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
ACR’s Systems and Technologies

TRIAD Screen Shot 2 – QA/QC Review
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
Rave-CTMS Integration – Study Reimbursement & Case Management Data
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