

# **RTOG Common Data Management System Implementation**

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# Radiation Therapy Oncology Group (RTOG)

- Implemented three trials in Medidata Rave
- Single and multi-step registration
- Trials implemented in the following research areas:
  - Brain tumors
  - Breast cancer
  - Gastrointestinal cancer (RTOG-1112)
  - Genitourinary cancer (RTOG-1115)
  - Gynecologic cancer
  - Head & neck cancer (RTOG-1216)
  - Lung cancer
  - Sarcoma
  - Symptom management

# ACR's Systems and Technologies

- CTMS (Clinical Trial Management System)
  - Designed to suit our unique needs (e.g., manage our membership and reimbursement)
  - Power builder, MS SQL Server
- EDC (Electronic Data Capture)
  - Clinical web data entry system (Used for non oncology trials)
  - Java, MS .NET, MS SQL Server
- Randnode for subject enrollment using NCI's OPEN (Oncology Patient Enrollment Network)
- Custom integrations among these systems:
  - OPEN, TRIAD, CTEP/RSS, CTMS, RAVE
  - Java, MS .NET, MS SQL Server



# ACR's Systems and Technologies

- **TRIAD (Transfer of Images And Data)**
  - ACR proprietary clinical trial image and data management system – implemented at over 200 clinical trial sites for ACR RTOG/ACRIN
  - Key features
    - Controlled access of various user types
    - DICOM metadata de-identification of PHI tags based on the latest DICOM standard and supplement (Anonymization)
    - Clinical Trial protocol based validation check on DICOM metadata of submitted images
    - DICOM parsing, image viewing, “plug-in” DICOM viewers and metadata operations
    - Build-in QA/QC workflow
    - GCP validated and complied with audit trail on system events
    - Flexibility of integrating with other data management systems via service oriented architecture
  - Technologies
    - MS .NET
    - MS SQL Server
    - DICOM standards

# ACR's Systems and Technologies

## TRIAD Screen Shot 1 – Site Submission

The screenshot displays the TRIAD Clinical Trials web application. The top navigation bar includes 'TRIAD Home' and 'Clinical Trials'. The main content area is titled 'CT Submission for Site: University of Pennsylvania Medical Center(4202) and Trial: COMPARISON OF FFDM WITH DIGITAL BREAST TOMOSYNTHESIS FOR SCREENING CALL-BACK(4006)'. It features options to 'Choose Files From Computer' or 'Choose Files From PACS', with buttons for 'Choose Files', 'Choose Folder', 'Delete', 'Move to Submission Queue', and 'Send To Device'. A table lists DICOM studies with columns for 'DICOM Study', 'Study Description', 'Study Date', 'Image', 'Study Time', 'Modality', 'Accession Number', 'Attachment', 'Comments', and 'Validation Result'. Below this, a 'Submission Queue' section includes an 'Anonymize & Upload' button and a table with columns for 'Subject ID', 'Time Point Id', 'Time Point Description', 'Submission Type', 'Site Name', 'Trial Name', 'Study Description', 'Study Date', 'Anonymize and UpL...', 'Cancel', 'Summary', 'Anonymizatio...', and 'Validation Result'.

DICOM Study	Study Description	Study Date	Image	Study Time	Modality	Accession Nu...	Attachment	Comments	Validation Result	
<input checked="" type="checkbox"/>	3704	NSA CT CHEST...	1/1/2003		11:28:18 AM	CT		<a href="#">Comments</a>	Pending Validation	
<input checked="" type="checkbox"/>	Series Instan...	Series Descrip...	Number Of files	Series Number	Modality	Attach...	Open	Meta Data	Clean Pixel Da...	Comments
<input checked="" type="checkbox"/>	2.16.840.1.114...	Recon 2: LOW D...	150	4	CT			<a href="#">View</a>	<a href="#">Clean</a>	<a href="#">Comments</a>
<input checked="" type="checkbox"/>	2.16.840.1.114...	LOW DOSE SCR...	150	3	CT			<a href="#">View</a>	<a href="#">Clean</a>	<a href="#">Comments</a>
<input checked="" type="checkbox"/>	2.16.840.1.114...	SCOUT	1	2	CT			<a href="#">View</a>	<a href="#">Clean</a>	<a href="#">Comments</a>

Subject ID	Time Point Id	Time Point Description	SubmissionTy...	Site Name	Trial Name	Study Description	Study Date	Anonymize and UpL...	Cancel	Summary	Anonymizatio...	Validation Result
<input checked="" type="checkbox"/>	001_0001	Optional	Optional	ClinicalTrial	University o...	COMPARIS...	1/1/2003					

# ACR's Systems and Technologies

## TRIAD Screen Shot 2 – QA/QC Review

The screenshot displays the TRIAD Clinical Trials application interface. The main window is titled 'Worklist Preview' and shows a list of studies for 'IMAE ARCHIVE - RTOG 0522 - PET'. The interface includes a navigation menu on the left, search filters, and a detailed table of study data.

**Navigation and Search:**

- Menu: TRIAD Home, Clinical Trials
- Search Clinical Trials: Trial Number, Site Number, Date Received, Subject ID, Study Date, Study Status, Modality, Series Status.

**Worklist Preview:**

Studies for IMAE ARCHIVE - RTOG 0522 - PET

Buttons: View Images, Send to PACS, Assign To Worklist, Update Status, Update Subject ID

Site Name: Lahey Clinic Medical Center

Subject ID	Submit D...	Study De...	Submis...	Study Da...	Images	TimePoint ...	Validation	Attachm...	Status	Comme...	Publishe...	Publishe...	Export S...
BM_Lahey Cl...	5/16/2013	CHEST	BenchMark	1/5/2001			Validation	View (0)	Submitted	Comments	N/A	N/A	No
Series D...	Number ...	Modality	Images	MetaData	Clean Pix...	SubmitD...	Submit T...	Attachm...	Submit...	Series St...	Commen...	Publishe...	Published...
MEDICAL ...	15	CT		Metadata	Clean	5/16/2013	8:15 AM	View (0)	user teste...	Submitted	Comments	N/A	N/A
SCOUT	2	CT		Metadata	Clean	5/16/2013	8:15 AM	View (0)	user teste...	Submitted	Comments	N/A	N/A

Site Name: University of Pennsylvania Medical Center

abc	5/17/2013	Thorax^1...	ClinicalTrial	11/1/2004			Validation	View (0)	Submitted	Comments	N/A	N/A	No
abc	5/17/2013	Head	ClinicalTrial	1/31/2001			Validation	View (0)	Submitted	Comments	N/A	N/A	No
Series D...	Number ...	Modality	Images	MetaData	Clean Pix...	SubmitD...	Submit T...	Attachm...	Submit...	Series St...	Commen...	Publishe...	Published...
CT Head	1	CT		Metadata	Clean	5/17/2013	10:19 AM	View (0)	site user u...	Submitted	Comments	N/A	N/A

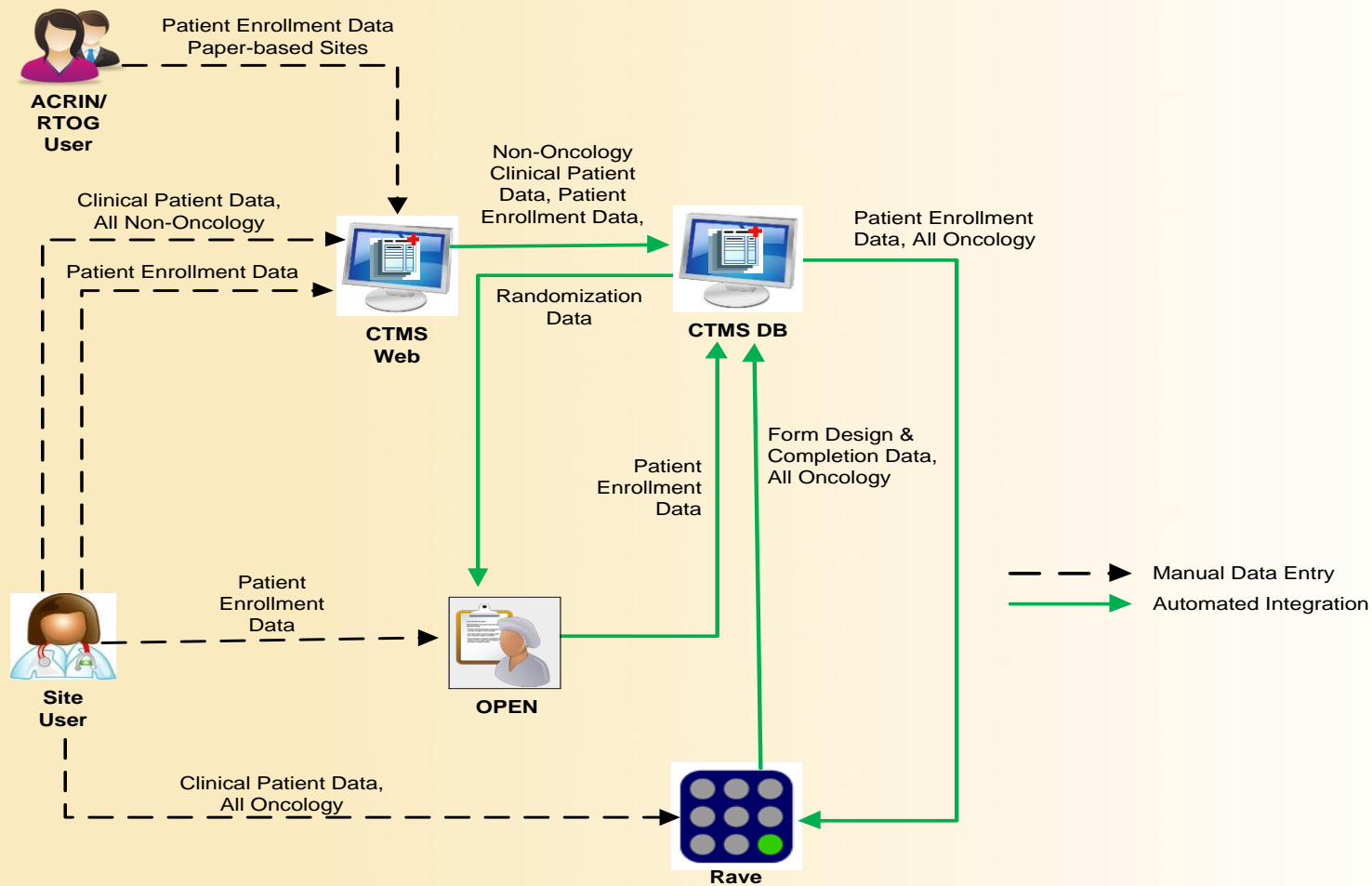
Explore Worklists: My Worklists, Manage Worklist, Create New, Edit, Delete, Deactivate

Worklist: acr\_bms\_test, NeST WorkList - 1, NeST WorkList - 2

# INTEGRATIONS

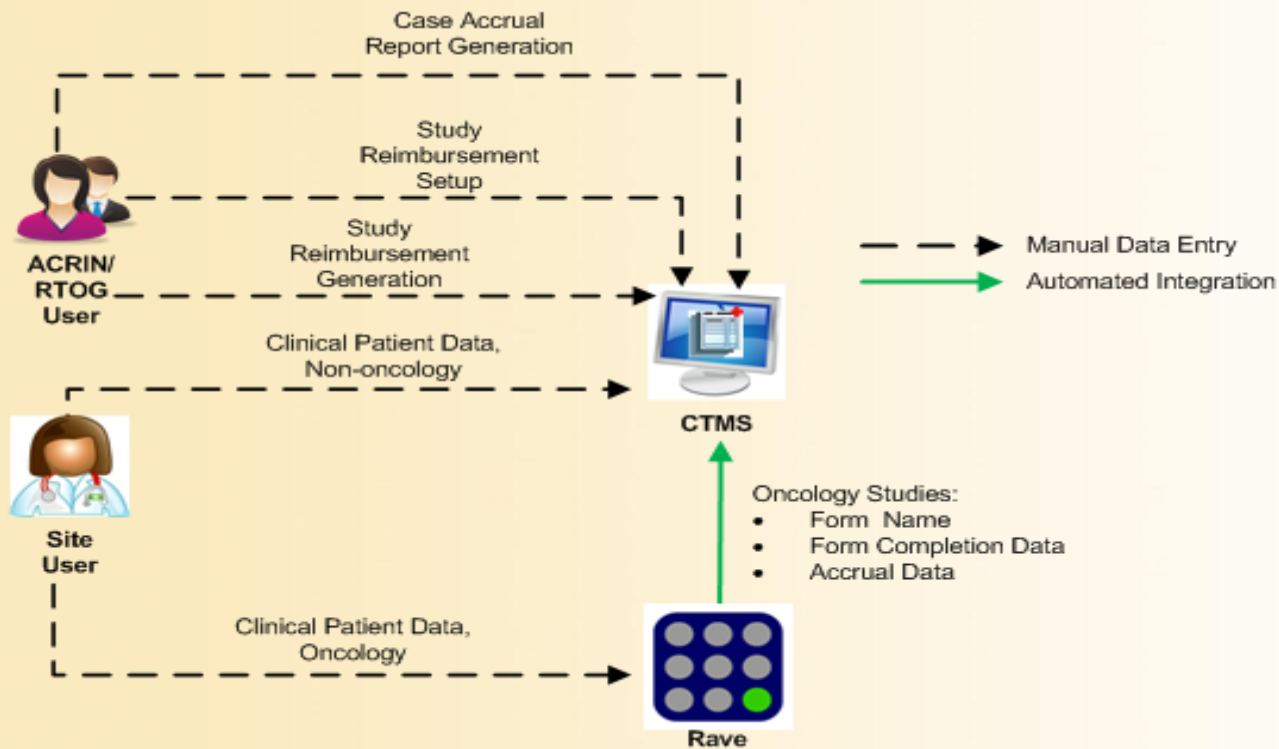
- **SUBJECT ENROLLMENT**
  - Data and functionality required to support the multi-step enrollment of a subject in Rave
- **STUDY REIMBURSEMENT**
  - Data and functionality required to support study reimbursement in CTMS for studies whose data is collected in Rave
- **CASE MANAGEMENT DATA**
  - Data and functionality required to support the generation, in CTMS, of case accrual reports that contain additional information connected to reimbursement
- **TRIAD - CTEP/RSS/RAVE**
  - Data and functionality required to push imaging data from TRIAD to Rave
- **DATA WAREHOUSE**
  - Aggregate data from legacy CTMS, DICOM Image Storage, Rave trials

# RTOG CTMS-Rave Integration – Subject Enrollment Data



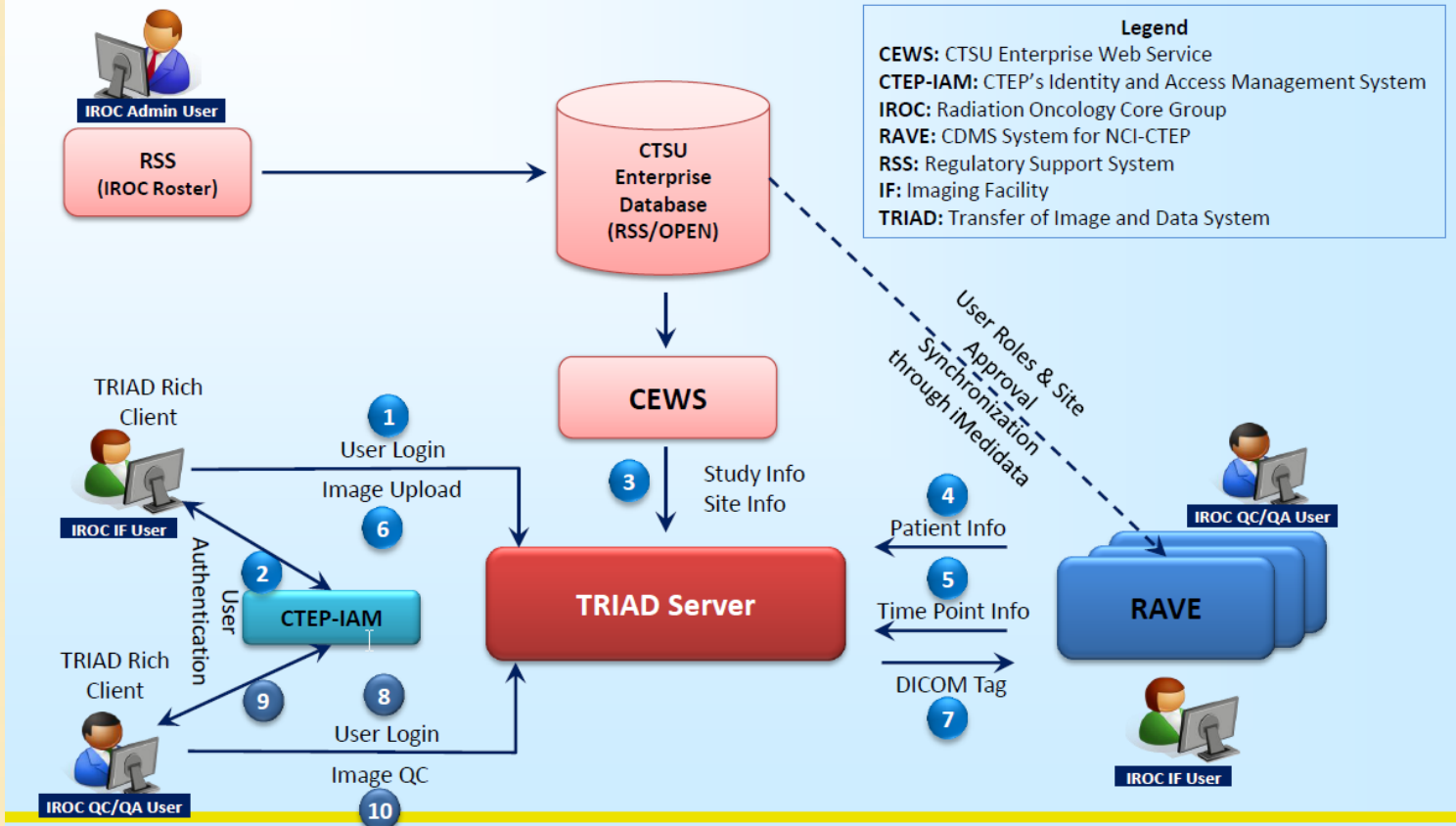


# Rave-CTMS Integration – Study Reimbursement & Case Management Data



# TRIAD Integration

## TRIAD Integration – Schematic Diagram



# What Works Well

- Medidata offers many features to facilitate integration
  - **iMedidata** –
    - Single-sign on for all Rave studies across cooperative groups
  - **Rave Web Services** –
    - Made it possible for IT to easily push and pull data from Rave to integrate with our existing systems
    - Developing the ability to push Radiation Therapy objects directly to Rave
    - Web services integrate disparate technologies
    - Meet challenging timeline
    - Resources – Small group able to accomplish a lot



# Our Challenges

- **Calendaring (Big for us) –**
  - In our CTMS we developed a calendar so sites would know what forms to expect when
  - In Rave, with the dynamic rollout, log forms, and Add Event functionality doesn't do this the same way, making it really difficult to evaluate our membership. *We haven't really solved this yet.*
  
- **Cross-Study Reporting –**
  - Our sites are members. We do a lot of cross study reporting to evaluate their performance. *We haven't really solved this yet.*



# Our Challenges

- **Automatic notification system –**
  - Reminder emails sent out to the RAs who registered the subject for QOL and other forms
  - Rave, with the global setting would trigger on all overdue forms across study and not on only specific form and user
  
- **Support –**
  - Medidata support has been great, but there are few people serving a large group, so we would have liked to have a larger support team.

# Thank You