IROC Digital Data
Quality Assurance
Y. Xiao, IROC Philadelphia RT
Michael Weldon, Ohio State University

NCTN Structure
- 5 U.S. groups (4 adult and 1 pediatric) and 1 Canadian group
- More centralized functions for operational efficiencies
- Will optimize use of scientific innovations
- LAPS provide leadership in development and conduct of clinical trials in association with the adult clinical trial groups

Legend:
- Centralized functions:
  - Clinical Institutional Review Board
  - Cancer Trials Support Unit
  - Radiotherapy/Imaging Cores
  - Common Data Management
  - System Control Hosting
- 3D lead Academic Participating Sites (LAPS)
- Operations
- Statistics and Data Management
- Tumor Banks
- Memorial Sites

Fig. 1.
NRG Committee Structure

Centralized data submissions, review and analyses
TRIAD Integration

- CTSU is currently supporting the American College of Radiology (ACR) team to integrate their TRIAD (Transfer of Image and Data) application with CTEP-IAM, RSS and Rave.
- The primary objective of RSS-TRIAD-Rave integration is to streamline the clinical trial image submission process and to increase the imaging QA/QC efficiency, QA productivity and data accuracy.
- This integration will support all the LPO trials with imaging/Radiotherapy component.
- This integration is released to production on a pilot basis in the middle of September 2013.
General User Workflow

Explanation for the numbered items on the previous slide

1. The user logs into TRIAD
2. The user is authenticated by CTEP-IAM system
3. TRIAD access CEWS to get the list of studies and sites the user has access to. User will select the study and site for which they want to upload the image
4. TRIAD will get the patient list from Rave for the study and site selected by the user
5. TRIAD will also get the list of time points from Rave
6. User selects the patient and time point and upload the radiological image
7. TRIAD extract the DICOM tag data and upload that to a Rave form for the specific patient
8. IROC user logs into TRIAD, and perform QC on the selected patient’s image
9. The IROC user is authenticated by CTEP-IAM system

10. They record the QA/QC results on a Rave form

Integration Details

- User Access
  - CTEP-IAM
  - Rostering
  - Roles
- Study Setup to Support Integration
  - Protocol Documentation
  - Rave Forms
  - RSS Flags
- User Support
  - Access Issues
  - TRIAD Application Issues
Rostering and Roles

- What the site user should do
  1. Set permanent password for CTEP-IAM
  2. Contact their affiliated group to be added to the roster
  3. Contact their CTSU Site Administrator to be assigned the appropriate role

- What the QC user should do
  1. Set permanent password for CTEP-IAM
  2. Contact their QC Center administrator to request a QC Center role on the CTSU roster
  3. User contacts Lead Protocol Organization (LPO) to be assigned Rave user access

- Don’t Sweat
  – Automated e-mail from CTSU regarding temporary access this is your reminder to complete step #2

Resources

- Resources
  – CTSU Help Desk: ctsucontact@westat.com or 1-888-691-8039
  – CTEP Registration: ctepreghelp@ctep.nci.nih.gov or 703-738-9171
  – CTEP-IAM website: https://eapps-ctep.nci.nih.gov/iam/index.jsp
  – CTSU website: www.ctsu.org
    • TRIAD Help Sheet
    • CTEP-IAM Fact Sheet

- http://triadhelp.acr.org
  – More documents and webex sessions coming
http://triadhelp.acr.org

NCI-Sponsored Trials
TRIAD is the only image management workflow system that tightly integrates with National Cancer Institute's (NCI) National Clinical Trials Network (NCTN) core systems allowing research personnel at NCTN research sites to submit data and images for the trials that are part of NCTN.

Users who will use TRIAD for image management for NCTN trials will utilize their CTEP-IAM user name and password to login. TRIAD also provides DICOM header data to NCTN systems (None) for automatically populating the protocol specific forms. Please review the documents in Quick Links to find out how to use TRIAD for NCTN trials.

Quick Links
- Instructions on Getting Access to TRIAD
- CTEP-IAM Account Registration Link
- TRIAD Installation Link
- TRIAD Installation and User Guide

Additional Resources

NRG Protocol Template
Radiation Therapy Section Highlights
5.2.4 Definition of Target Volumes and Margins

Note: All structures must be named for digital RT data submission as listed in the table below. The structures marked as “Required” in the table must be contoured and submitted with the treatment plan. Structures marked as “Required when applicable” must be contoured and submitted when applicable. Resubmission of data may be required if labeling of structures does not conform to the standard DICOM name listed. Capital letters, spacing and use of underscores must be applied exactly as indicated.

Entries in the first column of the list below will be entered and edited by the QA Staff. The PIs are required to specify the information in the second, third columns. The detailed specifications have to include crucial items such as boundary definitions and margins.

<table>
<thead>
<tr>
<th>Standard Name</th>
<th>Description</th>
<th>Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>GTV_7000</td>
<td>GTV to receive 70 Gy</td>
<td>Required</td>
</tr>
<tr>
<td>IGTV_7000</td>
<td>Volume enveloping GTV motion over the course of a respiratory cycle</td>
<td>Required when applicable</td>
</tr>
</tbody>
</table>

Structure Naming Rules

- Imaging/time point, e.g. CT1XXX, PT2XXX for phase 1 CT and phase 2 PET of adaptive processes;
- Structure description;
- Dose level for target volume or related non target volume;
- Structure expansion, e.g. 03 for 3 mm uniform expansion and PRV for non-uniform expansion;
- Anatomical location, e.g. L for left and Up for upper;
- Derivation of the structure, e.g. LivermGTV for Liver minus gross tumor volume.

J. Yu et al, IROC RT Centers, Red Journal, In Print
### 5.2.7 Compliance criteria

The compliance criteria listed here will be used to score each case. Given the limitations inherent in the treatment planning process, the numbers given in this section can be different than the prescription table. The Per Protocol and Variation Acceptable categories are both considered to be acceptable. Per Protocol cases can be viewed as ideal plans, and the Variation Acceptable category can include more challenging plans that do not fail at or near the ideal results. A final category, called Deviation Unacceptable, results when cases do not meet the requirements for either Per Protocol or Variation Acceptable. Plans falling in this category are considered to be suboptimal and additional treatment planning optimization is recommended.

- **$$V_{D_{10}}$$** (cc), $$V_{D_{20}}$$, $$V_{D_{30}}$$, $$V_{D_{40}}$$: Volume (cc or %) receiving D_{10}, D_{20}, D_{30}, D_{40}
- **$$D_{10}$$ (Gy), $$D_{20}$$ (Gy): Dose (Gy or %) to Volume (cc or % of total volume)
- **$$D_{min}$$ (Gy) or $$D_{max}$$ (Gy): Minimum dose is defined to a volume that is the total volume minus 0.03 cc
- **$$D_{min}$$ (Gy) or $$D_{max}$$ (Gy): Maximum dose is defined to a volume of 0.03 cc
- **$$D_{mean}$$ (Gy) or $$D_{mean}$$ (Gy): Mean dose in Gy or %
- **$$R_{100%}$$**: Ratio of 100% isodose volume over structure volume (SRT only)
- **$$R_{95%}$$**: Ratio of 95% isodose volume over structure volume (SRT only)

**Normalization of Dose**: The plan is normalized such that 95% of the PTV_{6000} volume receives prescription dose of 60 Gy.

#### Note: Deviation Unacceptable occurs when dose limits for Variation Acceptable are not met

### Target Volume Constraints and Compliance Criteria

<table>
<thead>
<tr>
<th>Name of Structure</th>
<th>Dosemetric parameter*</th>
<th>Per Protocol</th>
<th>Variation Acceptable</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTV_{6000}</td>
<td>D_{min}(Gy)</td>
<td>60</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>D_{max}(Gy)</td>
<td>60</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>D_{mean}(Gy)</td>
<td>54</td>
<td>51 to 54</td>
<td></td>
</tr>
<tr>
<td></td>
<td>D_{mean}(Gy) 66</td>
<td>66</td>
<td>66 to 69</td>
<td></td>
</tr>
</tbody>
</table>
### 13.2

**Digital Data Submission Requirements**

*This section for QA staff only*

<table>
<thead>
<tr>
<th>Item</th>
<th>Due</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Arm 1</strong></td>
<td></td>
</tr>
<tr>
<td>DICOM Items</td>
<td>DICOM CT Image</td>
</tr>
<tr>
<td></td>
<td>DICOM CT Image (Contrast)</td>
</tr>
<tr>
<td></td>
<td>PET Image</td>
</tr>
<tr>
<td></td>
<td>DICOM Structure</td>
</tr>
<tr>
<td></td>
<td>DICOM Dose</td>
</tr>
<tr>
<td></td>
<td>DICOM RT Plan</td>
</tr>
<tr>
<td>Screen Capture of Fusion</td>
<td></td>
</tr>
<tr>
<td>DVH Analysis Worksheet</td>
<td></td>
</tr>
<tr>
<td>Digital Data Submission Information Form</td>
<td></td>
</tr>
<tr>
<td>(Web link)</td>
<td></td>
</tr>
</tbody>
</table>

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**Clinical Perspective of implementing and using TRIAD**
What’s at The Ohio State University Medical Center

• The Ohio State Medical Center consists the James Cancer Hospital and Solove Research Institute, Ross Heart Hospital, and several other hospitals and research laboratories
• Became a comprehensive cancer center (CCC) in 1976
• Department of Radiation Oncology:
  – Employs 15 physicians, 10 dosimetrist, 11 physicists, 30+ therapists
  – Increasing to 9 linacs in Dec 2014 with expansion of medical center
  – Also includes many different treatment modalities, including HDR, LDR, SBRT, SRS, IORT, TBI/TSI

Clinical Trials Involvement

• Have participated in clinical trials with SWOG, Alliance, NRG, ECOG/ACRIN, COG, as well as internal studies
• Currently have been involved in 27 RTOG studies, of which 18 are open as of July 2014
• For RTOG 1005 and RTOG 1016, have submitted 52 and 40 patients respectively. Both trials started prior to the switch over to TRIAD
Implementing TRIAD

- RTOG 3501 was the first trial we had open which required submission via TRIAD
- At this point, TRIAD v4 was ready to be released, and our site was used as the first test site
- Specs were given to our IT group, and we began the process of implementing TRIAD in our department
- Ideally would run similarly to our original method (secure shell FTP), as the system worked well and was easy to use
- Characteristics we wanted:
  - Centralized access for all site users
  - Easy to use, easy to manage
  - Centralized tracking of data submitted by site for all users
  - Can access shared drive where data to be uploaded would be stored (preference of our site, instead of exporting directly to TRIAD)
  - Anonymizes patient data prior to submission
  - Works well for many users from many different areas in the same institution (should also work for small sites with few users as well)

Implementing TRIAD

- Needed to install TRIAD for dosimetrists to be able to submit data
- Originally tried to run TRIAD over Citrix, but as it is not installed as an executable, so we were unable to do so
- In addition, we learned that it installs under the User who installs it, specifically tied to their profile
- Successfully installed it on a virtual machine (VM), and which we used a remote accessing software to connect to
  - Required a Webex session and a few phone calls with TRIAD Help Desk
- Used a generic access so that only one version needed to be installed
  - Easier to trouble-shoot
  - Less work for IT in the long-run
  - Drive maps set to secure shared drive where clinical trials data is stored
Access and Data Submission

• Tested submissions were performed and successful
• Trials are divided between the accounts based on NCI funding
  – Clinical Trials: requires TRIAD login account (easy to obtain)
  – Clinical Trials (NCI Oncology): Requires CTSU account (Requires more time and paperwork)

Access and Data Submission

• Through discussion with RTOG and the TRIAD workgroup, we were allowed to delay submission until we had established TRIAD so it would function with our current setup
• Signing up for accounts is well documented, but a complicated process and is time consuming to get multiple people signed up and trained
• In addition, requires to be put on CTSU roster as a TRIAD User by data administrator, which at the time we did not know who it was (turned out to be a Data Admin in our CTO)
Access and Data Submission

- Through several meetings and impromptu training sessions, have managed to get 8 dosimetrists and 2 physicists signed up and able to use software
- Issues we’ve run into since installation
  - Frequent changes in password or inactivation of accounts.
    - Rectified by calling the help desk of either TRIAD or CTSU
  - Rejection of submitted data
    - RTOG 1005 was switched midway through the trial to TRIAD submission, along with changes in the structure naming convention, but we were not aware until after the first rejection Broadcast from NRG, physicist&dosimetrist take notice!
    - As a result, we have had 20 patients rejected due to structure name mismatch
    - Required 2 dosimetrists and 1 physicist ~3 hours per patient to rectify and re-submit
    - Solution: Whenever a trial is started, it is checked to see if it is TRIAD compliant. If so, a structure template is created specifically for that trial. Clinical research coordinators are asked to contact us if any trials are to be switched over to TRIAD as well.

Submission Method Checklist

- Characteristics we wanted:
  - Centralized access for all site users
    - **Check!**
  - Easy to use, easy to manage
    - With training, **Check!**
  - Centralized tracking of data submitted by site for all site users
    - User currently only sees what they have submitted, but this is being looked into
    - Can access shared drive where data to be uploaded would be stored
      - **Check!**
  - Anonymizes patient data prior to submission:
    - **Check!** (inherent in the system)
  - Works well for many users from many different areas in the same institution
    - After developing current setup, **Check!**
Next Step

- **Goal:**
  - To submit data for clinical trials reliably and efficiently
  - Minimize rejection of data

- Implement TRIAD beyond Radiation Oncology. Some trials are not involved in radiation therapy and will require CTO employees to submit

- Coordinate with clinical research managers in CTO to facilitate independent VM to install TRIAD on, to be managed by each site specific group

- Offer training and guidance to assist users to become familiar with process

Suggestions to new TRIAD users

- Based on institution size and number of clinical trials, determine what setup works best
- Coordinate with IT, radiation oncology and your clinical trials group to facilitate implementation
- For those who will be submitting data, make available published guidelines and create your own if necessary
- Determine who your TRIAD data administrator is, as they will be crucial to getting people added to CTSU roster
- Don’t be afraid to call the help desk!
- Pay attention to updates of your clinical trials, and whether new trials are TRIAD compliant
- Create structure templates for your clinical trials in your Treatment Planning System. This will save time in the long run
Future Options?

The Assistant is a combination of computer programs that are designed for both QA center (e.g. IROC) and institutions (hospitals/cancer centers).

For the institution: the Assistant does pre-submission check which includes completeness, data integrity and DVH criteria, etc. A pass-ticket is created upon successful check. The pass-ticket will be submitted together with the patient data to data center.

Guidance will be provided if the case failed the pre-submission check.

Acknowledgements

Y. Gong, J. Yu, T. Giaddui, W. Chen
D. Manfredi
U. Kocabas
Windows Client Installation and User Guide

TRIAD v4
Clinical Trials
Hardware & Software Requirements

Hardware requirements (recommended):
- 2 GB RAM
- 2.4 GHz Processor
- 60 GB Hard Disk space

Software requirements:
- Microsoft .NET 4.5 Framework Full Version (requires administrative privileges on the computer to install)
- OS: Windows 7 (32 or 64 bit)
Installation

- Please open the following link to install TRIAD 4 Windows Client:
  
  https://triadinstall.acr.org/triadclient/

- TRIAD will launch after the installation is completed successfully.
Login to TRIAD

- Users will need to have accounts to login to TRIAD
- There are two different ways to login to TRIAD:
  - CTEP-IAM account:
    - Users will need to have CTEP-IAM accounts with proper TRIAD user role to login to TRIAD for Clinical Trials (NCI Oncology). To receive a CTEP-IAM account, please use the following link [https://eapps-ctep.nci.nih.gov/iam](https://eapps-ctep.nci.nih.gov/iam) to get a CTEP-IAM account and contact your site lead RA to get a TRIAD role assigned.
  - TRIAD account:
    - Users who will submit images for trials that are not Clinical Trials (NCI Oncology) will need to get a TRIAD account to login. Please go to: [https://cr-triad4.acr.org/TRIADWeb4.0/](https://cr-triad4.acr.org/TRIADWeb4.0/) to register for an account.

- Same user may potentially have trials that will require them to login to TRIAD using both IDs.
Login to Clinical Trials Domain

Use the Username and Password that you have received when registered on TRIAD website.

Click onForgot Password to receive a link by email to reset new password.
Login to TRIAD Clinical Trials (NCI Oncology) Domain

Domain (selectable drop-down menu)

Use your CTEP IAM account to log into TRIAD Clinical Trials (NCI Oncology) domain.
Select Site & Trial Information

- Site/trial are from RSS for CTEP trials

Select the Site & Trial from the dropdowns for which the files are to be uploaded
Submission Sources

- TRIAD provides features for submitting files from multiple sources:
  - Local computer / network drive: Files can be located in local computer folders, local CD/DVD drives or network drives. There are two ways to get upload data:
    - Files: User can select single or multiple files
    - Folders: User can select a folder and by selecting folder, all files in the folder will also be selected automatically
  - PACS: TRIAD has ability to query PACS for the study to submit
Submit Files from Computer / Network Drive
Select ‘Choose Files from PACS’ and click ‘Choose Files’ button to open a new window to search for images in PACS.

Click ‘Manage’ to add information of PACS from where you will retrieve files.
Submit Files from PACS (2/8)

- Click on “Actions” from the top menu and select “Settings”

- In the Settings window, click on DICOM Server
Submit Files from PACS (3/8)

- Parameters on this window should be provided to external DICOM device / PACS for connectivity. You can also update them as needed.
Select 'Choose Files from PACS' and click 'Choose Files' button to open a new window to search for images in PACS.

Click 'Manage' to add information of PACS from where you will retrieve files.
Submit Files from PACS (5/8)

- Click “Add” in the pop-up window and provide details for your PACS.
- Click “Test Connection” to verify the connectivity.
- Click “Save” to save device details and close the window.

![Image of device management window with options for select device, description, IP address, AE title, port number, and actions to remove, test connection, add, and save.]

American College of Radiology
Submit Files from PACS (6/8) – Query / Retrieve

Select PACS from dropdown

Provide the ‘Search’ details (Patient ID is mandatory) and click on ‘Search Images’

Select the images from search results by clicking the checkboxes

Click on ‘Select Images’ to load the selected files into TRIAD preview panel.
Submit Files from PACS (7/8) -- Listen

- You can send files directly from your DICOM device
- Make sure that “Select Images” window opened before sending the images from the DICOM device
Select the images from search results by clicking the checkboxes.

Click on ‘Select Images’ to load the selected files into TRIAD preview panel.
Files selected from Computer/PACS are loaded into TRIAD preview panel
Click on ‘+’ icon to expand the DICOM study and view all the series in that study
View Images

- You can view the images loaded in the preview panel before moving them to “Submission Queue”
- Double click on the thumbnail to view images in series by using default “QC Viewer”.

Double click to view all images belongs to this series. For RT modality use study level.
• You may clean any patient data that may be on the images by using ‘Clean Pixel Data’ feature. The clean pixel data tool propagate across all images in the series.
• Open the clean pixel data window by clicking ‘Clean’ button.
• Draw a rectangle that would cover the data.
• Click ‘Apply Pixel Data Cleanup’ icon to clean the area selected.
Add Attachments

You may add non-DICOM files, such as anonymized reports, at study or series level by clicking ‘Select’ in the ‘Attachment’ column.
Click ‘View’ in the Metadata column to open the series metadata for the DICOM files in the preview panel.
Add Comments

You can provide comments for each series by clicking “Comments” link. Click ‘Save’ after entering comments in the pop-up window.
Move for Submission

Select the series / series that are ready for submission by clicking the check boxes.

Click ‘Move to Submission Queue’ button to move the studies to Submission Queue.
Submission Types

**CLINICAL TRIALS** – This submission type is used for almost all the submissions for trials. It’s used when patients are enrolled for the trial and a valid Subject ID is available. Actual patient images will be need to be submitted when this submission type is selected.

**QUALITY ASSURANCE** – Sites may need to submit images with quality assurance submission type to verify that they are following the trial protocol prior to starting to submit patient images for trial. Subject ID is created automatically for this submission type.

**TEST SUBMISSION** – Sites may use this type to submit test images to verify that system is working as expected. Subject ID is created automatically for this submission type.

**BENCHMARK SUBMISSION** – Sites will use this submission type for site credentialing mainly for RTOG. Subject ID is created automatically for this submission type.
Submission Queue

SUBMISSION: Clinical Trials Domain
Verify all the studies are moved into Submission Queue.

Enter the proper subject ID in “Subject ID” field in the Submission Queue. TimePoint ID and TimePoint Description fields are optional.

Verify all the columns shown in the queue

Select the Submission type from the dropdown.
- Clinical Trial -- default
- Test Submission
- Quality Assurance
- Benchmark
Submission Queue

SUBMISSION: Clinical Trials (NCI Oncology) Domain
Select the subject ID from the dropdown field coming from the RAVE system in the Submission Queue.

Select the Time point ID from the dropdown field coming from the RAVE system in the Submission Queue.
Verify all the columns shown in the queue.
Submission Type for Clinical Trials (NCI Oncology) Domain

Select the Submission type from the dropdown.
• Clinical Trial -- default
• Test Submission
• Quality Assurance
• Benchmark
Submission Queue -- Anonymization Result

You may view DICOM header anonymization results by clicking ”Anonymization Result” button. Both the Original Value and De-identified value are shown in the results pop-up windows.

An ‘Export’ button is also available to export the anonymization results in the form of pdf or word document and save it in your computer.
Validation Result

1. Click the “Validation Result” to check whether the series have the values to satisfy for the requirements of the trial
2. You may also check how many of the series are in Range or Out of range of the validation parameters and how many are not validated
3. System will allow you to submit the studies irrespective of the validation result

Click to Check the validation result for RT structure
Validation Result for RT structure
Click “Complete Submission” when you are ready to submit the files to ACR.

Anonymization and validation will be done in the background even if you did not select “Anonymization Result” or “Validation Result” before.

System shall change the status to ‘Green Color’ after the files are submitted successfully.
TRIAD Support

- If you have any questions or issues, please contact ACR TRIAD support services
- Support Hours: 8am – 5pm EST Monday – Friday except ACR observed holidays
- Support contact:

  ✓ For RT trial submissions with TRIAD-specific questions please contact TRIAD-Support@acr.org or 703-390-9858
  ✓ For Imaging trial submissions with TRIAD-specific questions please contact TRIAD-Support@acr.org or 215-940-8820