ATC Informatics Committee Report

Walter R. Bosch, D.Sc.
ATC Steering Committee Meeting
October 2, 2008
Philadelphia, PA

ATC Informatics Committee

Mission

- Share pertinent information and provide input regarding the latest informatics technology available and/or used at the QA Centers/Cooperative Groups
- Periodically review and assess the ATC's informatics infrastructure and developmental schedule.

Membership

- Walter Bosch (Chair)
- Joe Deasy (Co-Chair)
- John Matthews
- Richard Hanusik
- Huy Duong
- Brenda Young (liaison ACRIN/RTOG)
- Joel Saltz (liaison caBIG)

ATC Informatics Committee Report

- QuASA²R Update & Development Timeline
- CERR Integration
- Uniform Structure Names
- Consensus Contouring
- ITC Data Exchange Support Efforts
- Related Informatics Efforts: View, OPEN, ...

ATC QuASA²R (Quality Assurance Submission, Archive, Analysis, and Review) System

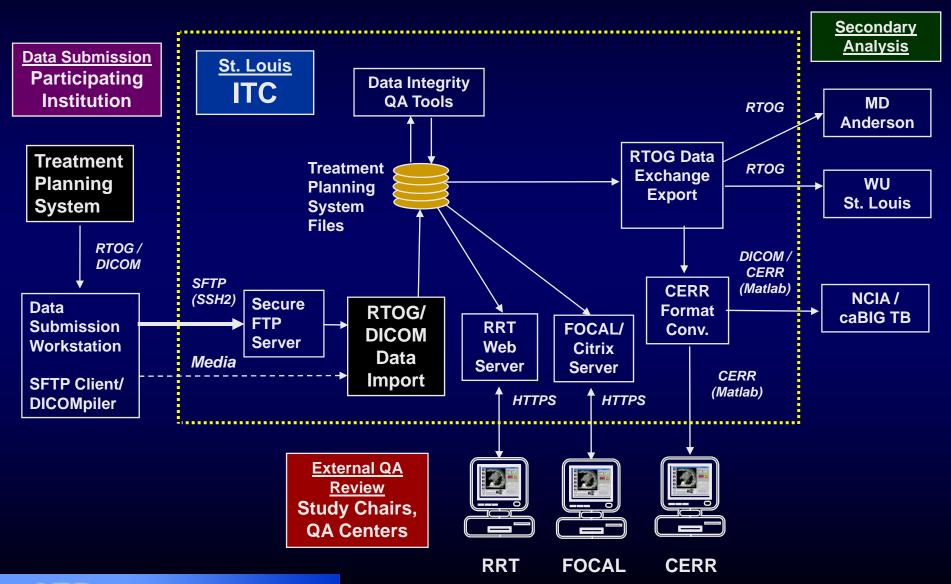
Constraints

- Tools must support DDIQA as well as PCQA workflow
- New imaging and treatment technologies, e.g., IGRT, ART, require new QA workflows, new tools.
- System must maintain continuous support for ongoing protocols
- Development budget is limited

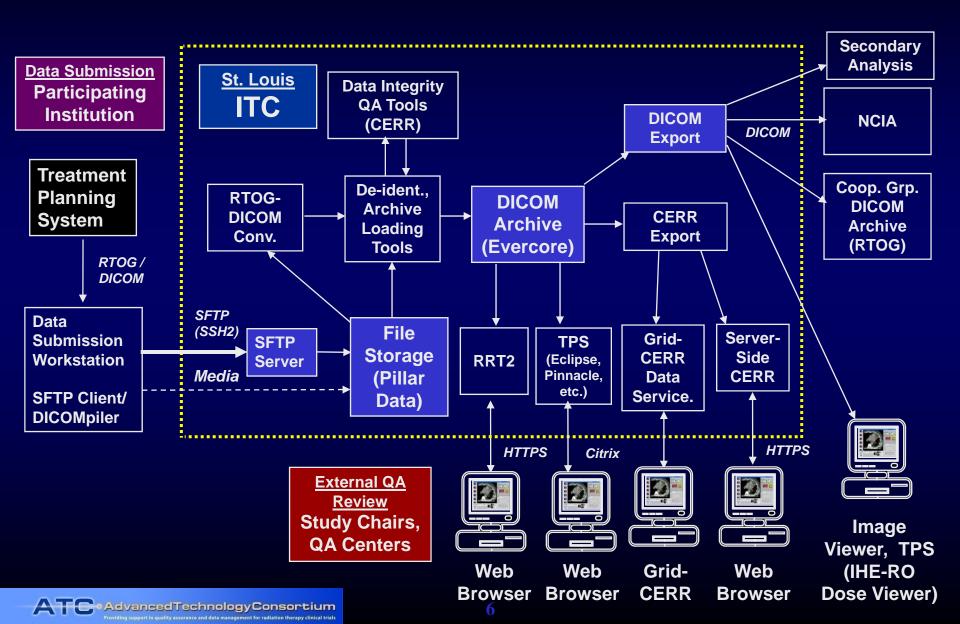
Approach

- Use modular approach to enable stepwise implementation, testing, and upgrades, while maintaining service to ongoing studies
- Invest in the interfaces, i.e., data standards (DICOM, IHE-RO) and support for TP vendor data export
- Use commercial "off-the-shelf" and open-source software wherever possible and focus custom software development efforts only on features not otherwise available.

QuASA²R - Current Components and Data Flow



QuASA²R - Development Plan



Pillar Data Systems Network Attached Storage

- System installed at ITC Jan 2008
 - Setup, training, filesystem creation
- SFTP server integration/testing Feb 2008
 - Used for exchange of vendor DICOM Spatial Registration data for IHE-RO Domain Pre-testing
- ITC data backup system integration Feb 2008
 - Nightly updates of compressed backup datasets
- RRT secure HTTP server integration Feb 2008
 - RTOG closed protocol cases accessible on RRT
- System Upgrade/Update May 2008
 - Software update (improved NFS performance, stability)
 - +10 TB additional capacity
 - + CIFS (Windows file sharing) for TeraMedica Evercore

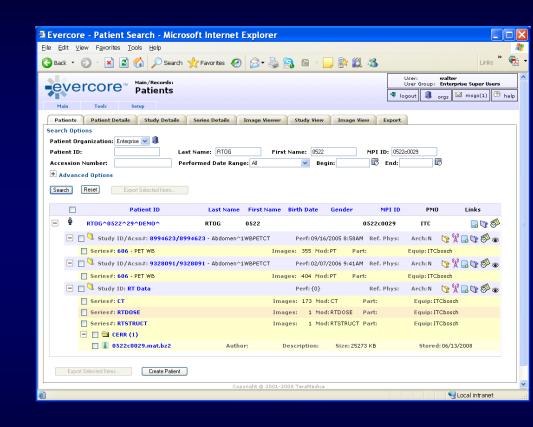
ITC TeraMedica Evercore Archive

- Installation at ITC, June 9-12, 2008
 - TeraMedica Evercore Archive v. 4.5.1
 - OS: Windows 2003 Server Enterprise x64
 - Database: MS SQL Server 2005 x64
 - Servers: (2) DELL PowerEdge 2950 Servers with quadcore 3GHz Xeon processor, 16 GB RAM, GB ethernet
 - Primary database server, secondary archive server
 - Primary archive server, secondary database server
 - Storage: Pillar Data Systems NAS (20 TB)



ITC Evercore® Progress to Date

- Preliminary configuration of EvercoreTM Organizations (PMO, STMO, FMO) for Clinical Trials data management
- Operational Testing
 - Loading of DICOM, non-DICOM (CERR) data
 - Q/R from MIMvista, K-Pacs
- Requirements definition for tools to load DICOM, CERR data into archive
 - Re-identification
 - Create new DICOM instances
 - Referential integrity check



Diagnostic Image / RT Review Tools

- Tools currently being evaluated for review of PET, MR, CT images and RT data:
 - MIMvista
 - Velocity AI
- Features
 - CT, MR, PET registration (rigid, deformable)
 - RT Structure Set, RT Dose display





Timeline for QuASA²R Upgrades (1)

	Project	Date
1	 Pillar Data Storage System Stable support for existing QuASA²R components Flexible foundation for DICOM Archive 	Installed Jan 2008, Upgraded May 2008 • Data backup, SFTP, RRT, Evercore operational
2	ITC DDIQA Server/Tape Backup Upgrade	Begin Summer 2008Phase 1 is operationalPhase 2 is in progress
3	DICOM-based RT Archive (TeraMedica)Support for wide range of imaging and RT datasets	Installed June 2008Prelim. ConfigurationTesting in progress
4	 Data format conversion tools DICOM conv. for legacy (RTOG) data CERR conv. for phantom dosimetry CERR conv. for distributed case review 	 Work in progress Starting Jan 2007 Batch conv. Apr 2008 Data service is work in progress

Timeline for QuASA²R Upgrades (2)

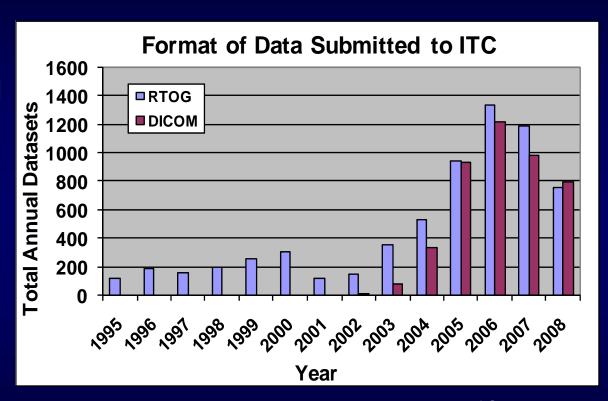
	Project	Date
5	Digital Data Integrity QA workflow tools (CERR) • DDIQA Server • Data anonymization / ID reconciliation • Archive loading • Case data management (inventory, revision) • DICOM consistency checks (DVTk) • Structure naming / Structure editing / Dose summation	 Begin Summer 2008 DDIQA server, CERR installed May 2008 Migration of existing tools to new platform in progress
6	Diagnostic Image/RT Review Tools • MIMvista • Velocity AI	Evaluation in progressQ/R tests with Evercore June 2008
7	QuASA ² R / Commercial TPS Integration	Begin Fall 2008

Timeline for QuASA²R Upgrades (3)

	Project	Date
8	Grid-enabled CERR for production case review at ITC • Secure download, seamless review • Anticipatory data push	 Begin Fall 2008 Collaborative work in progress with J. Deasy (WU), J. Saltz (Emory)
9	 Server-side review tools Image Digest / QA Report Generator (CERR) Multi-planar (T/S/C) tool for contour and dose review 	Begin Spring 2009 • Collaborative work with J. Deasy (WU), J. Saltz (Emory)

RTOG/DICOM TP Data Formats

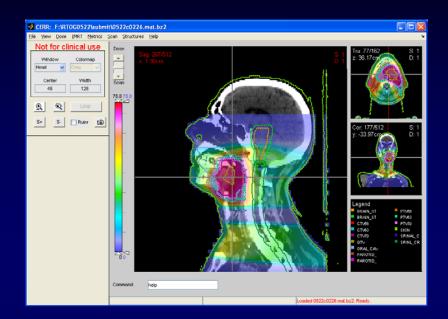
- 2008 is the first year in which the majority of datasets submitted to ITC were DICOM.
- The proportion of DICOM datasets is expected to grow as updated TP systems with DICOM export are installed and older versions are no longer supported.
 - Pinnacle³ (7.6, 8.0)
 - XiO (4.3.x)

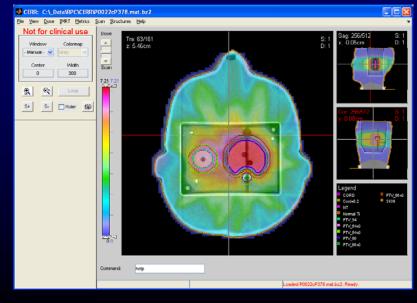


Datasets processed as of Sept. 15, 2008

Data Format Conversion using CERR

- Data format conversion
 - RTOG 0522 treatment planning data export to NCIA as CERR, DICOM
- Transfer of RPC
 Phantom Data for evaluation of Film Dosimetry
 - Since April 2008, 256 RPC
 Phantom Datasets have been converted to CERR for comparison with film/TLD dosimetry using FilmQA tool





NCIA RTOG 0522 Project

- ACRIN 4500: Quantitative PET (PET/CT) preand post-treatment images submitted to ACRIN, forwarded to NCI Archive
- RTOG 0522: CT, Structures, Doses, Plans submitted to ITC (DICOM or RTOG Data Exchange), forwarded to NCI Archive (DICOM)
 - Digital data integrity, protocol compliance QA
 - RT data (CT, Structures, Doses) format conversion
 - Data (DICOM and CERR) upload to NCIA

RTOG 0522/NCIA Project

 Assess feasibility of accessing/using the RTOG 0522 dataset (DICOM RT data objects as well as advanced imaging, FDG-PET/CT in treatment assessment manner) components as a reference data set.





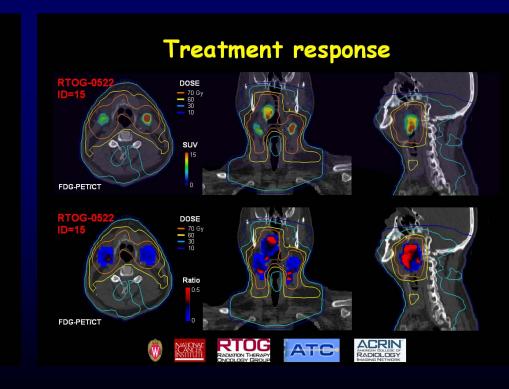






RTOG-0522 TRIAL

Robert Jeraj, Chihwa Song, University of Wisconsin
John Freymann, Justin Kirby, Carl Jaffe,
Vikram Bhadrasin, Jim Deye, NIH/NCI
Walter Bosch, Joe Deasy, Yu Wu, Divya Khullar,
Jim Purdy, ATC/ITC, Washington University
Anthony Levering, ACRIN
Betty O'Meara, Mike Gillin, RTOG
Kian Ang, MD Anderson



Grid Computing and RT Clinical Trials

The caBIG In Vivo Imaging middleware is used to deploy existing CERR software as an integrated communication and review tool for Radiation Therapy clinical trials, institutional credentialing, and case quality assurance.

Application of caGrid® Middleware to Facilitate Quality Assurance for Advanced Technology Radiation Therapy Clinical Trials

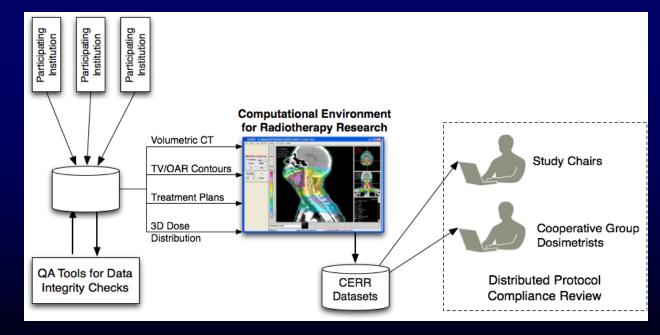
Joel H. Saltz¹, MD, PhD, Ashish Sharma¹, PhD, Tony C. Pan¹, MS Walter R. Bosch^{2,3}, DSc, Joseph O Deasy³, PhD, James A. Purdy¹, PhD

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Medical

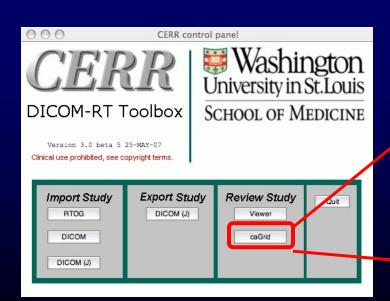
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- Simplified and secure distribution of data to reviewers
- Capture reviewer scoring, modifications for subsequent analysis



Components of Grid Enabled CERR

- A caGrid data service for storing CERR objects
 - Stores the metadata of the CERR MATLAB objects in a XML database
 - Provides Query and high performance data transfer from/to the client
- CERR client is modified to support grid interactions
 - Grid based Query/Retrieve interface
 - Grid security interface

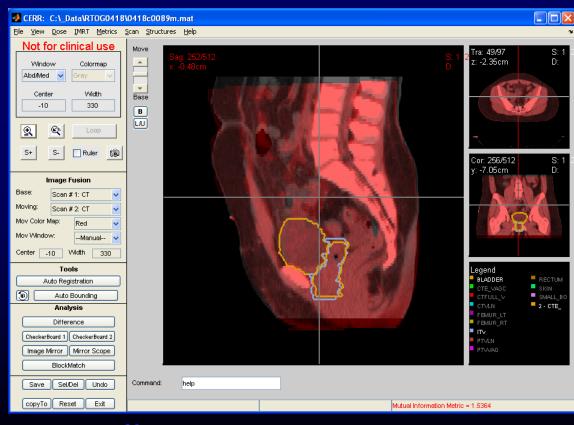


Grid Q/R GUI

9 🔿 🔿	gridQRGUI
Query Parameters	
Archive	
Institution	
Sponsor ID	
Protocol ID	
Subject ID	
Submission ID	
CERR Data Service Locati	ions
http://140.254.80.	174:8080
Query Data Service	Retrieve Selected Data

Data Review using CERR

- RTOG 0418
 - Evaluation of ITV using registration of fullbladder (planning) CT and empty-bladder CT scans.
 - Multi-planar display
 - Images
 - Structures
 - Dose
 - Protocol CaseQA using
 - CERR
 - WebEx



Uniform Structure Names

- Work in progress with RTOG Informatics Committee and Advanced Technology Integration Committee
- Draft proposal (9/5/08)
 - OAR names derived from list used for RTOG AT trials
 - Indicate laterality for paired organs
 - TV names include prescription dose (Gy)
 - PRV names include margin (mm)
- Parallel effort to define codes for ROI types in DICOM segmentation objects.

Uniform Structure Names for RT Clinical Trials

DRAFT

A Uniform Tissue Naming Proposal for Use in RT Clinical Trials

Walter R. Bosch, D.Sc.

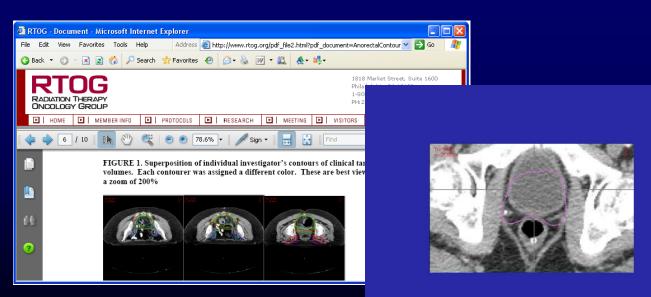
Background

Consistent naming of contoured structures used in radiotherapy treatment planning is essential to facilitate the comparison of dose-volume statistics across patients for quality assurance and outcomes analysis. Maintaining consistency in structure names is particularly important (and challenging) in multi-institutional clinical trials, in which treatment planning data are collected from many participating institutions. Differences in treatment planning techniques and local languages are among the factors that contribute to variations in the names used to identify structures.

The Image Guided Therapy QA Center (ITC) has developed a Digital Data Integrity QA process to examine submitted RT treatment planning data for completeness and consistency. This process involves resolving discrepancies between submitted and protocol-specified structure names. For some data sets, the mapping between submitted and protocol-specified structure names is obvious, and the process of assigning standard names using ITC tools is straightforward. Other cases, however, require visual inspection of images and contours to identify structures. For trials involving disease sites with many organs at risk, e.g., H/N IMRT, the effort required to correctly identify all structures can be substantial.

ATC Support for RTOG Consensus Image Segmentation Atlases

- Pelvic Lymph Node Volumes for Prostate Cancer
- Post-op Prostate Contours Atlas
- Anorectal Atlas
- GYN Atlas for CTV Delineation in Post-op Cervical and Endometrial Cancer



RTOG



ATC Efforts in Support of RT Data Exchange Standards

- DICOM Working Group 7
 - Maintenance of current DICOM RT information object definitions
 - Development of next-generation RT objects
- IHE-RO
 - Define profiles for interoperable use of existing standards (e.g., DICOM)
- Direct Support for TP Vendor Data Export Efforts

DICOM: 2nd Generation RT Objects

- Some limitations of current DICOM RT objects
 - Complex referential structure means changes in one object may necessitate changes in others objects just to maintain referential integrity.
 - Difficulty in retrieving a collection of RT objects for a given phase of a patient's treatment
 - New DICOM objects offer better representation for image segmentation
 - Multiple uses of RT Plan for prescription, plan development, approval, delivery.
 - Complex conditions of a common RT Plan object used in multiple contexts, many optional attributes

DICOM WG-7 Activities

- New RT objects (larger number of smaller objects)
 - Workflow instructions
 - Physician Intent, RT Planning Prescription objects
 - RT Course ("container") object support for unmanaged workflow, clinical trials submissions
 - Use new DICOM segmentation (surface, volume) and registration (rigid, deformable) objects
 - Radiation Set (fraction group)
 - Separate radiation delivery objects per treatment modality: Carm Photon Beam, C-arm Electron Beam, C-arm Ion Beam, Tomotherapeutic Photon beam, Non-isocentric Photon Beam

DICOM WG-7 Meeting Schedule

- WG-7 meetings addressing the design of 2nd -generation DICOM RT objects:
 - Oct 30 Nov 2, 2007 Los Angeles, CA
 - Dec 10-14, 2007 Las Vegas, NM
 - Apr 22-25, 2008 NEMA HQ
 - June 16-19, 2008 Santa Fe, NM
 - Oct 21-24, 2008 Charleston, SC
 - Mar 17-20, 2009 Washington, DC

IHE-RO Update



- ATC is an Organizational Member of the International Integrating the Healthcare Enterprise (IHE) as of March, 2008, and remains fully committed to supporting the mission and vision of IHE in Radiation Oncology.
 - Active participation in IHE Radiation Oncology Technical Committee
 - Distribution of IHE-RO Test Data and Test Tools via ITC Secure FTP server
 - Participation in 2008 IHE-RO Connectathon Test Committee (Jul 31 – Aug 5, 2008, Houston)

IHE-RO Profiles

- 2007 IHE-RO Profile
 - Basic Treatment Planning Inter-operability Profile was tested at Aug 2007 Connectathon
- 2008 IHE-RO Profiles
 - Multimodality Registration Profile to be tested at Aug 2008
 Connectathon in Houston and demonstrated at ASTRO 2008
 - Treatment Delivery Workflow Profile is not yet ready for Connectathon
- 2009 IHE-RO Profiles
 - Treatment Delivery Workflow
 - Advanced Plan Integration Electrons, Dynamic plans, Compensators, Bolus, Dose compositing

IHE-RO TC Meeting Schedule

- Technical Committee Meetings
 - Sept 25-27, 2008 Boston, MA
 - Dec 15-19, 2008 Mountain View, CA
 - Mar 23-25, 2009 Washington, DC
 - June 3-9, 2009 Domain Pre-testing, Erlangen, Germany
 - Sept 14-21, 2009 Connectathon, Washington, DC
 - Nov 5-7, 2009 Post-ASTRO, Chicago, IL
 - Jan 25-29, 2010 location TBD

ITC Support of TP Vendor Data Export Development and Testing – 2008

BrainLAB

- Received DICOM data 5/29/2008 (CTs, RTstruct, RTplan, RTdose, Rtimages)
- RTdose was not multi-frame; Beams missing ITC required iso-center position

CMS

- Received incorrectly registered RTdose for HFP patient
- CMS agrees and is investigating

Nucletron

- SPOT-Pro (brachy seed) is ATC compliant as of 4/7/2008
- Received US images from Wm Beaumont (3/26/2008) and Nucletron (prerelease software) – deemed too far from DICOM standard
- SonoTECH (European HDR planning system)
 - Vendor Complete as of 4/11/2008.

Tomotherapy

Clarification re availability of Hi-ART 3.x with DICOM export capability (6/6/2008)

Varian Eclipse

- Have received non-compliant data from multiple sites (frequently from Japan)
- Data processed at ITC with non-production import code

Related Informatics Efforts

- MAX QARC
- TRIAD ACR
- VIEW QARC, ACR
- OPEN CTSU
- CDMS caBIG
- Docu-MART CTEP, CALGB, ECOG, SWOG

ATC IT Infrastructure

- IT infrastructure at ATC member centers has grown to support local QA workflow:
 - QuASA²R focuses on ITC workflow
 - TPS-based DDIQA tools and repository
 - RRT web-based segmentation and dose review
 - CERR multiplanar, multimodality segmentation and dose review
 - Portable RT viewer
 - Server-side
 - DICOM archive (TeraMedica Evercore®)
 - MAX focuses on QARC workflow
 - DICOMmunicator image submission and review
 - RRT web-based segmentation and dose review
 - CERR MAX integration, added QARC functionality

Related Informatics Efforts: QARC MAX

- Meeting at QARC (5/6/08)
 - Bosch, Sharma, FitzGerald, Urie, Ulin, Laurie, Hanusik
 - Review features (data management, QA workflow support, audit trail) of the MAX IT infrastructure
 - Plan caGrid integration for distributed reviews using MAX.
 - Assess the effort needed to produce a non-QARCspecific instance (4-6 mo x 1 FTE).

Related Informatics Efforts: VIEW

VIEW Consortium

- First trial identified
 - NCCTG Second Line Therapy for NSCLC
 - CALGB, SWOG, ECOG, NCIC, CTSU
 - 1,000 patients / 5,000 CT scans
- QARC recipient of images, logging, site liaison, tracking, and reporting
- ACRIN will then receive images from QARC for quality control and archiving
- June 2008 activation planned

Related Informatics Efforts: ACR TRIAD

ACR TRIAD

- Software in final beta testing
- CT, MRI, PET/CT, and Ultrasound from various vendors tested
- Formal validation plans for the application in process
- Suitability as a DICOM RT application not yet determined





The OPEN System...

- Is a standardized web-based environment for enrollment of all patients in clinical trials across the NCI-sponsored Cooperative Group Clinical Trials Program.
 - Supports all treatment and associated ancillary studies for the Cooperative Groups.
 - Is a partner system to the Regulatory Support System and will support the same set of trials.
 - Available for all authorized users, regardless of Group affiliations.
- Collects the information needed to credential and enroll patients.
- Is integrated with the CTSU Enterprise System.
 - Utilizes existing protocol data, regulatory data, and roster data for validation rules.
- Integrates the existing Group registration/randomization systems
 - Performs the randomization and any custom validation checks.
 - Provides real-time treatment assignment back to OPEN to present to the site Registrar.





Example Registration Flow

- A site user enters information through an on-line enrollment screen;
- OPEN exchanges messages with the lead Group systems;
- The Group system responds with patient id, treatment arm, etc.



Clinical Data Management System – Remote Data Capture

CDMS Procurement Background



- The National Cancer Institute (NCI) is purchasing licensing rights for a commercial clinical data management system (CDMS) software product and related installation, support and maintenance services to support the conduct of cancer clinical research in the NCI Clinical Research Enterprise.
- The <u>system will be made available free of charge to all NCI-supported</u> organizations conducting cancer clinical trials.
- It is an unlimited-user, perpetual license.
- Can be used for all cancer trials, including industry.
- Cannot be used for non-cancer trials under this license

Purpose of the CDMS Procurement

- Will deliver full-function clinical data management capability to the entire NCI-supported clinical research community, irrespective of a given organization's ability to pay for such a system.
- The new system will allow researchers to share information with other caBIG compatible systems and tools, within the given research organization, with other research organizations and with NCI itself.

Related Informatics Efforts: Docu-MART

- Document Management, Authoring, Review, and Tracking System
- Authoring tool
 - Predefined structured protocol templates (XML)
 - Selection Wizard auto generation of draft document
 - Pre-populate 80-90% of Protocol Document based on template and approved Concept or Letter of Intent
 - Auto generation of Protocol Submission Worksheet and Change memo
 - Protocol completeness check
- Online review, commenting, tracking

The following information was excerpted from a presentation given at the September 18, 2007 Group Chairs Meeting:

Docu-MART Features to Aid Cooperative Group Protocol Development

- Standardized protocol format and structure . . . pre-populated sections:
 - Concept submission form
 - Pharmaceutical Information Record
 - CAEPR information.
 - Informed Consent
 - AE Reporting Guidelines
 - CRADA/CTA
- Identifies required sections for GOG to complete during authoring stage
- Tracks reviewer participation . . . system generated email reminders with deadlines
- Performs completeness check prior to submission to NCI
- Auto-generation of change memo
- Reconciliation report allows site to submit revised "clean" version only
- Highlights changes made in addition to NCI requested changes
- Allows for real-time independent access to document status without the need to query NCI