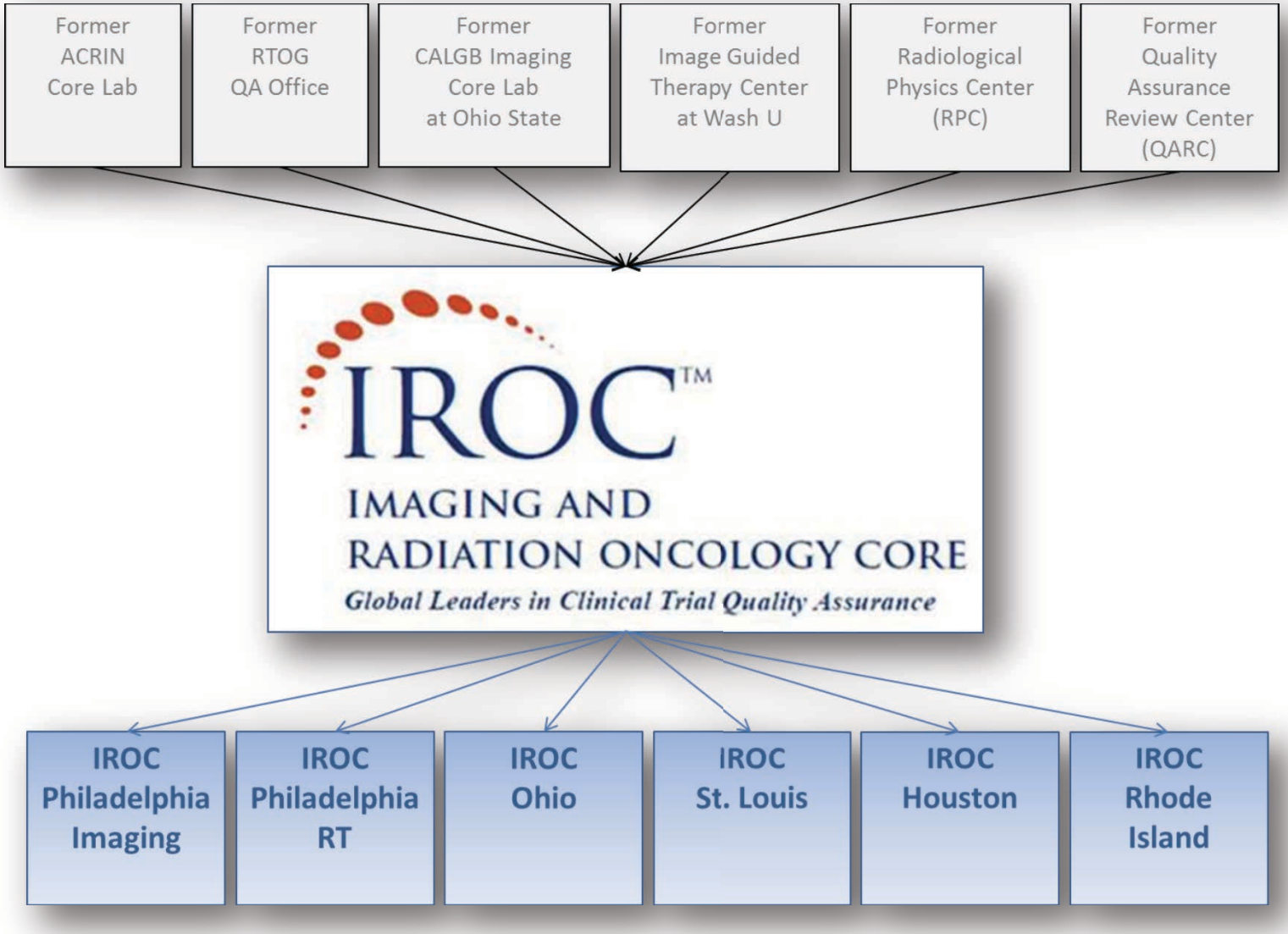

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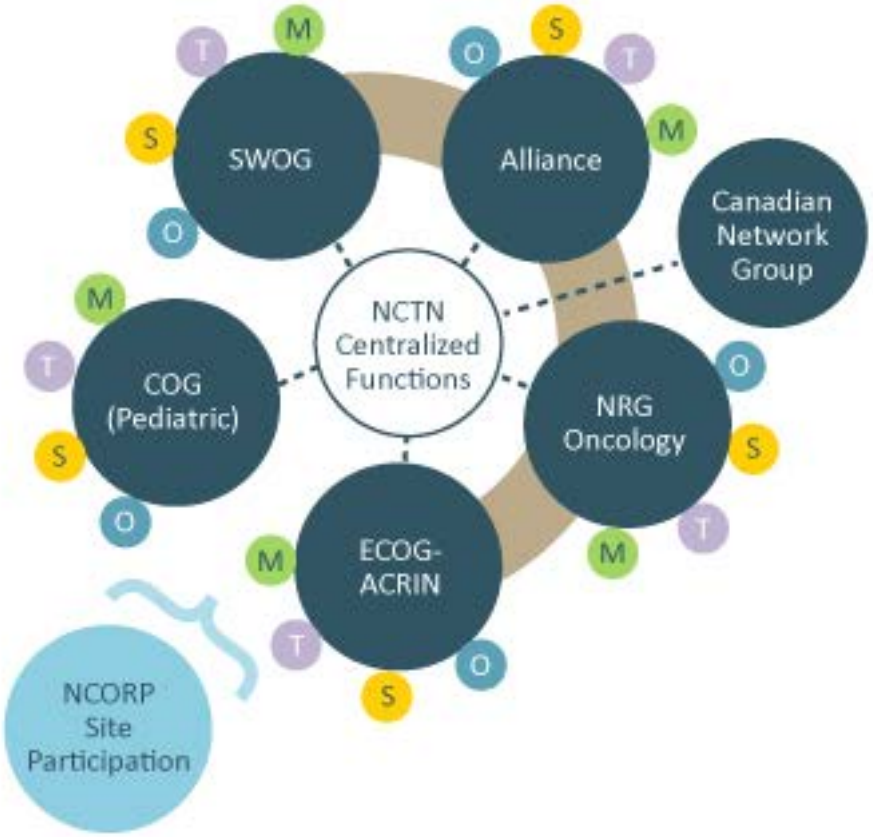
NCI National Clinical Trials Network Structure



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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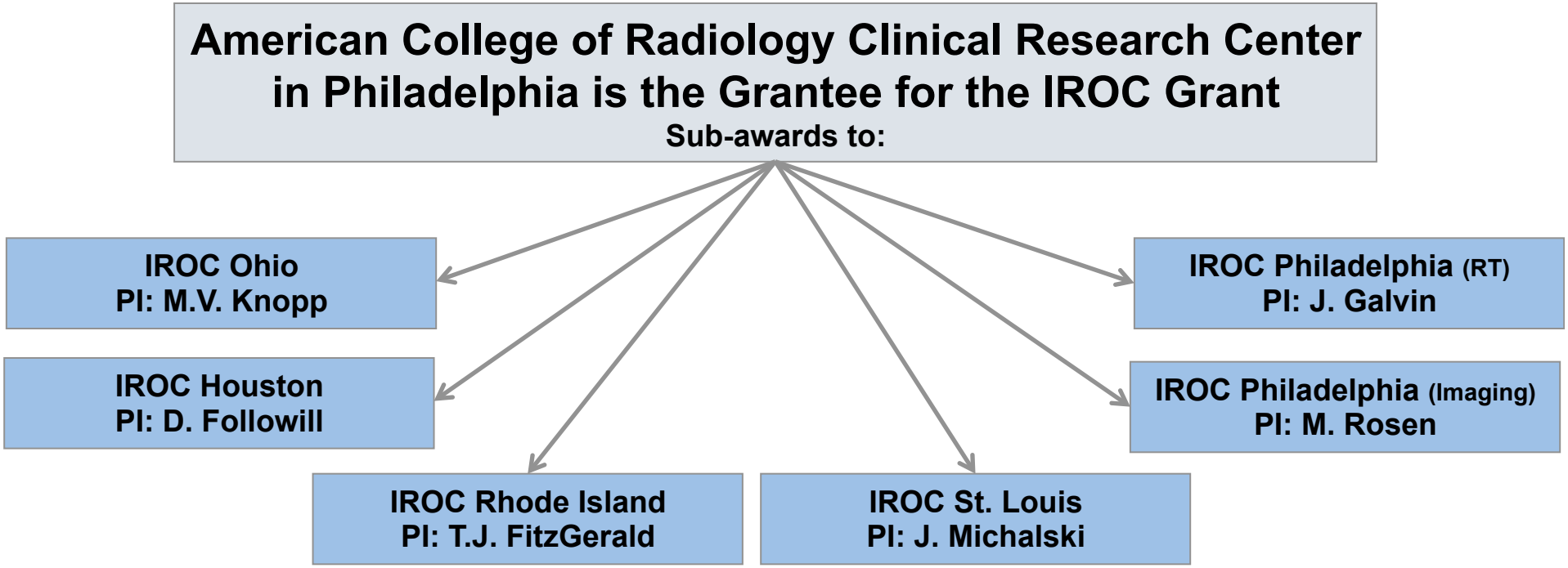
IROC's Structure



IROC Executive Committee

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

IROC Admin: King/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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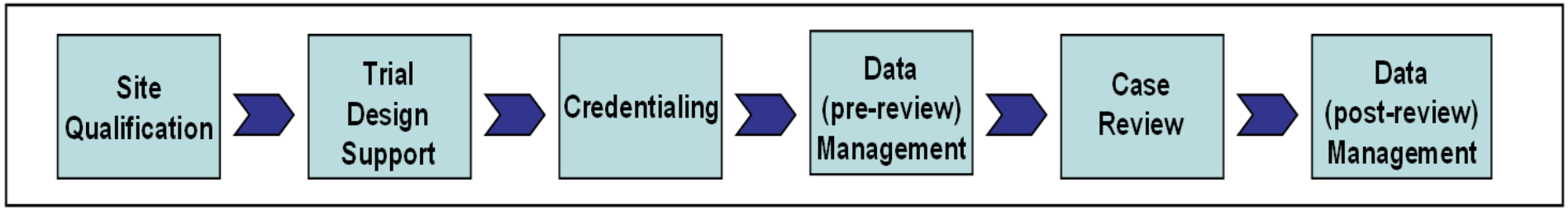
IROC's Core Services

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 key contact center for all RT credentialing questions.

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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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MD Anderson

IROC Houston Quality Assurance Center

Tel: 713-745-8989

Home | Credentialing | Participating Institutions | New Participant Demographics Form | Facility Questionnaire

Credentialing

ACOSOG | ALLIANCE | CALGB | COG | COMS | CTSU | ECOG-ACRIN | GOG | NCCTG
NRG | NSABP | RTOG | SWOG | Credentialing FAQ | Credentialing Status Inquiry

Alliance

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
Credentialing Requirements

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
Credentialing Requirements

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

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http://rpc.mdanderson.org/RPC/home.htm

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A031201

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.

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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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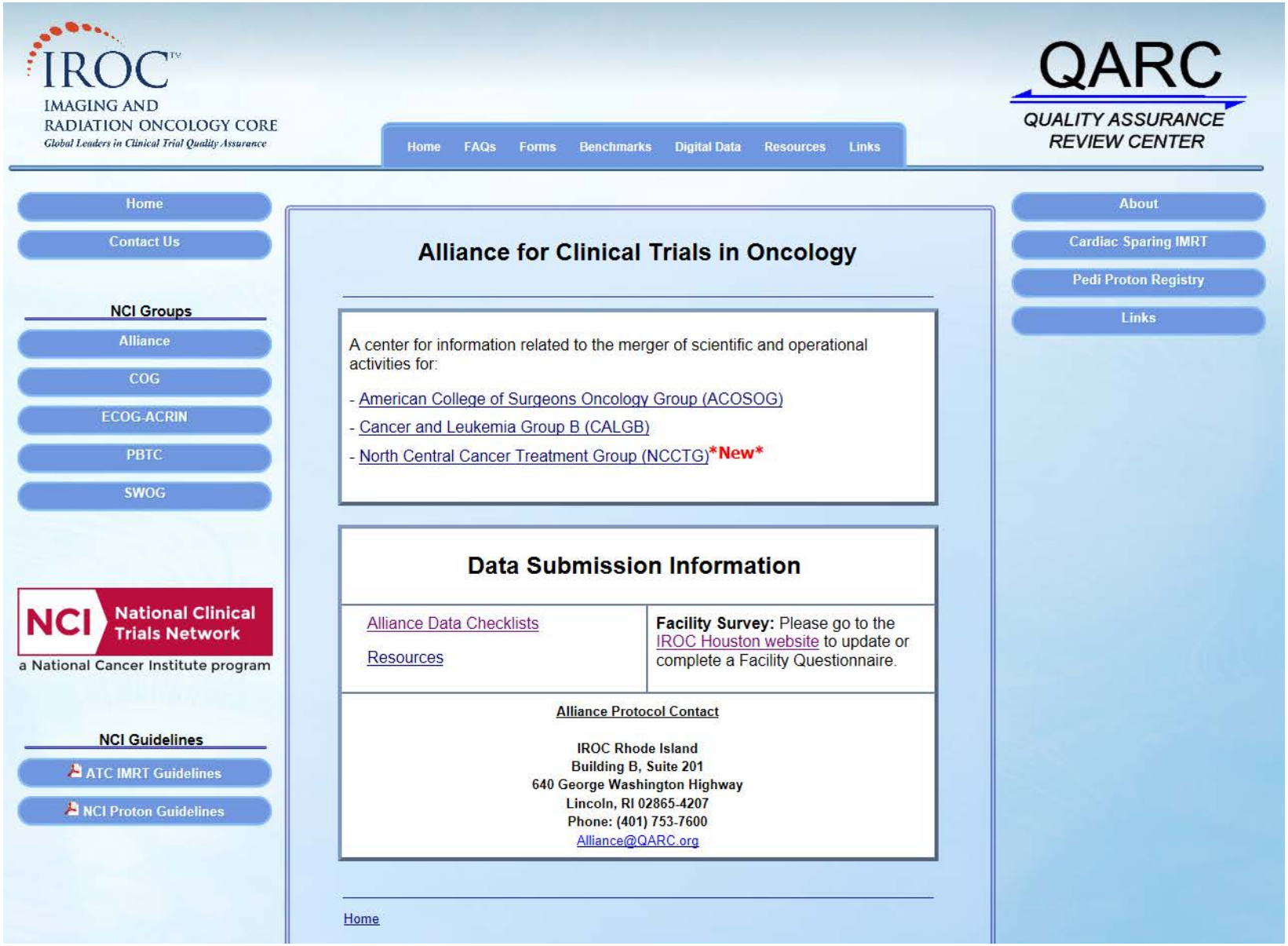

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https://www.QARC.org/

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Home
Contact Us

NCI Groups
Alliance
COG
ECOG-ACRIN
PBTC
SWOG

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Guidelines
ATC IMRT Guidelines
NCI Proton Guidelines

About
Cardiac Sparing IMRT
Pedi Proton Registry
Links

Alliance for Clinical Trials in Oncology

Checklists

- A011202 Checklist
- A021302 Checklist
- CALGB 30610 Checklist
- CALGB 31102 Checklist
- CALGB 50801 Checklist
- CALGB 70806 Checklist
- CALGB 80803 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

ALLIANCE A011202

Checklist for Submission of Radiation Oncology Quality Assurance Materials

Patient Initials: _____ Registration #: _____ RT Start Date: _____

Sender's Name: _____ Phone #: _____

Email: _____

Radiation Oncologist: _____ Email: _____

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:

DATE SUBMITTED	
_____	Operative & pathology reports for lumpectomy/mastectomy procedure
_____	Copy of digital RT Treatment Plan (DicomRT or RTOG format)
_____	Treatment planning system summary report that includes the MU calcs, beam parameters, calculation algorithm, and volume of interest dose statistics
_____	DRRs of each treatment field (3D) or orthogonal isocenter images (IMRT)
_____	Prescription sheet for the ENTIRE treatment
_____	RT-1 Dosimetry Form www.qarc.org/forms/IROC_RT-1DosimetrySummaryForm.pdf
_____	Motion Management Reporting Form (if applicable) www.qarc.org/forms/IROC_MotionManagementForm.pdf
_____	Explanation if recommended doses to organs at risk are exceeded

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

_____	Completed RT Daily Treatment Chart, including prescription, daily and cumulative doses
_____	RT-2 Total Dose Record www.qarc.org/forms/IROC_RT2RadiotherapyTotalDoseRecord.pdf
_____	Documentation listed above showing modifications from the original submission (if not previously submitted).

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.

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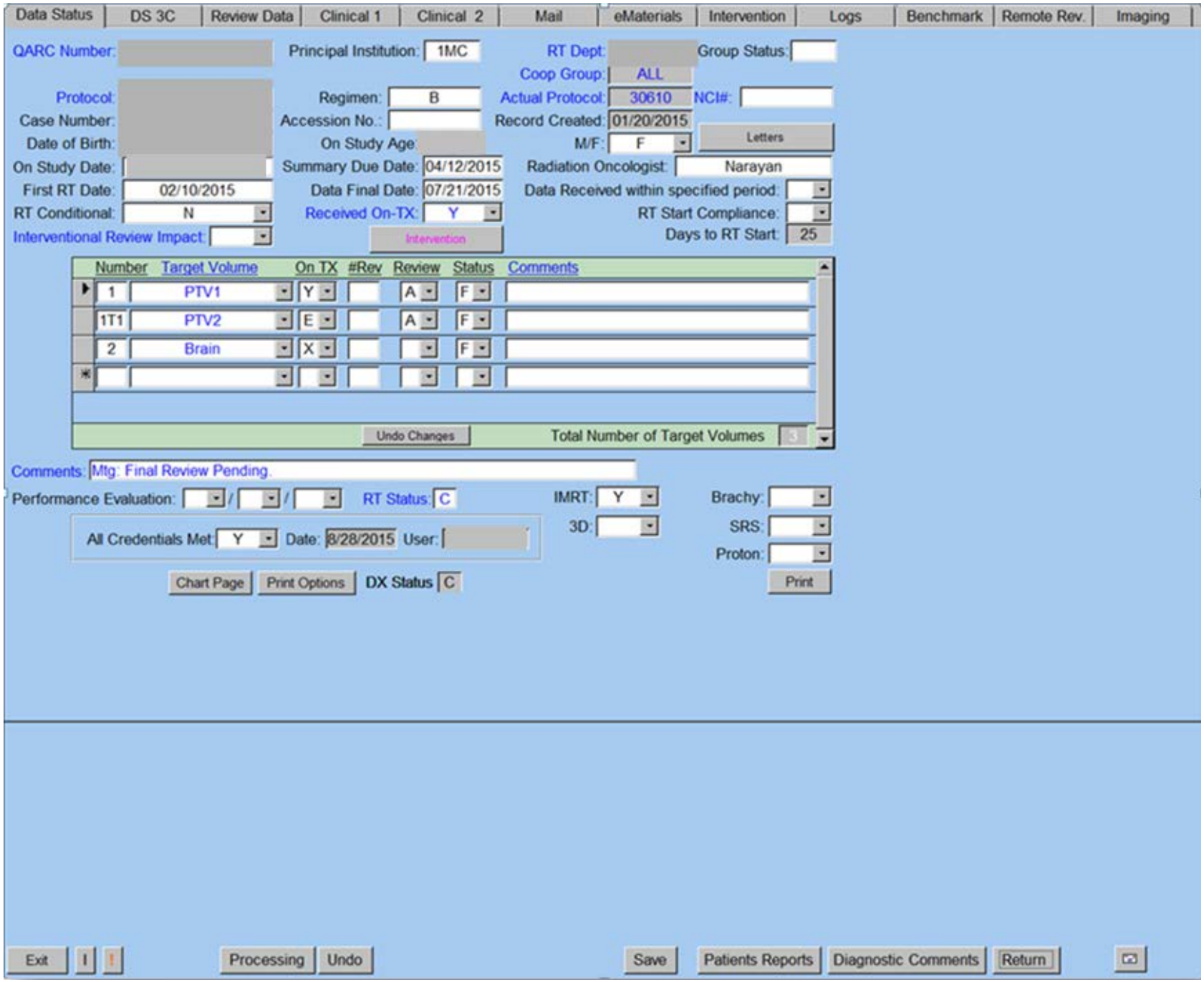
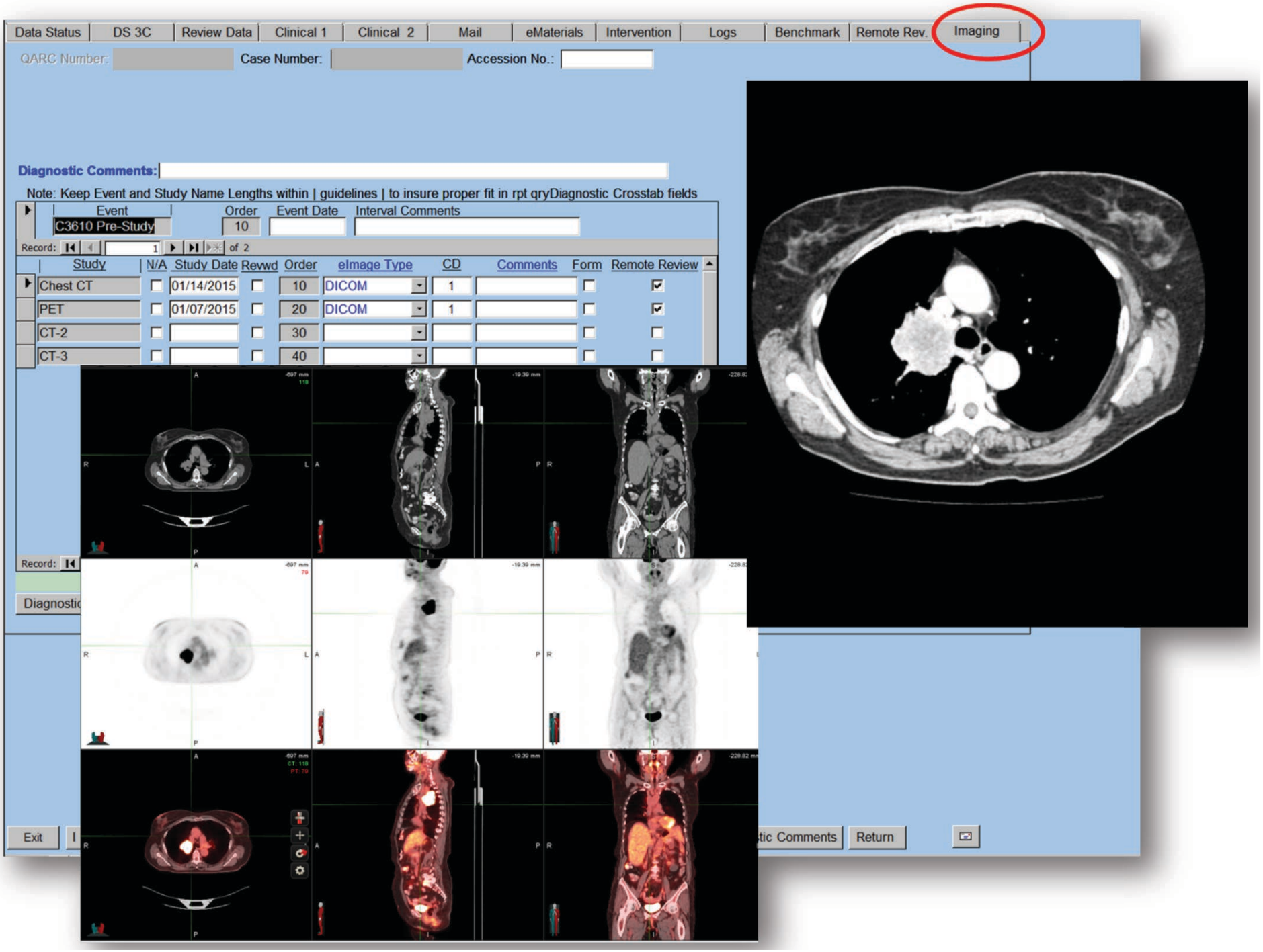
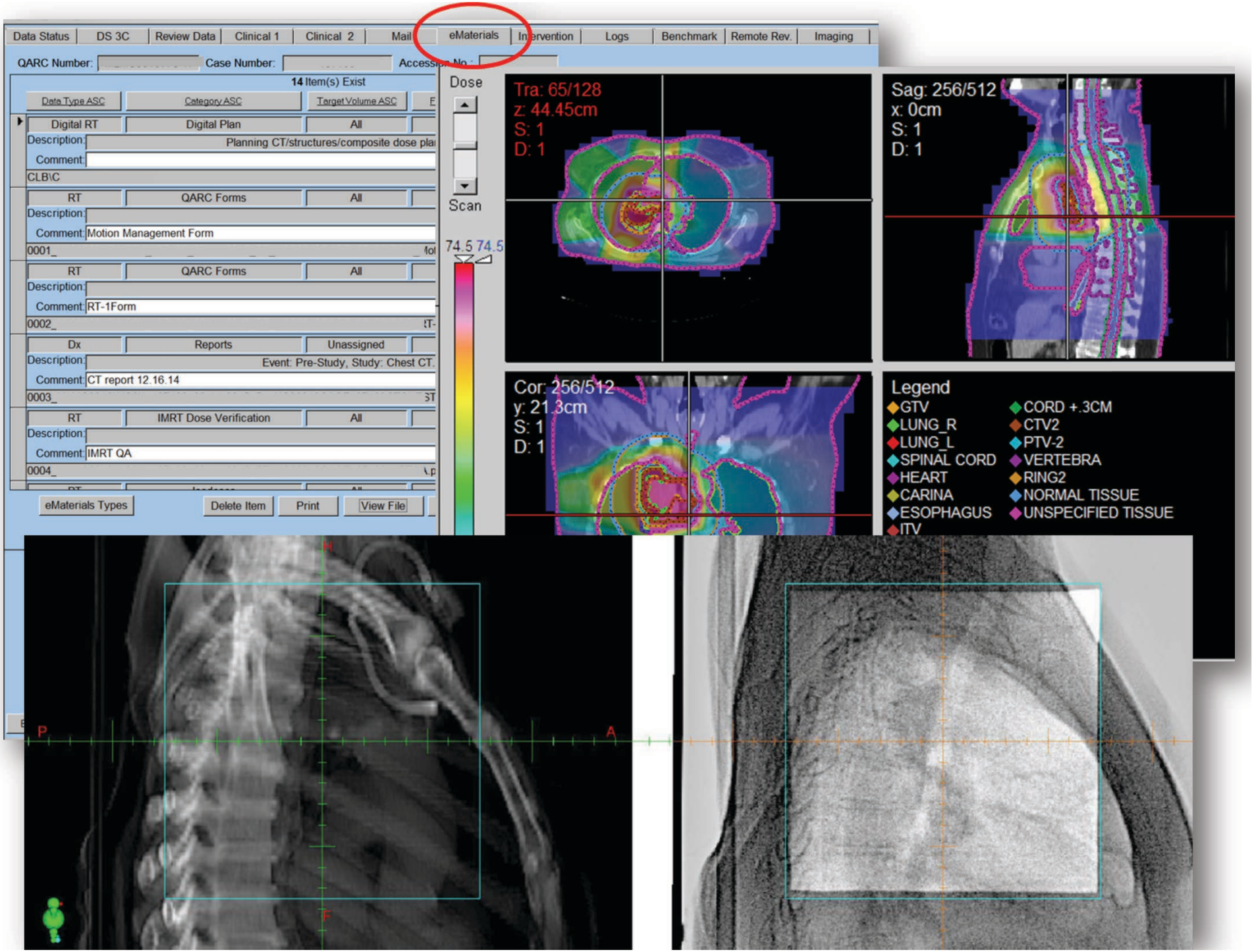

Data Status
DS 3C
Review Data
Clinical 1
Clinical 2
Mail
eMaterials
Intervention
Logs
Benchmark
Remote Rev.
Imaging
QARC Number:
Principal Institution: 1MC
RT Dept:
Group Status:
Coop Group: ALL
Protocol:
Regimen: B
Actual Protocol: 30610
NCI#:
Case Number:
Accession No.:
Record Created: 01/20/2015
Date of Birth:
On Study Age:
M/F: F
Letters
On Study Date:
Summary Due Date: 04/12/2015
Radiation Oncologist: Narayan
First RT Date: 02/10/2015
Data Final Date: 07/21/2015
Data Received within specified period:
RT Conditional: N
Received On-TX: Y
RT Start Compliance:
Interventional Review Impact:
Intervention
Days to RT Start: 25
Number
Target Volume
On TX
#Rev
Review
Status
Comments
1 PTV1 Y A F
1T1 PTV2 E A F
2 Brain X F
Undo Changes
Total Number of Target Volumes
Comments: Mtg: Final Review Pending.
Performance Evaluation: / /
RT Status: C
IMRT: Y
Brachy:
3D:
SRS:
All Credentials Met: Y
Date: 8/28/2015
User:
Proton:
Chart Page
Print Options
DX Status C
Print
Exit
Processing
Undo
Save
Patients Reports
Diagnostic Comments
Return


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 plan
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

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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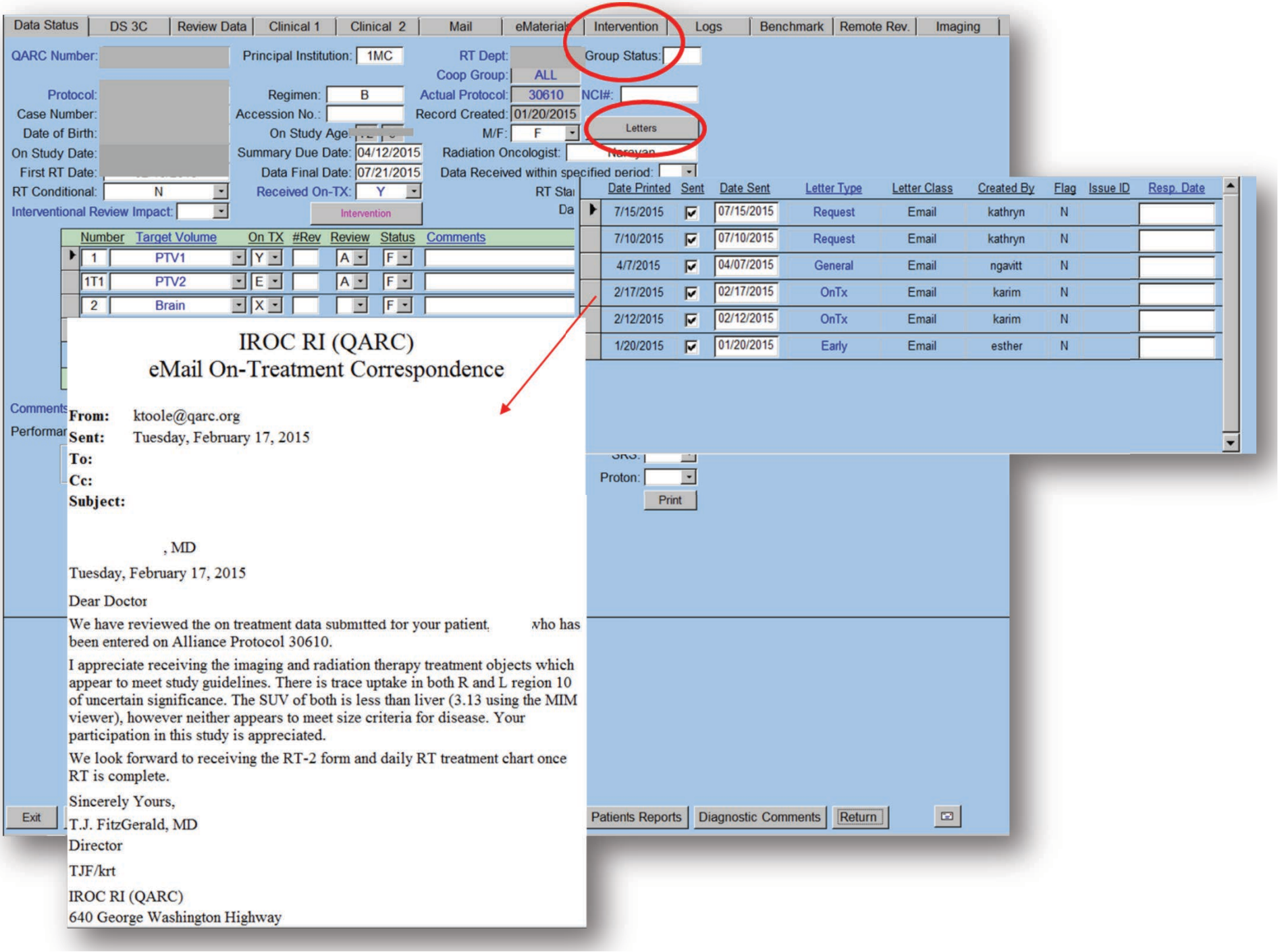


IROC RI (QARC)
eMail On-Treatment Correspondence

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

, MD

Tuesday, February 17, 2015

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.

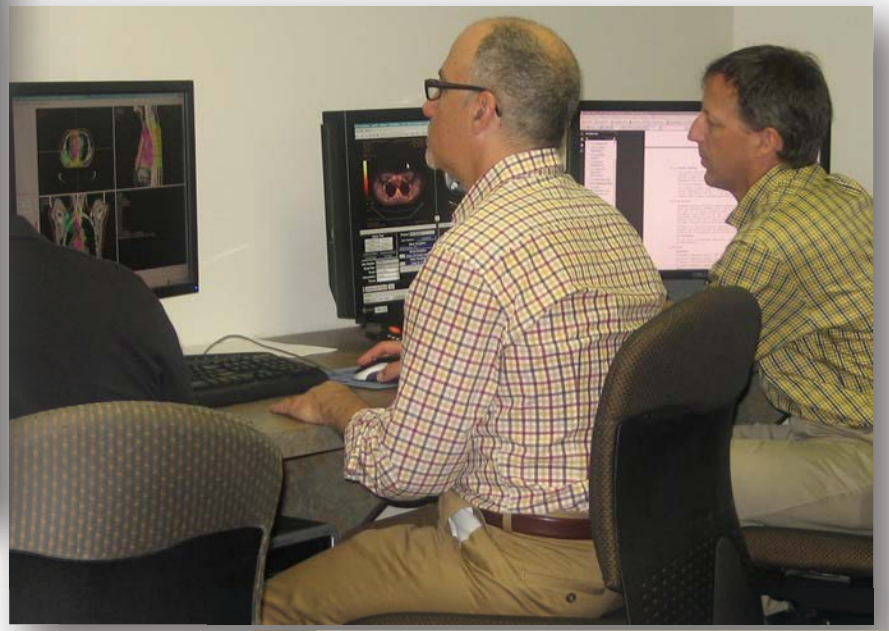
Sincerely Yours,

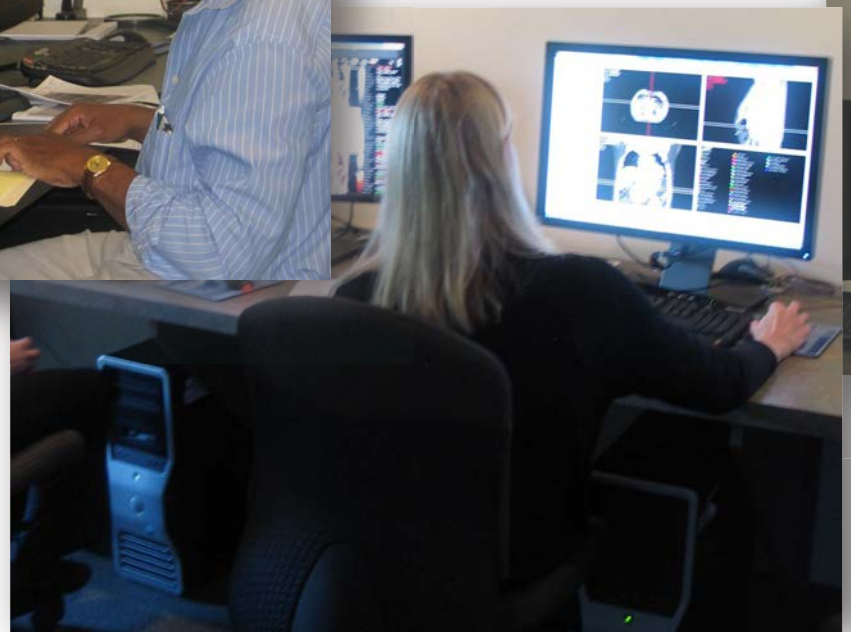
T.J. FitzGerald, MD
Director

TJF/krt

IROC RI (QARC)
640 George Washington Highway


DEC





PATIENT RT REVIEW DATA SUMMARY

Name: RT Dept:

Acc. Number: Case Number:

Coop Group: ALL Protocol: 80803 Rad. Oncologist:

Dose Summary

Target Volume	Average Fraction Dose	Protocol Fraction Dose	Fraction Dose Variation	Total Dose	Protocol Total Dose	Total Dose Variation	Volume Compliance
Esophagus	180 cGy	180 cGy	0 %	5040 cGy	5040 cGy	0 %	Appropriate

Reference Points

Reference Point	Reference Point Name	Dose Received	Protocol Dose	Percent Variation
A	Cord	4182 cGy	0-4500 cGy	0 %
B	Stomach	5365 cGy	0-5400 cGy	0 %

QARC Comments

Volumes and doses are appropriate.

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

cc

28-Aug-2015

T.J. FitzGerald, MD
Director

Phone:(401) 753-7600 Fax:(401) 753-7601

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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.

A B S T R A C T

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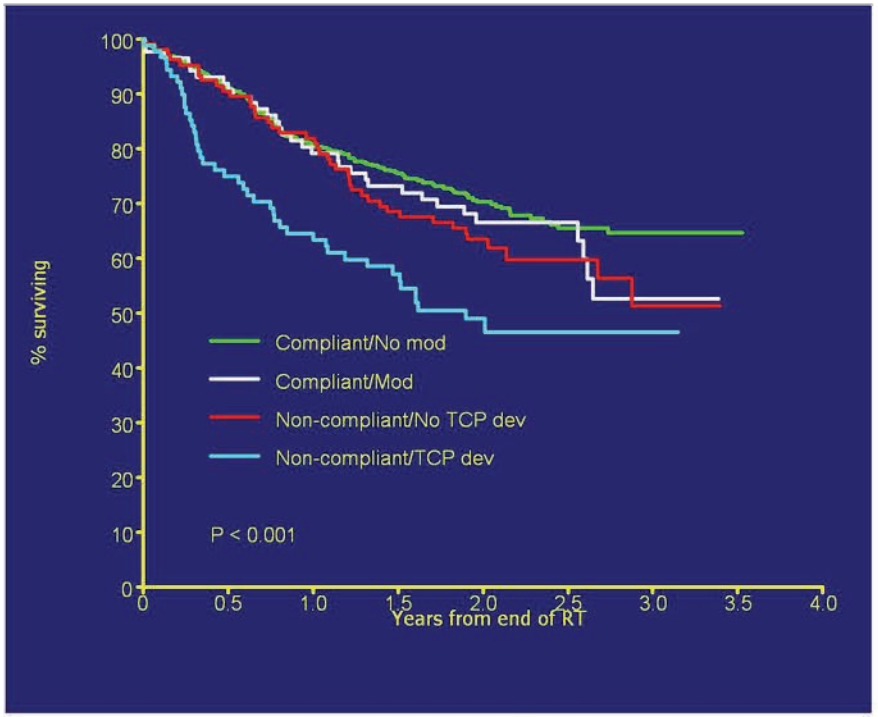
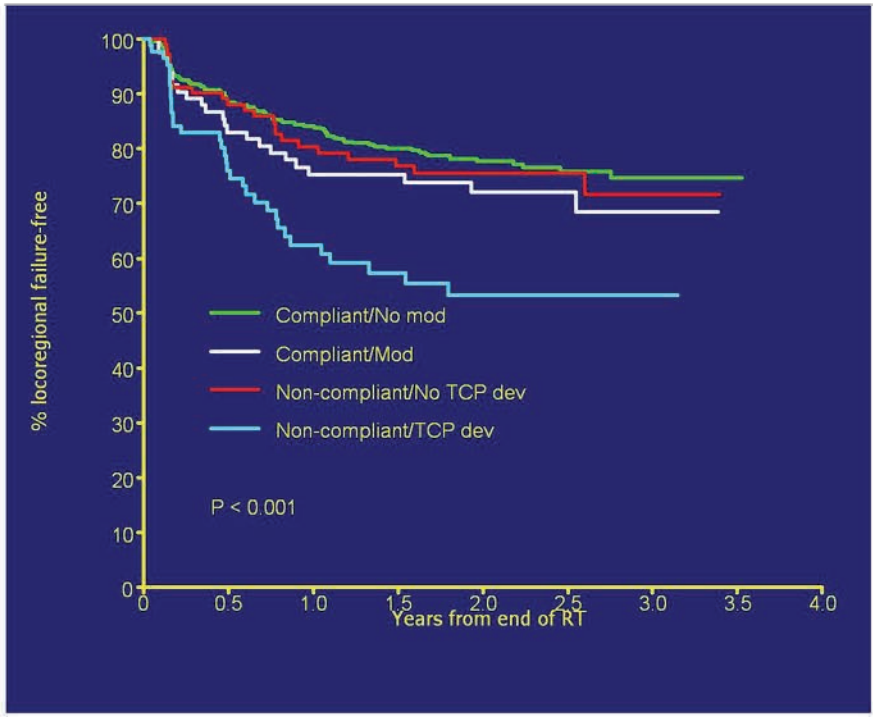
Critical impact of radiotherapy protocol compliance in the treatment of advanced HNSCC: Results from TROG 02.02



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

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

IROC IMAGING AND RADIATION ONCOLOGY CORE

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

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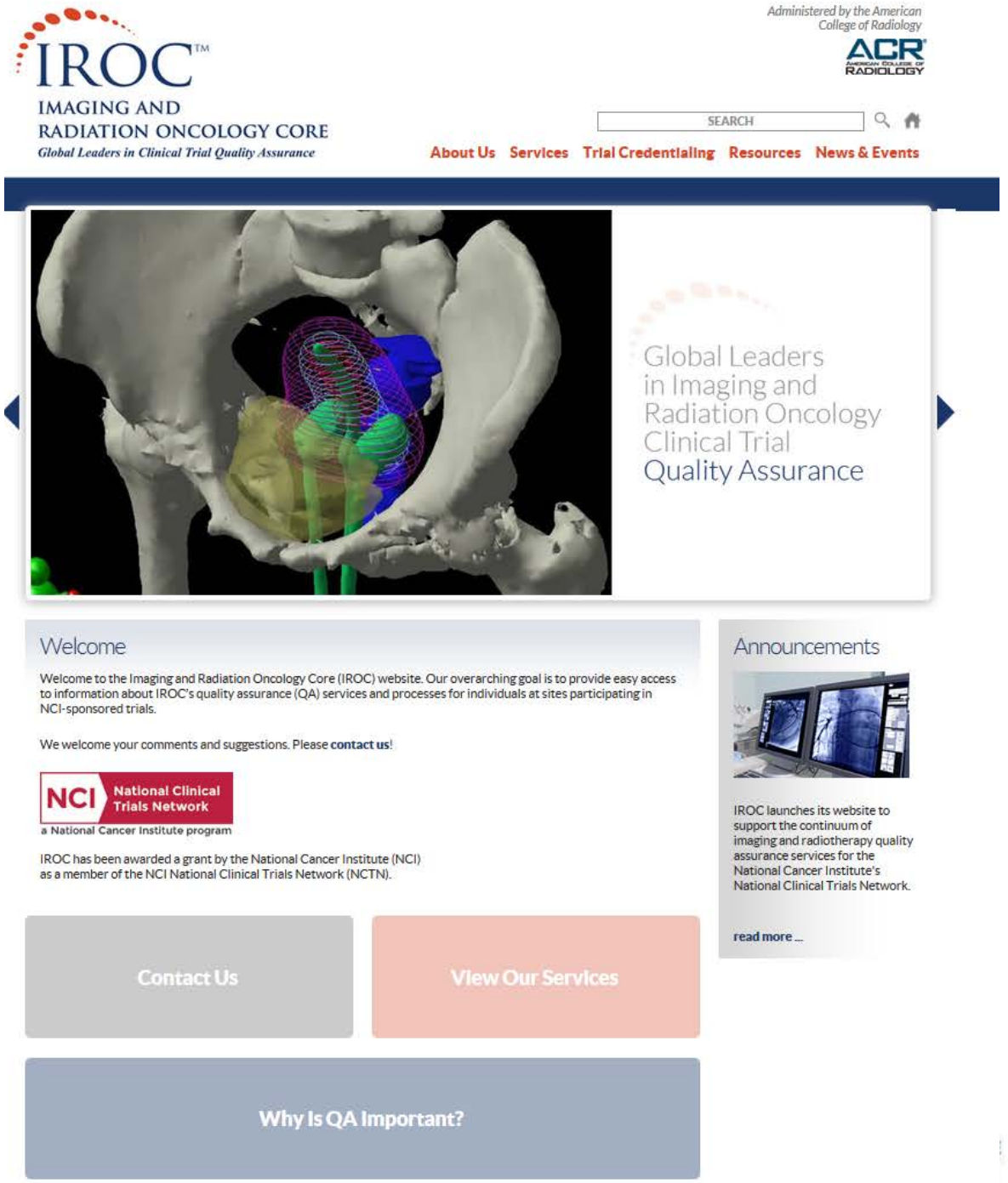
IROC
IMAGING AND
RADIATION ONCOLOGY CORE
Global Leaders in Clinical Trial Quality Assurance

https://www.irocqa.org/



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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**!

NCI National Clinical Trials Network
a National Cancer Institute program

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?

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 ...

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

 Terms Of Use **Privacy Statement** **Login**

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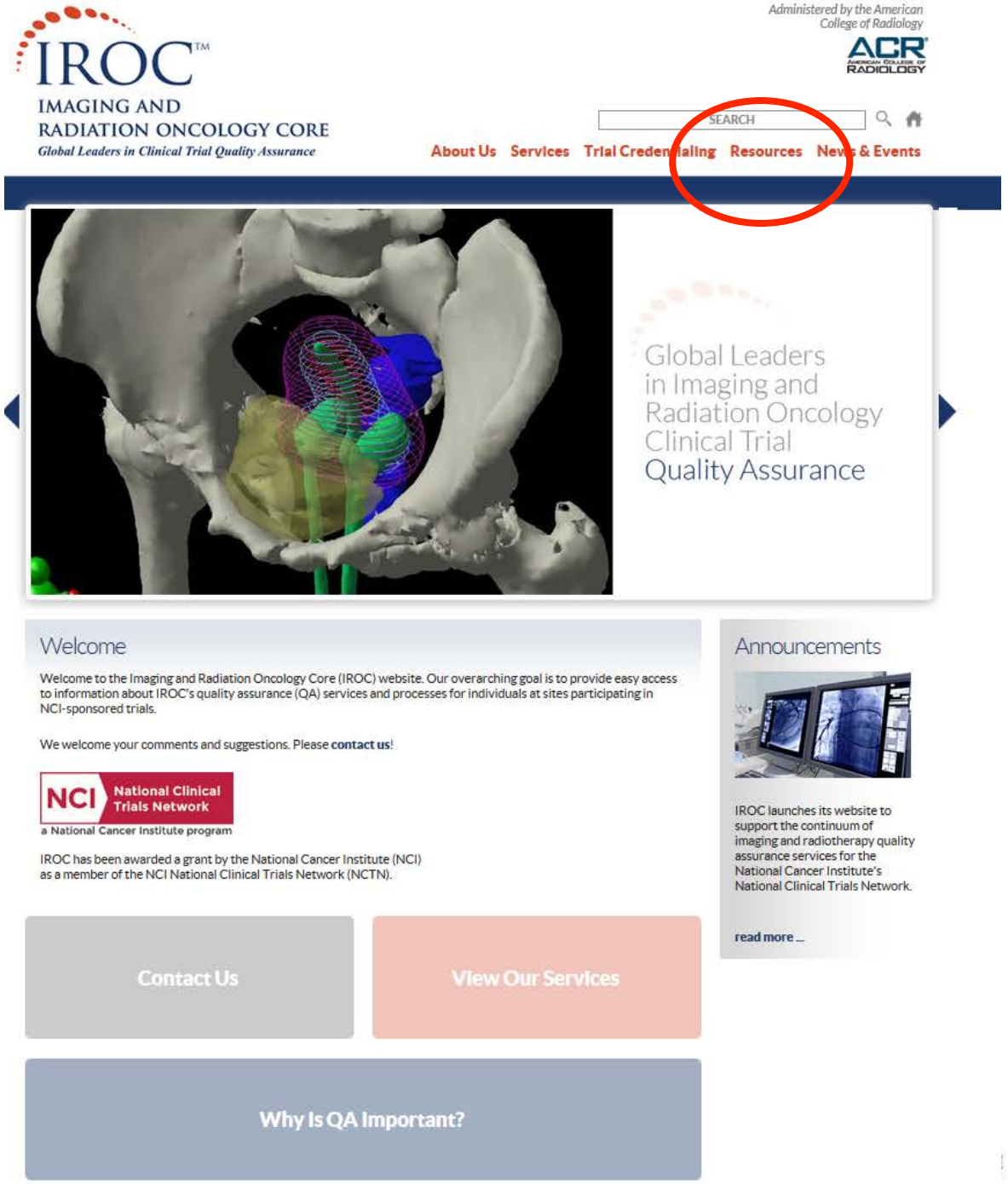

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TRIAD

TRIAD for RT QA

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.

TRIAD® ACR IMAGE AND INFORMATION EXCHANGE

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