



# Imaging and Radiation Oncology Core (IROC) Cooperative



**IROC**<sup>™</sup>  
IMAGING AND  
RADIATION ONCOLOGY CORE  
*Global Leaders in Clinical Trial Quality Assurance*

**ACR**  
AMERICAN COLLEGE OF  
RADIOLOGY

2014 SWAAPM Meeting  
Jessica Lowenstein, M.S.  
Assistant Director of IROC - Houston  
Saturday, April 12, 2014

# Clinical Trial Groups

Current

March 1, 2014

RTOG

NSABP

GOG

NCCTG

CALGB

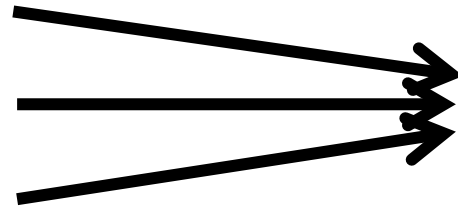
ACOSOG

ECOG

ACRIN

SWOG

COG



NRG Oncology



Alliance



ECOG/ACRIN



SWOG



COG

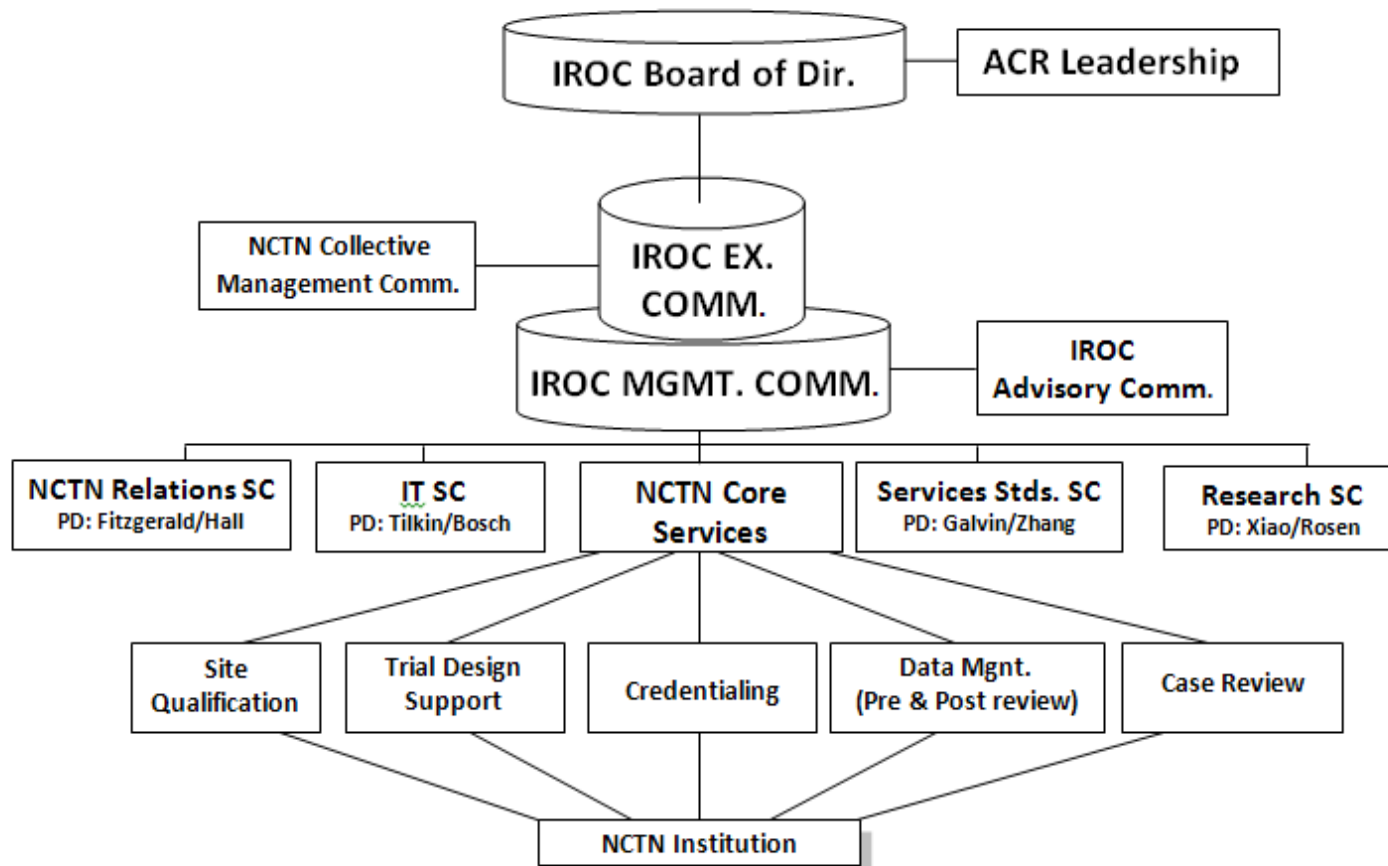




# IROC Mission

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 Leadership Structure



# IROC's Five General Core Services

- 1. Site Qualification (Houston)**  
(FQs, ongoing QA, 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), Philly (I), Ohio)**  
(tiered system to minimize institution effort)
- 4. Data Management (Houston, Philly(RT &I), Rhode Is., St. Louis)**  
(pre-review, use of TRIAD, post-review for analysis)
- 5. Case Review (Houston, Philly(RT), Rhode Is., Ohio)**  
(Pre-, On-, Post-Treatment, facilitate review logistics for clinical reviews)

Site  
Qualification

Trial  
Design  
Support

Credentialing

Data  
(pre-review)  
Management

Case  
Review

Data  
(post-review)  
Management

# IROC – Site Qualitication

1. Facility Questionnaire (on-line)
2. OSLD/TLD
3. Particle Beam Approval

**Facility Questionnaire (Demographics and Technical Information)**

All textboxes are editable. Please review the data below verifying its completeness. Use the appropriate  to periodically register modifications or additions. Use the appropriate  button at the end of the form to verify that the information is correct.

**General Institution Information**

Institution Name:	21st Century Oncology-Englewood		
Address:	Englewood Radiation Therapy Regional Ctr.		
	571 Medical Drive		
City:	Englewood		
State:	FL	Country:	USA



supplied number?

**Other Personnel** - List any other individuals who will be involved with

<http://localhost:3722/Forms2/Questionnaires/PlanningResourcesForm.aspx> Local intranet

# Trial Concept and Protocol Consultation Key Contact Offices

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

Houston will be reviewing all patients treated with brachytherapy



# IROC – Credentialing RT

## **Tier 0**

Update protocol appropriate information on FQ and data transfer capability

## **Tier 1**

Protocol Specific KA, Pre-Treatment review of 1<sup>st</sup> patient only, EXBT and Brachytherapy Benchmarks

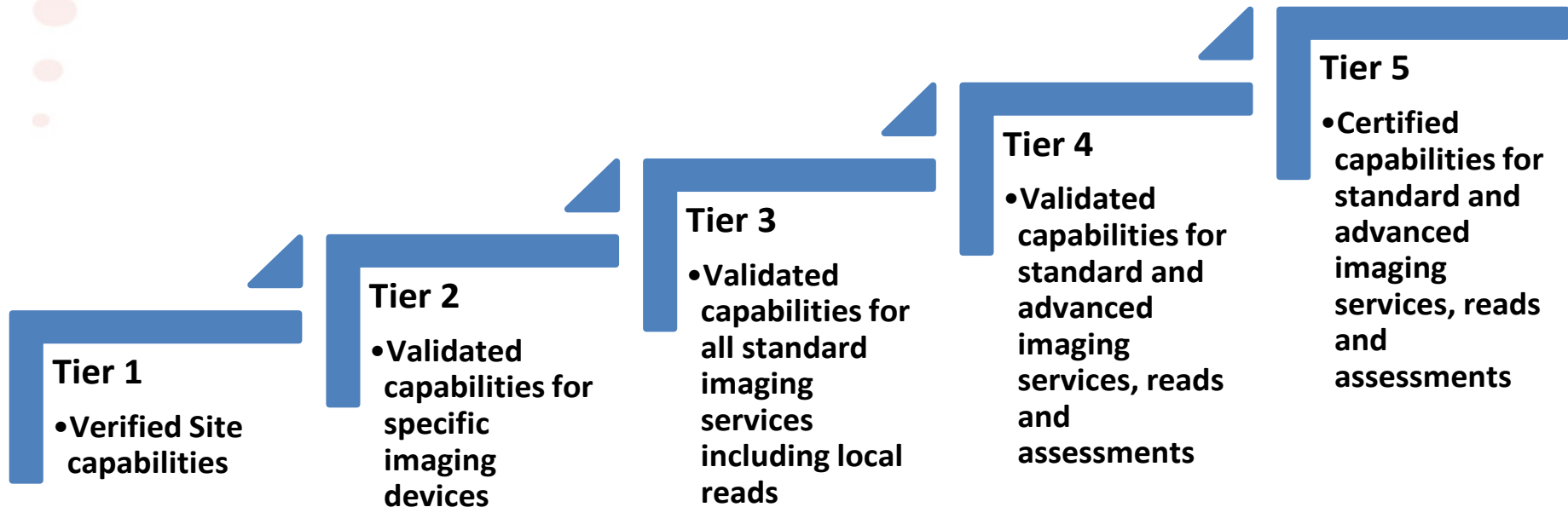
## **Tier 2**

Independent measurement of treatment deliveries

## **Tier 3**

This tier is reserved for protocols that push the limits of the lower tiers

# IROC- Credentialing Imaging



# IROC – Data Management

1. Management of data both pre-review and post-review
2. Common data entry site – TRIAD
3. RAVE – what data should be captured and review of data entered correctly
4. Post-review for analysis

# IROC – Case Review

## Patient Case Clinical and Technical Reviews

**Pre-Treatment** (formerly Rapid Review)

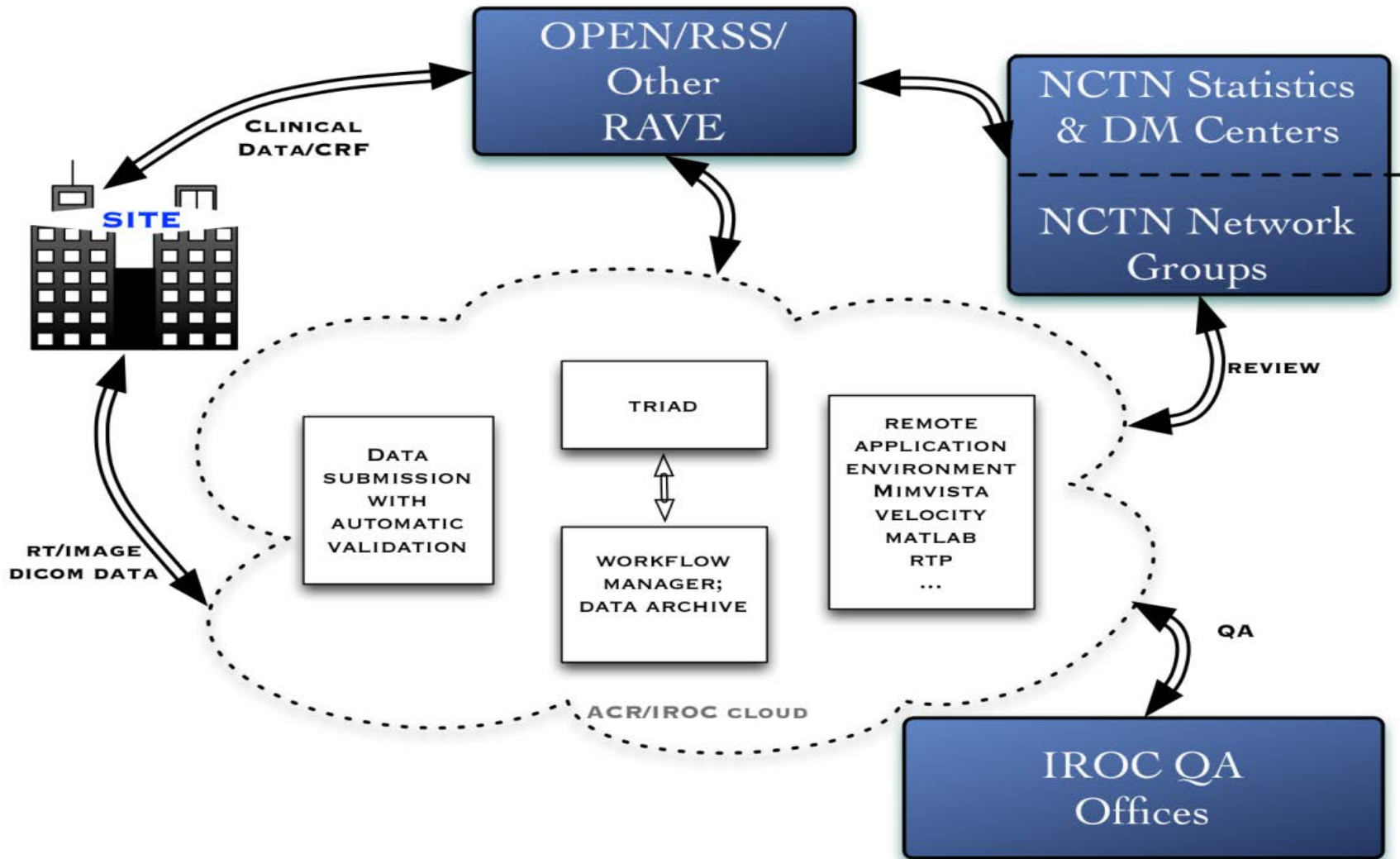
**On-Treatment**

**Post-Treatment** (formerly Retrospective Review)

**IROC facilitates the logistics and data organization for the clinical reviews.**

Groups will supply clinicians.

# The ACR/IROC Cloud



# 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.

# Where to find information on TRIAD

The screenshot displays the RTOG website interface. At the top left is the RTOG logo (RADIATION THERAPY ONCOLOGY GROUP). To the right are links for Contact Us, Data Center Logon, Site Tools, Search, and a GO button. Below this is a dark red navigation bar with white text for HOME, ABOUT US, PATIENTS, CLINICAL TRIALS, PUBLICATIONS, CORE LAB, RESEARCHERS, RESEARCH ASSOCIATES, and NEWS. The CORE LAB tab is highlighted in a yellow box, and a blue arrow points to it. A dropdown menu is open under CORE LAB, listing: Active Downloads, Advanced Technology Radiation Therapy, Contouring Atlases, Standardized Naming Conventions, RTQA Submission Information, RTQA Protocol Prescription Guidelines, Approval Process, Education/Training, Advanced Imaging, and Contact RTQA. Below the navigation bar is a large image of the Hazelrigg-Balter Radiation Oncology Center building with a fountain in the foreground. To the right of the fountain is a photo of a child with a teddy bear being attended to by medical staff. Further right is a photo of a doctor in a white coat pointing at a large monitor displaying medical images. Text on the left side of the screenshot reads: "The Radiation Therapy Oncology Group is a recognized leader in working to increase survival and improve the quality of life for cancer patients." Text on the right side of the screenshot reads: "Department of Radiation Oncology" and "The University of Alabama at Birmingham".

**RTOG**  
RADIATION THERAPY  
ONCOLOGY GROUP

Contact Us | Data Center Logon | Site Tools | Search  GO

HOME | ABOUT US | PATIENTS | CLINICAL TRIALS | PUBLICATIONS | **CORE LAB** | RESEARCHERS | RESEARCH ASSOCIATES | NEWS

- Active Downloads
- Advanced Technology Radiation Therapy
- Contouring Atlases
- Standardized Naming Conventions
- RTQA Submission Information
- RTQA Protocol Prescription Guidelines
- Approval Process
- Education/Training
- Advanced Imaging
- Contact RTQA

Department of Radiation Oncology

The University of Alabama at Birmingham

*The Radiation Therapy Oncology Group is a recognized leader in working to increase survival and improve the quality of life for cancer patients.*

Core Lab Tab of the RTOG website

Active Downloads

Advanced Technology  
Radiation Therapy

Contouring Atlases

Standardized Naming  
Conventions

RTQA Submission  
Information

RTQA Protocol Prescription  
Guidelines

Approval Process

Education/Training

Advanced Imaging

Contact RTQA

TRIAD

Core Lab > TRIAD

[TRIAD Fact Sheet](#)

[TRIAD Information](#)

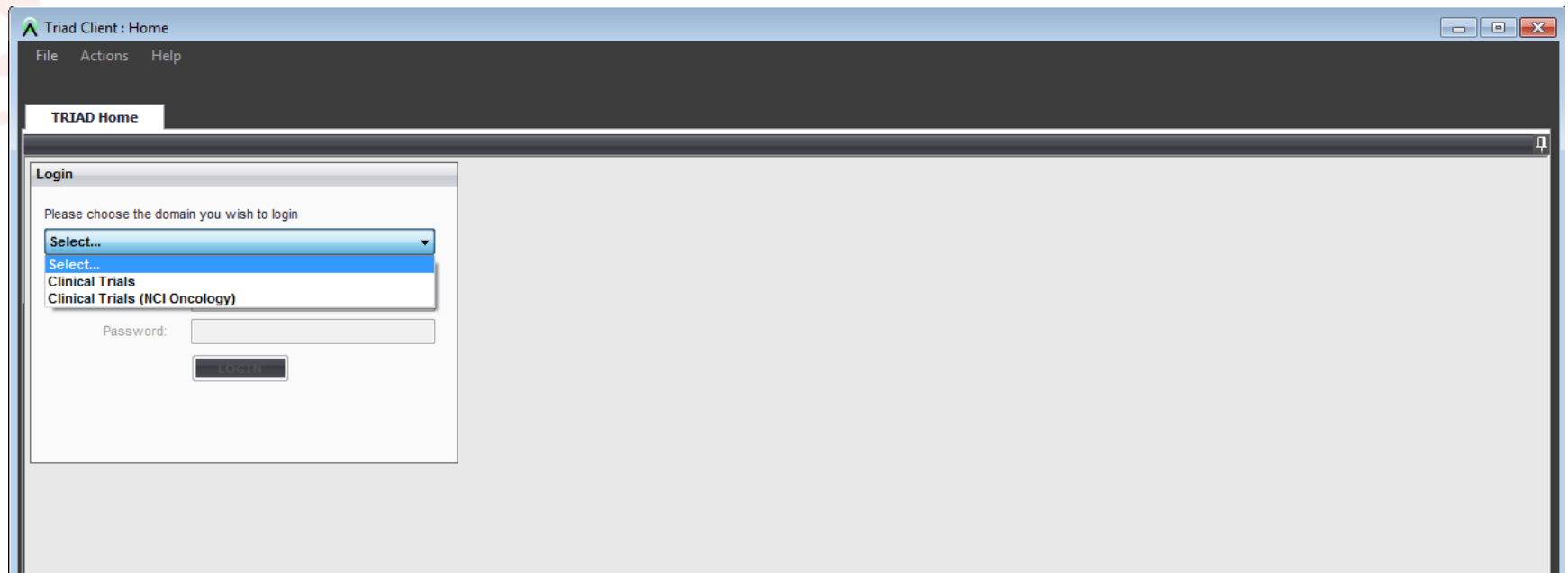
[TRIAD Installation and User Guide](#)

[Digital Data Submission Form \(DT\)](#)





# What does TRIAD look like



Select Clinical trials ( NCI oncology) note: this title will be changing soon to be more clear

# Log in page using the CTEP –IAM interface

Triad Client : Home

File Actions Help

TRIAD Home

Login

Please choose the domain you wish to login

Clinical Trials (NCI Oncology)

Username:

Password:

IAM-SSO

You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only.

Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.

By using this information system, you understand and consent to the following.

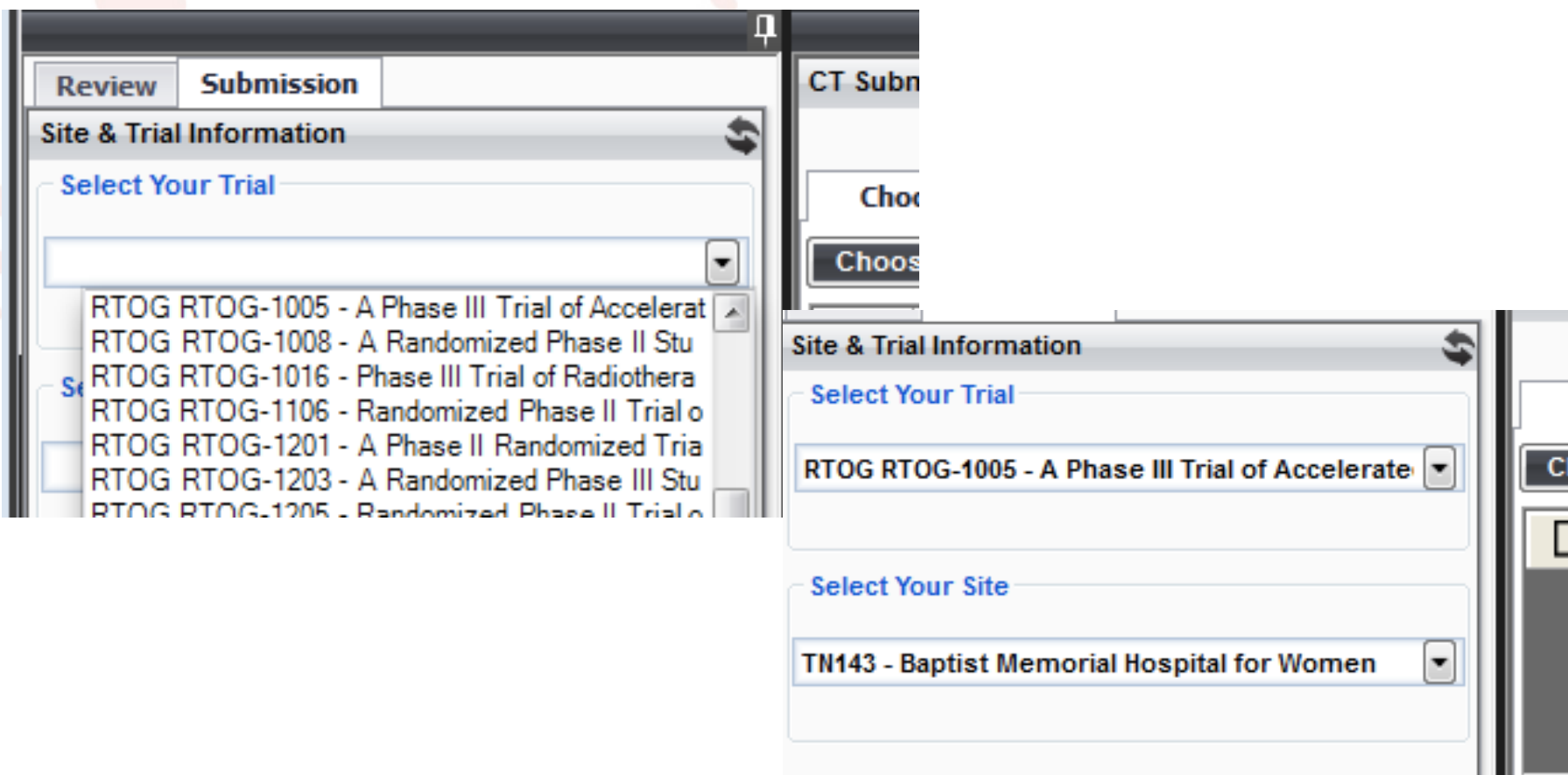
You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, record, and search and seize any communication or data transiting or stored on this information system.

Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

I Agree and Logon Reset

[Forgot Password?](#) [Reset Password?](#) [Annual Registration](#) [Request New Account](#)

Select the Trial you want to submit, and your site will pre-populate in the next box



## What if I do not see the trial I want to submit for?

TRIAD : Clinical Trials (NCI Oncology)

File Actions Help

Logout : MANFREDID1  
Choose DICOM Viewer : QC Viewer

TRIAD Home Clinical Trials (Oncology)

Review Submission

Site & Trial Information

Select Your Trial

- RTOG RTOG-0631 - Phase II/III Study of Image-
- RTOG RTOG-0815 - A Phase III Prospective Ran
- RTOG RTOG-0839 - Randomized Phase II Study
- RTOG RTOG-0920 - A Phase III Study of Postop
- RTOG RTOG-0926 - A Phase II Protocol for Patie
- RTOG RTOG-1005 - A Phase III Trial of Accelerat
- RTOG RTOG-1008 - A Randomized Phase II Stu**
- RTOG RTOG-1016 - Phase III Trial of Radiothera
- RTOG RTOG-1106 - Randomized Phase II Trial o
- RTOG RTOG-1201 - A Phase II Randomized Tria

CT Submission for Site:

Choose Files From Computer Choose Files From PACS

Choose Files Choose Folder Delete Move to Submission Queue Send To Device

<input type="checkbox"/>	DICOM Stud...	Study Descri...	Study Date	Image	Study Time	Modality	Accession N...	Attachment	Comments	Validation Res...
<input type="checkbox"/>										

<input type="checkbox"/>	Non-DICOM File Type	File Name	File Size	Open
<input type="checkbox"/>				

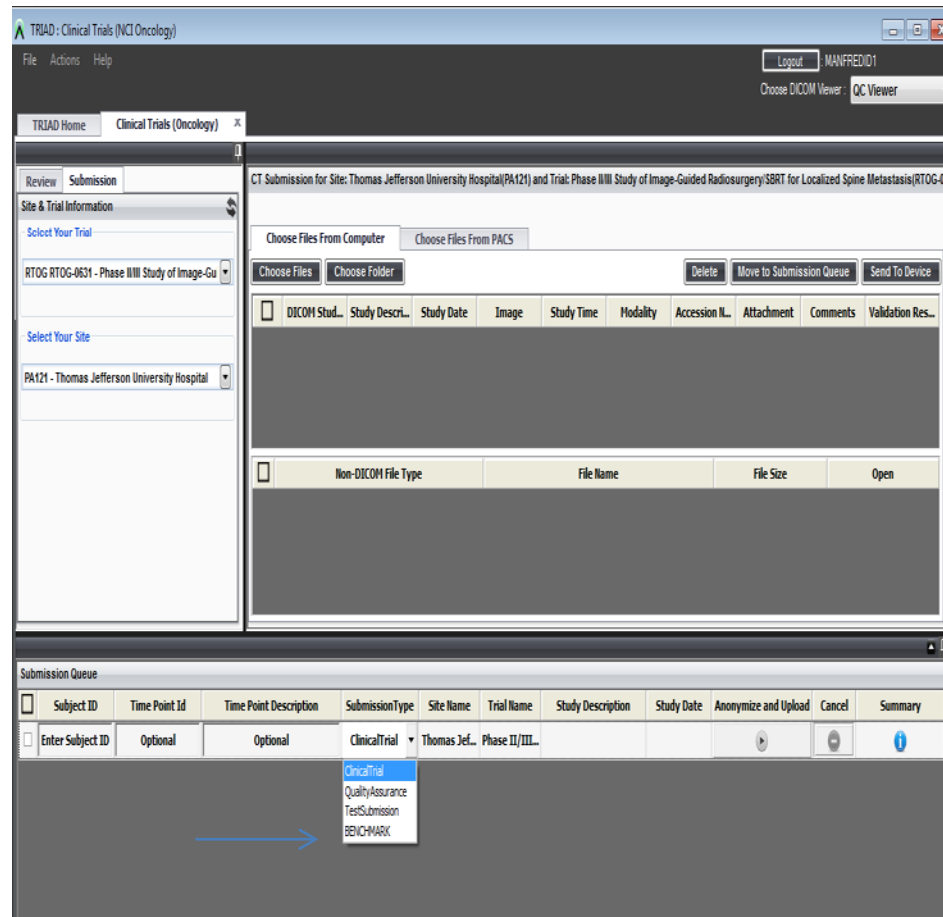
Submission Queue

<input type="checkbox"/>	Subject ID	Time Point Id	Time Point Description	SubmissionType	Site Name	Trial Name	Study Description	Study Date	Anonymize and Upload	Cancel	Summary
<input type="checkbox"/>											

Your site **must** have IRB approval for the trial to submit cases. If your IRB has expired you will not be able to submit to TRIAD. CTSU will need an updated IRB

# Trials that have RT credentialing

- To submit IGRT and Benchmarks for trials
- Once you select data to import and send to submission you can select “Benchmark” to submit.
- Note: the term benchmark will be changing to ***RT credentialing***



# Once imported select *Move to submission*

TRIAD : Clinical Trials (NCI Oncology)

File Actions Help

Logout : MANFREDID1  
Choose DICOM Viewer : QC Viewer

TRIAD Home Clinical Trials (Oncology)

Review Submission

Site & Trial Information

Select Your Trial

RTOG RTOG-0815 - A Phase III Prospective Randc

Select Your Site

PA121 - Thomas Jefferson University Hospital

CT Submission for Site: Thomas Jefferson University Hospital(PA121) and Trial: A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy with or without Sho

Choose Files From Computer Choose Files From PACS

Choose Files Choose Folder Delete Move to Submission Queue Send To Device

<input type="checkbox"/>	DICOM Stud...	Study Descri...	Study Date	Image	Study Time	Modality	Accession N...	Attachment	Comments	Validation Res...
<input type="checkbox"/>	2179	PROSTATE	4/30/2013		9:35:40 AM	RTPLAN		Select	Comments	Pending Valida...
<input checked="" type="checkbox"/>	Series Insta...	Series Descr...	Number Of Fi...	Series Num...	Modality	Attach...	Open	Meta Data	Clean Pixel ...	Comments
<input checked="" type="checkbox"/>	1.2.840.1136...		117	2	CT			<a href="#">View</a>	Clean	<a href="#">Comments</a>
<input checked="" type="checkbox"/>	2.16.840.1.11...		1	1	RTDOSE			<a href="#">View</a>	Clean	<a href="#">Comments</a>
<input type="checkbox"/>	2.25.6546332...	Posda DVHs - ...	1	1	RTDOSE			<a href="#">View</a>	N/A	<a href="#">Comments</a>
<input checked="" type="checkbox"/>	2.16.840.1.11...		1	1	RTSTRUCT			<a href="#">View</a>	N/A	<a href="#">Comments</a>

Non-DICOM File Type File Name File Size Open

Submission Queue

<input type="checkbox"/>	Subject ID	Time Point Id	Time Point Description	SubmissionType	Site Name	Trial Name	Study Description	Study Date	Anonymize and Upload	Cancel	Summary

## Data moved to submission section

- Place a Check mark next to the case to submit
- Enter the Case number under subject ID
- Submission Type.  
Select *Clinical* for cases  
*Benchmark* for credentialing data
- Click Anonymize and upload

TRIAD : Clinical Trials (NCI Oncology)

File Actions Help

Logout : MANFREDID1  
Choose DICOM Viewer: QC Viewer

TRIAD Home Clinical Trials (Oncology)

Review Submission

Site & Trial Information

Select Your Trial

RTOG RTOG-0815 - A Phase III Prospective Randc

Select Your Site

PA121 - Thomas Jefferson University Hospital

CT Submission for Site: Thomas Jefferson University Hospital(PA121) and Trial: A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy with or without Sho

Choose Files From Computer Choose Files From PACS

Choose Files Choose Folder Delete Move to Submission Queue Send To Device

DICOM Stud...	Study Descri...	Study Date	Image	Study Time	Modality	Accession N...	Attachment	Comments	Validation Res...
2179	PROSTATE	4/30/2013		9:35:40 AM	RTPLAN		Select	Comments	Pending Valid...

Non-DICOM File Type File Name File Size Open

Submission Queue

Anonymize & Upload Delete From Queue

Subject ID	Time Point Id	Time Point Description	Submission Type	Site Name	Trial Name	Study Description	Study Date	Anonymize and Upload	Cancel	Summary
1200	Optional	Optional	ClinicalTrial	Thomas Jef...	A Phase III ...	PROSTATE	4/30/2013 9:...			
Enter Subject ID	Optional	Optional	ClinicalTrial	Thomas Jeffe...	A Phase III P...					

Click to start Upload operation.

# Anonymization and Validation Summary

- To see how the data was anonymized click on the word *Summary*
- To see how the validation either passed or failed- click on the word *Success or Failed*

The screenshot shows the TRIAD Clinical Trials (NCI Oncology) interface. A 'Submission Summary Form' window is open, displaying the following information:

Clinical Trial Submission : Comprehensive summary 1/19/2014 2:47:33 PM	
SubjectID	1200
TimePointID	
TimePoint Description	
Submission Type	ClinicalTrial
Site Name	Thomas Jefferson University Hospital
Trial Name	A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy with or without Short-Term Androgen Deprivation Therapy for Patients with Intermediate-Risk Prostate Cancer
Patient Name	0938c0120
Study Description	PROSTATE
Study Date	4/30/2013 9:35:40 AM
Series Count	4
Series Description	
Number Of Files	120
Number Of DICOM Files	120
Number Of Non-DICOM Files	0
Total Size	67.23 MB
Anonymization Status	<a href="#">Success</a>
Validation Status	<a href="#">Failure</a>
Submission Status	Not Completed
Uploader	MANFREDID1
Submission Time	
Error	

Below the summary form, a 'Submission Queue' table is visible:

	Subject ID	Time Point Id	Time Point
<input checked="" type="checkbox"/>	1200	Optional	
<input type="checkbox"/>	Enter Subject ID	Optional	

A blue arrow points to the 'Summary' button in the submission queue table.



# Anonymization Summary

You can compare how it was originally identified and how TRIAD de-identified it

The screenshot displays the TRIAD Clinical Trials (NCI Oncology) web application. A central window titled "Anonymization Result Display" is open, showing a comprehensive summary of a clinical trial submission. The submission was made on 1/19/2014 at 2:47:33 PM. The trial is identified as "PROSTATE A Phase III Prospecti..." at the "Thomas Jefferson U..." site. The submission details include a Subject ID of 1200, a Study ID of 2179, and a Study Date of 4/30/2013. The summary table below compares original values with de-identified values for various tags.

Subject ID	Site Name	Study ID	Site #	Study Description	Trial Name	Study Time	Trial #	Study Date
1200	Thomas Jefferson U...	2179	0	PROSTATE	A Phase III Prospecti...	9:35:40 AM	0	4/30/2013
Series Instance UID		Series Description		Series #		Series Date		
2.16.840.1.113669.2.931128.443370300.20130513133943.191...				1				
Tag Description	Tag Number	Original Value		De-identified Value				
Accession Number	0008,0050			0				
Referring Physician's Name	0008,0090			UNKNOWN				
Station Name	0008,1010	pinncm0		pinncm0				
Physician(s) of Record	0008,1048	Mark Shaves						
Patient's Name	0010,0010	0938c0120		1200^PA121^RTOG-0815				
Patient ID	0010,0020	0938c0120		1200				
Patient's Birth Date	0010,0030							
Patient's Sex	0010,0040	M		M				
Clinical Trial Sponsor Name	0012,0010			American_College_of_Radiology				
Clinical Trial Protocol ID	0012,0020	0938		RTOG-0815				

The interface also shows a "Submission Queue" with an "Anonymize & Upload" button and a "Submission Summary Form" window. The background shows the main application menu and navigation options.

# Structure Validation

If your Validation Status is a Success then all of the Structures that were required in the protocol were submitted and labeled correctly.

**Clinical Trial Submission : Comprehensive summary**  
1/19/2014 2:47:33 PM

SubjectID	1200
TimePointID	
TimePoint Description	
Submission Type	ClinicalTrial
Site Name	Thomas Jefferson University Hospital
Trial Name	A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy with or without Short-Term Androgen Deprivation Therapy for Patients with Intermediate-Risk Prostate Cancer
Patient Name	U938012U
Study Description	PROSTATE
Study Date	4/30/2013 9:35:40 AM
Series Count	4
Series Description	
Number Of Files	120
Number Of DICOM Files	120
Number Of Non-DICOM Files	0
Total Size	67.23 MB
Anonymization Status	Success
Validation Status	Failure
Submission Status	Not Completed
Uploader	MANFREDI01
Submission Time	
Error	

**Validation Result**

Subject ID	Site #	Site Name	Trial #	Trial Name	Study ID	Study Description	Study Date	Study Time
1712	0	Central Maryland Rad...	0	A Phase III Trial of A...	11506	RT BREAST	12/27/2013	02:42:50 PM

Series Instance UID	Series Description	Series #	Series Date
2.16.840.1.113669.2.931128.850200440.2...		1	

Tag	Actual Tag Value	Rule	Result
ISO CT1			
SETUP CT1			
CALC CT1			
SPB ISO CT1			
SURG_BED		mathareal PTV_SURG_BED,	
SGN		CTV_SURG_BED,	
SGN		BREAST_IPSL,	
skin less 5mm		THYROID,	
CTV_IVB		SKN,	
PTV_IVB		PTV_IVB_EVAL,	
PTV_IVB_EVAL		PTV_IVB,	
CTV_SURG_BED		LUNG_CNTR,	
PTV_SURG_BED		LUNG_IPSL,	
PTV_SURG_BED_EVAL		HEART,	
LUNG_IPSL		CTV_IVB,	
LUNG_CNTR		BREAST_IPSL,	
HEART		BREAST_CNTR,	
THYROID		FLASH,	
BREAST_CNTR		BREAST_IPS	

# Structure Validation

If your Validation Status is labeled as failure then all of the Structures that were required in the protocol were NOT submitted and/ or labeled correctly.

The screenshot displays the TRIAD Clinical Trials (NCI Oncology) web application. The main content area shows a 'Validation Result' window for a study. The table below details the validation findings.

Subject ID	Site #	Site Name	Trial #	Trial Name	Study ID	Study Description	Study Date	Study Time
1682	0	Saint Joseph Mercy O...	0	A Phase III Trial of A...	abc			12:00:00 AM

Series Instance UID	Series Description	Series #	Series Date
2.16.840.1.114337.64954674509.18352.1...		1	

Tag	Actual Tag Value	Rule	Result
StructureSetROISequence( 3006,0020 )	patient, BREAST_CNTR, SURG_BED, CTV_WB, HEART, LUNG_IPSI, LUNG_CNTR, PTV_WB, PTV_WB_EVAL, SKIN, THYROID, CTV_SURG_BED, PTV_SURG_BED, PTV_SURG_BED_E,	<b>musthaveall</b> PTV_SURG_BED, CTV_SURG_BED, BREAST_IPSI, BREAST_CNTR, THYROID, SKIN, PTV_WB_EVAL, PTV_WB, LUNG_CNTR, LUNG_IPSI, HEART, CTV_WB, SURG_BED, BREAST_CNTR	<b>X</b>

Buttons at the bottom of the table: Show All, Show series in range, Show series out of range, Show series not validated.

# IROC Home Page (www.irocqa.org)



IMAGING AND  
RADIATION ONCOLOGY CORE

Global Leaders in Clinical Trial Quality Assurance [About Us](#) [QA Services](#) [Credentialing](#) [Trials](#) [Resources](#) [News & Events](#)

Global Leaders  
in Imaging and  
Radiation Oncology  
Clinical Trial  
Quality Assurance

## Welcome

Welcome to the recently launched Imaging and Radiation Oncology Core (IROC) Website. Our goal is to provide easy access to information about IROC's quality assurance (QA) services and processes for individuals at all levels participating in NCI-sponsored trials. We keep the community of researchers up to date about new Website content, materials and functionality through periodic announcements that are archived on the Website.

We welcome your comments and suggestions. Please contact us!

[Contact Us](#)

[View Our Services](#)

## Announcements



IROC launches its quality assurance Website to support the National Cancer Institute's National Clinical Trials Network. [read more ...](#)

## Why Is QA Important?

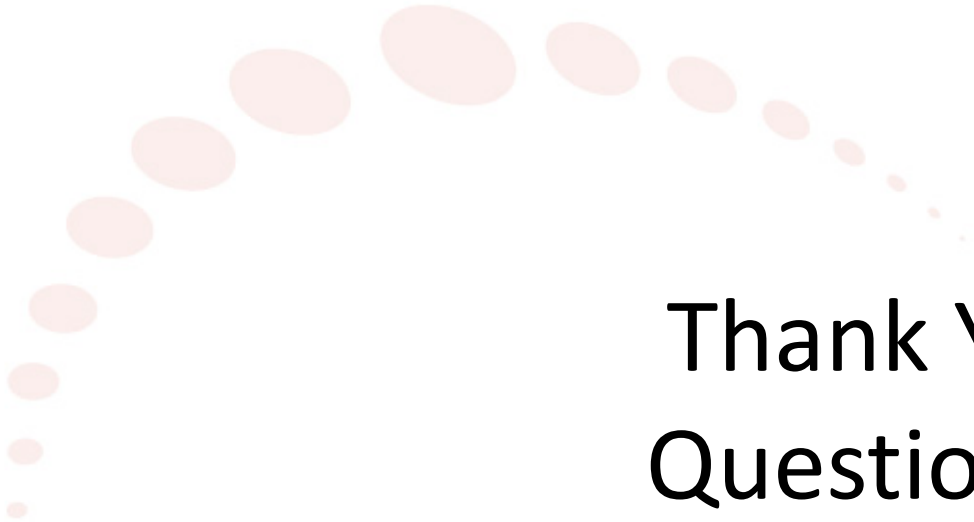
### Quality Assurance Centers

- ACE Diagnostic Imaging Core Laboratory  
IEOC Philadelphia - Imaging
- Imaging Core Laboratory  
IEOC Ohio
- Image Guided Therapy Center  
IEOC SL Seattle

- Quality Assurance Service Center  
IEOC Rhode Island
- ACE Radiation Oncology Core Laboratory  
IEOC Philadelphia - RT
- Radiological Physics Center  
IEOC Houston

# Summary

- 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.
- Collaboration and feedback from NCTN Groups is required.
- Groups to have complete accessibility to data.



Thank You  
Questions?

# 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**

# Accessing TRIAD

- NRG sites: The Lead RA must first update their RTOG roster and submit it to membership, once notified by membership you then contact CTSU to update in their system as well



# Accessing TRIAD

- NON- NRG sites need to update their rosters directly through the CTSU helpdesk
- As protocols are amended, RT data for all NRG trials will be submitted via TRIAD

# Validation Failure

- Currently even if the structure validation failed. The import to TRIAD is still completed.
- You may be requested to resubmit the case correctly once it is QA'd.
- Please note that it did not comply and submit your next case correctly.

# Structure Validation

- In the near future however, structures names that do not match the list in the protocol or are missing required structures will not be imported into TRIAD
- The issues will need to be resolved at the site before it can be submitted to TRIAD

# Structure Validation

- Tell your physics and dosimetry staff to always access the protocol on the website for the most up to date version.
- 2 weeks prior to this implementation a broadcast will go out indicating the affective date as each trial is rolled out.
- Ensure your dosimetry staff know when this will be enforced