# QuASA²R – A Digital Data Quality Assurance Submission, Archive, Analysis and Review System for Advanced Technology Clinical Trials in Radiation Therapy

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ATC Advanced Technology Consortium
Providing support in quality assurance and data management for radiation therapy clinical trials

## 1 ABSTRACT

**Purpose:** The QuASA²R clinical trials quality assurance (QA) system, developed by the Image-guided Therapy QA Center (ITC), provides multiple cooperative groups one of the most advanced medical informatics infrastructures currently in use for radiation therapy clinical trials QA. The recently renewed ATC grant has provided funds for further refinement/development of this system. A status update of QuASA²R for protocol case data QA, submission, archive, analysis, and review is presented.

**Method and Materials:** Development of QuASA²R is guided by the considerable experience and success of ITC computer scientists and QA personnel in supporting advanced technology clinical trials, recognition of QA tool needs for future protocols involving emerging technologies (e.g. IGRT, ART), and compatibility with caBIG infrastructure. ITC has embraced a flexible, modular architecture with emphasis on well-defined interfaces, which allows integration of commercial "off-the-shelf" and open-source software and focuses custom software development/enhancements on features not otherwise available. This approach enables step-wise implementation and upgrading of system components while providing continuous support of ongoing protocols.

**Results:** A major update of QuASA²R is underway involving replacement of current treatment-planning-system-based imaging/treatment planning/verification database with specialized DICOM archive software supporting a tiered storage structure. The DICOM archive supports diagnostic imaging, DICOM RT objects, and meta-data related to diagnosis, treatment, and outcomes assessment for protocol patients. Updates to QA utilities that aid ITC staff in performing *Digital Data Integrity QA (DDIQA)* continue to be implemented. The open-source CERR software system has been integrated into QuASA²R for format conversion, QA review, and secondary data analysis.

**Conclusion:** The QuASA²R system has demonstrated a continuing robustness, having archived over 7300 datasets. Its modular design allows updates to meet changing requirements of advanced technology clinical trials. Experience with new updates and a roadmap for future upgrades over the next 12 months will be presented.

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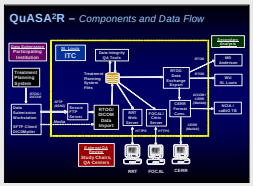
## 2 QuASA²R: Quality Assurance Submission, Archive, Analysis, and Review System

The QuASA²R system at ITC supports data collection, QA review, and outcomes analysis for cooperative-group and industrial/pharmaceutical clinical trials involving advanced-technology radiotherapy including

- Radiation Therapy Oncology Group (RTOG) [1,2]
- National Surgical Adjuvant Breast and Bowel Project (NSABP)
- New Approaches to Brain Tumor Therapy (NABTT)
- Japan Clinical Oncology Group (JCOG)
- European Organization for Research and Treatment of Cancer (EORTC).




The QuASA²R system has been developed using a step-wise approach, since adding new capabilities must not disrupt continuous support of ongoing protocols. [3]

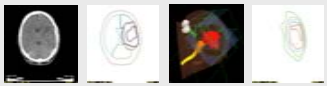
- Modular architecture with emphasis on well-defined interfaces
- Integration of commercial "off-the-shelf" and open-source software
- Custom software component development focused on QA features required, but not otherwise available.

## 3 Data Collection and Quality Assurance for Advanced Technology RT Clinical Trials

The Image Guided Therapy QA Center (ITC), as part of the Advanced Technology QA Consortium (ATC), collects images and volumetric treatment planning (TP) data for Quality Assurance and outcomes analysis in AT clinical trials.

TP datasets generally consist of the following data objects:

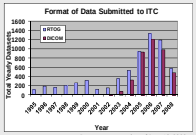
- Volumetric CT images
- Structure set defined by axial slice contours for target volumes and organs at risk
- Treatment plans, including beam geometry and dosimetric weighting for EBRT and source locations, strengths, (and dwell times) for brachytherapy.
- 3-D dose distributions (per fraction group) in Gy.



## 4 Formats for Data Submission

Both RTOG Data Exchange format and DICOM RT objects are in widespread use to represent images, contours, plans, and doses used in radiotherapy treatments.

- Approximately 50% of data submitted to ITC is in RTOG Data Exchange format and 50% in DICOM objects.
- The proportion of DICOM datasets is expected to grow as new and updated TP systems come into clinical use.




Datasets processed as of June 13, 2008

## 5 Assisting the Development of ATC Compliant Data Export from Commercial TP Systems

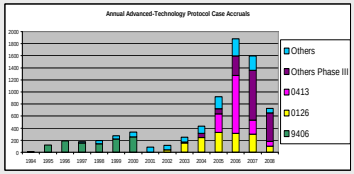
- ITC maintains the RTOG Data Exchange format specification and has published a DICOM Conformance Statement to specify requirements for data submission.
- ITC works directly with TP system vendors to evaluate ATC compliance of data exported from new and updated software.
- ITC participates in the DICOM standards process
  - ❖ WG-7 (Radiotherapy Objects) – currently working on development of next-generation DICOM RT objects
  - ❖ WG-18 (Clinical Trials) – Clinical Trials ID, de-identification profile
- ITC represents the ATC as a Member of Integrating the Healthcare Enterprise (IHE) International, serving in the following capacities:
  - ❖ IHE-Radiation Oncology Technical Committee member
  - ❖ IHE-RO Connectathon Test Committee member

Current Status

- A total of 20 Commercial TP systems (11 vendors) have implemented ATC-compliant data export. (See table at right and at http://atc.wustl.edu)
- More than 600 institutions are able to submit TP data to ITC.

## 6 Digital Data Submitted to ITC

Over the past 14+ years, more than 7300 complete treatment planning (TP) data sets have been submitted to the ITC by institutions participating in Advanced-Technology RT Trials. The chart below shows the annual accrual of protocols cases for these studies. (Data as of June 2008.)




## 7 Digital Data Integrity Quality Assurance

Experience in facilitating the collection and review of protocol case datasets continues to show the necessity for Digital Data Integrity QA (DDIQA) of submitted data.

- Approximately one in four submissions requires some form of human intervention to yield a complete dataset that can be reviewed for protocol compliance and used for outcomes analysis [4].
- Inconsistencies in submitted data arise from several sources and may be minimized, but not eliminated.
  - ❖ Submitted data must be reviewed for completeness and consistency before protocol compliance QA can be performed.
  - ❖ Support for efficient DDIQA workflow remains an essential feature of the QuASA²R system.

The ITC DDIQA Process includes the following steps

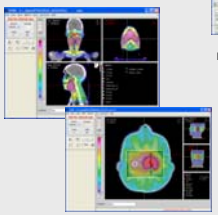
- Check spatial registration among images, structures, and doses.
- Add dose distributions for fraction groups and check dose scaling
- Rename structures to protocol-compliant names to allow comparison of dose-volume statistics across cases
- Calculate DVHs for protocol-required structures using consistent geometry and dose bins.

## 8 Computational Environment for Radiotherapy Research (CERR)

Integration of the open-source CERR software[5] provides several important QA review capabilities to QuASA²R and implements functions not readily available in commercial software.

As an imaging/treatment planning data review tool, CERR facilitates QA of target-volume and organ-at-risk contours and dose distributions.

- Multi-planar (T/S/C) views
- Multi-modality image registration (PET/CT)
- Full- and empty-bladder evaluation of ITV for cervical cancer treatment.

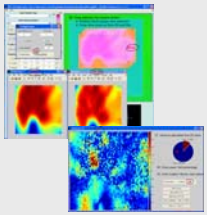


Data Format Conversion

- RTOG Data Exchange to DICOM and CERR formats
- CERR is used to prepare RT datasets for inclusion in the National Cancer Imaging Archive
- CERR is used to transfer TP data for RPC Phantom Dosimetry Tests

Film Dosimetry Tool

- Used to compare calculated doses exported from TP systems with measured doses (film and TLD) delivered to RPC phantoms
- CTs and 3-D dose distributions (in CERR format) are registered with scanned film measurements
- 2-D Gamma index calculation



Work is also underway to develop compatible interfaces between the QuASA²R system and the NCI Cancer Bioinformatics Grid (caBIG) infrastructure. A demonstration of caGrid connectivity for distributed treatment plan review using CERR was presented at the RSNA 2007 meeting [6].

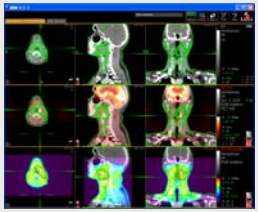
(Collaborative application of caGrid® Middleware in development by Joel Saltz, Ashish Sharma, and Tony Pan at Ohio State Univ.)

caGrid-Enabled CERR

- caGrid data service stores CERR Matlab objects
- Grid-based Query/Retrieve interface
- Grid security interface
- Reviewers access images, store review results at ATC image archives

## 9 New Imaging and Treatment Modalities

With the emergence of new imaging and radiotherapy treatment modalities has come the need to test these techniques is clinical trials. Functional imaging for target definition and response assessment, 4-D imaging for motion assessment, 2-D and 3-D image-guided treatment delivery, and adaptive radiotherapy techniques represent new sources of data that must be reviewed and analyzed for these trials.

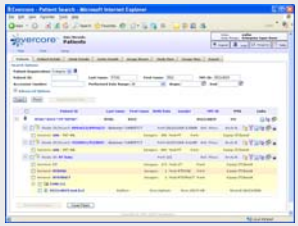


The ITC is currently evaluating commercial systems for quantitative evaluation of images and RT data. An example of such tools is the registered display of CT images, structure contours, doses, and pre-treatment PET scans for an RTOG 0522 IMRT dataset using MIMvista® (shown above).

## 10 TeraMedica Evercore® Archive and caBIG

To manage the collection and evaluation of images and RT data objects, the ITC is replacing the current imaging/treatment planning/verification (ITPV) database (which utilizes a commercial treatment planning vendor's file format) with the Evercore® DICOM RT archive (TeraMedica, Milwaukee, WI). This archive will provide storage for diagnostic imaging, DICOM RT objects, and meta-data related to the diagnosis, treatment, and outcomes assessment for protocol patients.

The TeraMedica Evercore® archive has been installed at ITC and will form the foundation of next-generation informatics infrastructure.



ITC Progress to Date

- Installation of Evercore® software
- Preliminary configuration of Evercore Organizations (PMO, STMO, FMO) has been carried out for Clinical Trials data management
- Operational Testing, including loading of DICOM and non-DICOM (CERR) data and Q/R from MIMvista, K-Pacs
- Requirements definition for tools to load DICOM, CERR data

## 11 Summary and Conclusions

- The ITC QuASA²R system has supported data integrity QA and protocol compliance QA for a growing number of Advanced Technology clinical trials, enabling RT data acquisition, QA evaluation, and outcomes analysis in these studies.
- The QuASA²R system has demonstrated a continuing robustness, with the capability to acquire ATC-compliant data sets from 20 commercial TP systems (11 vendors) and having now archived over 7300 volumetric data sets.
- The modular approach used by ATC(ITC) in developing QuASA²R has demonstrated a proven track record, allowing development of new capabilities to meet the ever changing requirements of advanced technology clinical trials, while maintaining continuous support for ongoing protocols. This approach emphasizes the use of
  - ❖ well-defined interfaces,
  - ❖ integration of commercial "off-the-shelf" and customizable open-source software products, and
  - ❖ limiting software development to tools not otherwise available
- The ITC continues to assist treatment planning manufacturers in developing ATC compliant data export capabilities and remains active in the development of the DICOM standard as well as IHE-RO profiles for improving the interoperable use of RT data.

## 12 References and Acknowledgements

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