Report: The Advanced Technology Consortium (ATC) - Image-Guided Therapy QA Center (ITC) Informatics Infrastructure: QuASA^{2}R (Quality Assurance Submission, Archive, Analysis, and Review) System

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INTRODUCTION

This report is intended to provide the Advanced Technology Quality Assurance (QA) Consortium (ATC) Council of Industry Participants (ACIP) background information regarding the ATC and its informatics infrastructure used to support RTOG and other cooperative groups' advanced technology clinical trials. The widespread clinical acceptance of advanced technologies such as three-dimensional conformal radiation therapy (3DCRT), intensity modulated radiation therapy (IMRT), stereotactic body radiation therapy (SBRT), and image-guided brachytherapy has motivated efforts to conduct multi-institutional clinical trials utilizing these modalities. For these trials, limited, 2D data (i.e., hard copy CT slices and a few planar isodose distributions) do not provide a sufficient data set for clinical trial case QA review. Case review for these advanced technology clinical trials require the acquisition and evaluation of volumetric image-based target volume(s), organs at risk, and three dimensional dose distributions.

The ATC is supported by a National Cancer Institute (NCI) U24 grant to Washington University (ATC-WU, U24 CA81647, James A. Purdy, Ph.D., Principal Investigator). The ATC functions as a "virtual entity" made up of the following clinical trials QA Centers: (1) Image-Guided Therapy QA Center (ITC – Washington Univ. in St. Louis and UC Davis); (2) Radiation Therapy Oncology Group (RTOG) Headquarters Dosimetry Group, (3) Radiological Physics Center (RPC, M.D. Anderson Cancer Center), and (4) Quality Assurance Review Center (QARC). The ATC grant provides the primary funding for the ITC and provides only supplementary funding to the other three groups to accomplish the ATC mission. The subcontract with the University California Davis Medical Center UCDMC) was established to accommodate Dr. Purdy's move to UCDMC in 2004. In this arrangement, the main component of the Image-guided Therapy QA center (ITC) resides at Washington University (henceforth referred to as ITC-WU), and is augmented by a branch at the University California, Davis (henceforth referred to as ITC-UCD).

The original ATC grant was awarded in response to NCI RFA CA-98-006 in 1`999 (J.A. Purdy, PhD, PI; July 1, 1999 to June 30, 2002). However, the ATC concept dates back even further, as it grew out of the pioneering efforts of the Washington University 3DQA Center (now referred to as the ITC) and RTOG, which in 1994 partnered to provide QA for the 3D Oncology Group (3DOG) to conduct a prostate dose escalation study (94-06) using 3DCRT [1-3]. In 2002, the Washington University ATC grant was successful in its first renewal application (J.A. Purdy, PhD, PI; July 1, 2002 to June 30, 2007), and in 2007 was again successful in its competitive renewal application (J.A. Purdy, PhD, PI; July 1, 2007 to June 30, 2012).

The overall mission of the ATC is to facilitate and support NCI sponsored advanced technology clinical trials, particularly those requiring digital data submission. The ATC strongly believes that

advanced medical informatics can create an environment in which clinical investigators can receive, share, and analyze volumetric, multimodality imaging, treatment planning and verification (ITPV) digital data. Our ultimate goal is to improve the standards of care in the management of cancer by improving the quality of clinical trials medicine. The goals as specified in NCI RFA CA-07-503 for our ATC grant renewal application are to be accomplished through the following *developmental*, *coordination*, and *service* objectives:

1. Eliminate duplication of infrastructure developmental efforts and facilitate sharing of QA resources among cooperative groups.
2. Help to insure that appropriate and uniform QA procedures and criteria for advanced technology trials are developed across all cooperative groups.
3. Facilitate/help manage the uniform credentialing of institutions for advanced radiotherapy trial protocols.
4. Facilitate/manage digital data protocol submission.
5. Facilitate/manage the QA review of submitted data.
6. Further the development of methods for rapid analysis of volumetric treatment planning data.
7. Assist clinical trial cooperative groups in the development of clinical trials protocols including: (a) credentialing requirements; (b) target volume definitions; (c) quality assurance procedures; and (d) data submission instructions.
8. Develop, implement, and maintain innovative methods for electronic exchange of digital planning data between institutions participating in clinical trials and between QA Centers.
9. Develop, implement, and maintain innovative web-based software tools to facilitate protocol digital data reviews by Study Chairs, Dosimetry Groups, the Radiological Physics Center (RPC), and the Quality Assurance Review Center (QARC).
10. Develop, implement, and maintain archival treatment planning and QA databases that can be linked with the cooperative groups' clinical outcomes databases.
11. Demonstrate understanding of and ability to achieve compatibility with existing software and electronic health record standards, including the Cancer Bioinformatics Grid (caBIG) and DICOM RT.

To accomplish these goals, we have organized the ATC's efforts around four specific aims listed below.

Specific Aim 1: Maintain and manage (and make incremental improvements as required to) the current electronic data submission of advanced technology protocol credentialing and case data, archival storage, and remote QA review process utilizing the ATC *QuASA^{2}R (Quality Assurance Submission, Archive, Analysis, and Review)* system.

Specific Aim 2: Develop novel web-based remote-review tools that will enhance the efficient and effective review of 3DCRT, IMRT, SBRT, and brachytherapy protocols. The tools and interfaces will be designed by a multidisciplinary team of experts in the quality assurance of clinical trials. The design infrastructure of these tools will assist the development of future protocol processes such as image-guided radiation therapy (IGRT) and adaptive radiation therapy (ART) [4, 5]. *QuASA^{2}R* is modular in architecture to promote the efficient design, testing, and implementation of tools and subsystems. Starting from a DICOM-based ITPV data archive with well-defined interfaces, our developmental approach will (a) allow the selective re-use and adaptation of existing *QuASA^{2}R* system components, (b)

enable the integration of a heterogeneous mix of commercial-off-the-shelf, open-source and custom software components; (c) facilitate testing and maintenance of system components, and (d) allow step-wise evolution/upgrading of the *QuASA^{2}R* system to support technological advances in radiation therapy clinical trials. Emphasis will be on the development and improvement of web-based remote-review tools that achieve compatibility with existing software and electronic health record standards, including the Cancer Bioinformatics Grid (caBIG) and DICOM RT, and maintaining/developing archival multimodality ITPV, credentialing, and QA databases for the advanced treatment modalities that can be linked with the cooperative group's clinical outcomes database.

Specific Aim 3: Assist cooperative groups in the development and management of advanced technology clinical trials protocols including (a) tumor/target volume and organ at risk definitions; (b) credentialing requirements and evaluation criteria; (c) electronic data submission requirements/instructions; and (d) quality assurance review procedures.

Specific Aim 4: Serve as an educational resource to the nation's clinical trial cooperative groups and participating institutions for support of advanced technology radiation therapy clinical trials.

To facilitate good communication among all ATC subcontractors, several ATC face-to-face (F2F) meetings and regularly (some weekly) scheduled teleconferences are held. As a minimum, we are meeting at least two of the three QA Centers and at each of the RTOG Semi-Annual Meeting each year. In addition, an ATC Steering Committee meeting is held each year and in 2009, an ATC Evaluation Committee meeting will be held.

With this background, we will now review the ATC(ITC) informatics infrastructure currently in use and the plans for further development.

ATC(ITC) INFORMACTICS INFRASTRUCTURE

The QuASA^{2}R (Quality Assurance Submission, Archive, Analysis, and Review) system was developed (and is maintained) by the ITC. The initial version of the system was used to support the 3D Oncology Group (3DOG) to conduct a nine-institution prostate dose escalation study using 3DCRT planning capabilities [2, 3, 6]. The system has continued to evolve and has been reported on at the 2000 and 2007 ICCR meetings [7]. It now 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 which will be described in a later section. Development of QuASA^{2}R is guided by (a) the considerable experience and success of ITC computer scientists, physicists, and QA personnel in supporting advanced technology clinical trials, (b) the recognition of QA tool needs for future protocols involving emerging technologies (e.g. IGRT, ART), and (c) compatibility with caBIG infrastructure. ATC(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 stepwise implementation and upgrading of system components while providing continuous support of ongoing protocols.

Data Submission

The current QuASA^{2}R system supports the submission of images and digital treatment planning data as either DICOM RT objects or RTOG Data Exchange Format files. (See http://atc.wustl.edu/resources for ATC RTOG Format specifications and DICOM conformance statements.) Diagnostic radiological images can be submitted as DICOM objects. Treatment verification images can be submitted as DICOM objects or JPEG files. Treatment planning system isodose images and DVH plots can be submitted as JPEG files. Files may be combined as "tar" or "zip" archives and may be compressed or encrypted (ZIP) prior to submission. The flow of information through the QuASA^{2}R system is diagrammed in **Figure 1.**

The QuASA^{2}R system supports Internet submission of data using the Secure FTP (SFTP/SSH2) network protocol. Data may also be submitted using CD (DICOM or RTOG formats) or Tape cartridge (RTOG format only) media. The ITC SFTP server (ITCsubmit.wustl.edu) provides secure submission of data with individual accounts for more than 600 institutions participating in advanced-technology protocols, as well as treatment planning manufacturers testing data export capabilities. Users may submit data files, but may not access other users' data or system files.

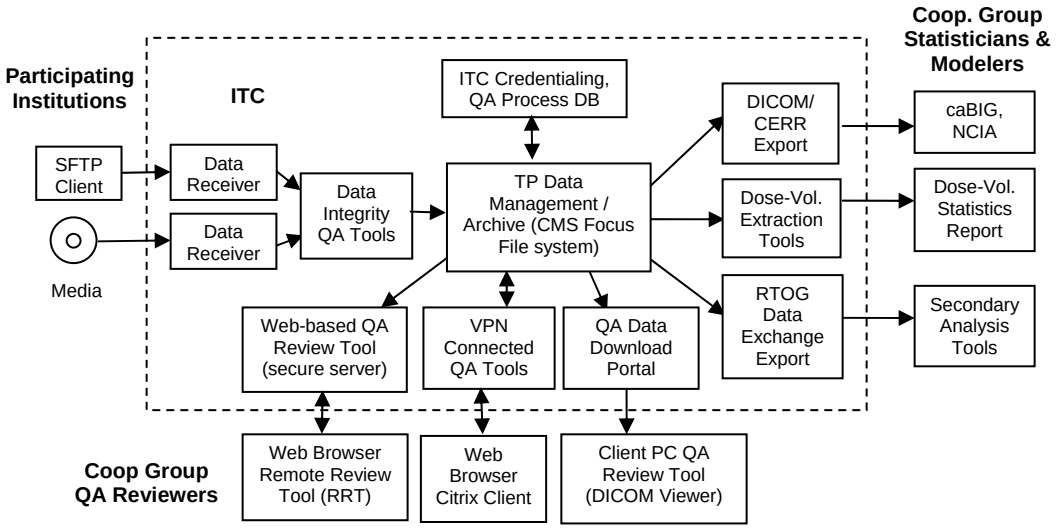

Figure 1. QuASA^{2}R (Quality Assurance Submission, Analysis, and Review, System) information flow.

The QuASA^{2}R system also includes a Windows/PC-based application software (ITC DICOMpiler) developed by the ITC and available from the ATC web site. Participating institutions can use this application for receiving DICOM data over a local area network, selecting objects to be submitted, anonymizing the data, and creating a DICOM fileset that can be written to CD-ROM or uploaded to the ITC via SFTP. A wide range of commercial and free-ware SFTP client and CD-burning software is available for use in submitting data to the ITC or QARC. Instructions for configuring SFTP clients are provided for four SFTP clients (WS FTP Pro, Filezilla, WinSCP3, and Linux sftp) on the ATC web site.

Note, 2008 is the first year for which the proportion of datasets submitted to the ITC using DICOM RT objects has exceeded 50% of the total (see **Fig. 2** below). This proportion is expected to increase as the number of treatment planning systems (TPSs) supporting export of DICOM RT objects continues to grow and as the major TPS vendors now shipping ATC-compliant DICOM-exporting versions eventually stop supporting their RTOG Data Exchange format exports.

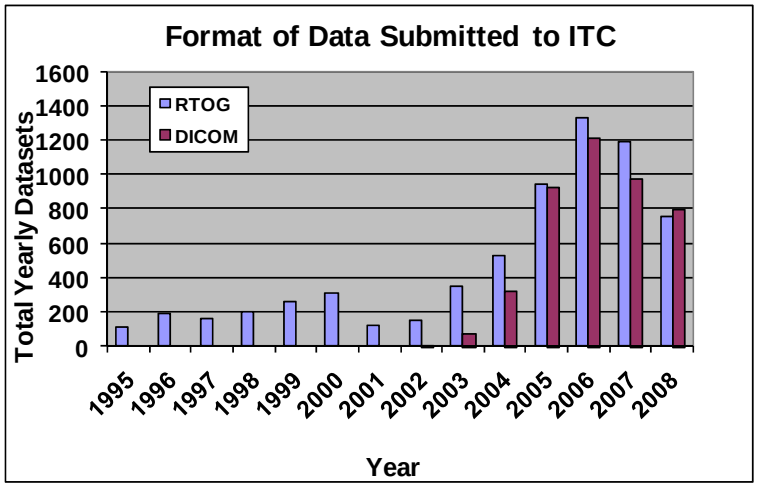

Figure 2. Number of protocol-case and credentialing (phantom) submissions received by the ITC per year showing the number submitted via RTOG Data Exchange and DICOM-RT formats.

The ITC continues to work directly with TPS vendors (mainly Dr. John Matthews), as well as through the DICOM standards process and the IHE-RO initiative (mainly Dr. Walter Bosch) to assist in the implementation of ATC compliant DICOM export capabilities in commercial TP software. Note, the ATC was approved as an Organizational Member of the International Integrating the Healthcare Enterprise (IHE) as of March 6, 2008. The ITC maintains a list of commercial ATC Compliant Treatment Planning Systems (TPS) on the ATC website which can produce data in a format suitable for submission on ATC-supported protocols.

QA Review

Case digital data submitted using the QuASA^{2}R infrastructure are imported into a proprietary (CMS) treatment planning and review file system as the first step in the process of *Data Integrity Quality Assurance (DIQA)*, which is performed by the ITC. During the import of DICOM or RTOG Data Exchange format files, these data are checked for completeness and consistency. Logs created by the import software are an important source of diagnostic information for identifying and correcting data format problems in submitted data, which result from user error or arise as new versions of TPS software are installed at submitting institutions.

The QuASA^{2}R system has a set of QA utilities that ITC staff use in performing DIQA including assuring uniformity in organ-at-risk/target-volume (OAR/TV) contour names and DVH calculations, as well as for correcting minor inconsistencies in submitted data sets. These tools are invoked from a scripted X11-based graphical “shell” program. Major functions available are identified below:

1. A *Data Import and File Transfer Panel* supports the import of submitted data into the QuASA^{2}R treatment review file system so they can be reviewed using the Remote Review Tool (RRT). It is used to transfer (and change of ownership) of files from private user directories on the SFTP server to a processing directory, auto-archive submitted data, extract data from ZIP or (gzipped) TAR archive files, correct anomalies in filenames, inventory the contents of DICOM and RTOG data exchange filesets, display

data conversion logs for diagnosis of data format problems, and retrieve archived copies of submitted data.

2. A *Contour Tools Panel* allows editing of contour names to ensure protocol-compliant naming, editing of protocol parameters in patient datasets, import of reviewer contours from the RRT, precise calculation of structure volumes, deletion of redundant and unnecessary structures, creation of structure unions (e.g., for paired organs), creation of target volume from base structures with user-specified margin, and checking margin (distance) statistics between selected target volumes and other structures.
3. A *DVH Tools Panel* provides re-calculation of DVHs from dose distributions and submitted (or edited) structure contours, editing of protocol parameters in patient datasets, and display/printing of submitted or re-calculated DVHs.
4. A *Plan Tools Panel* allows the combination of sub-plans (i.e., summing dose distributions), scaling of HDR dose distributions, display/printing of beam apertures, adding a beam to a plan (e.g., AP, RLat, LLat), editing a plan ID, printing of plan summaries, and interrogation of point doses at specified coordinates.

Once imported into the QuASA^{2}R treatment review file system and after DDIQA is completed, the data are reviewed for Protocol Compliance QA (PCQA) by a designated reviewer from the cooperative group from any Internet-connected web browser using QuASA^{2}R's thin client Remote Review Tool (RRT) as shown in **Figure 3**. The RRT displays DVHs and axial patient images with overlaid OAR/TV contours, as well as user-defined iso-dose curves. RRT users can also edit contours on axial images. re-calculate DVHs for these user-defined structures, and display point doses on axial images. The RRT is designed to be used with modest display hardware (1024x768 pixels) and uses image compression to optimize the use of network bandwidth. The RRT image display uses a fixed 512x512 format with zoom (by powers of two) to display axial images, structures and iso-doses. All functions are supported on zoomed images.

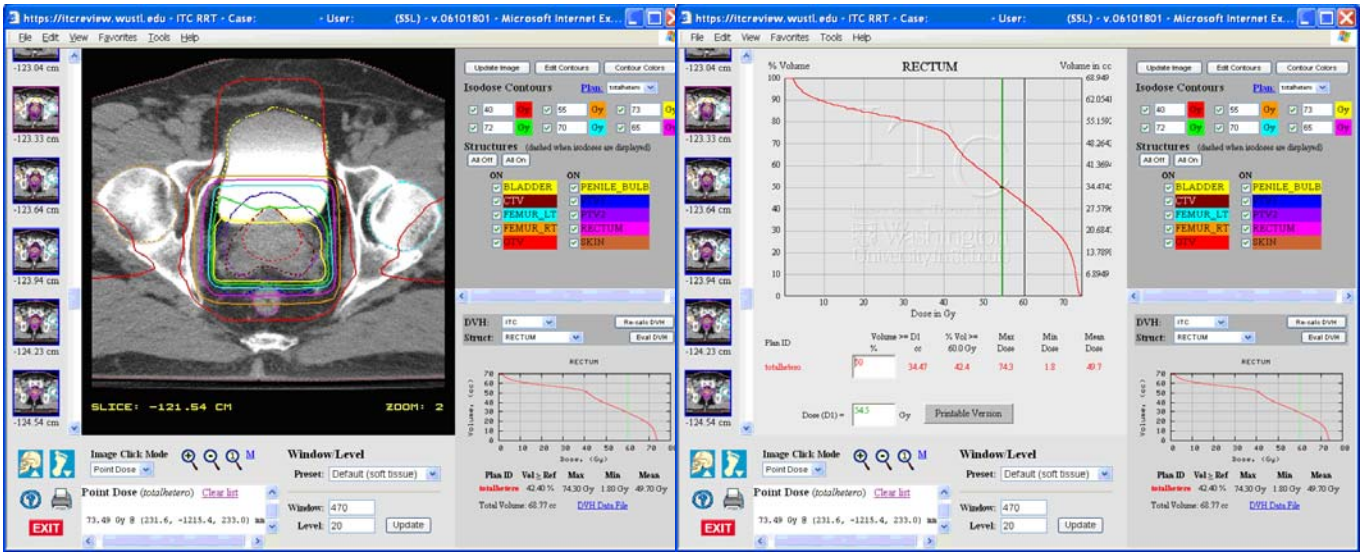

Figure 3. The web-based Remote Review Tool (RRT) displays target-volume and organs-at-risk contours, and selected isodoses overlaid on axial CT images, and dose-volume histograms, including dose-volume statistics (left). The RRT also provides java applets for interactive dose-volume histogram evaluation (right), distance measurement, and contour editing.

The RRT user interface is implemented using Common Gateway Interface (CGI) PERL scripts. These scripts invoke executable utilities (C-language, linked to proprietary libraries) to extract data from the CMS patient file system and to perform image rendering and DVH calculation. Open-source utilities are used to convert image formats and plot DVHs. Functions requiring rapid interactive response (contour editing, distance measure, DVH evaluation) are implemented as Java applets.

In addition to the RRT, several other mechanisms have been developed for review of case diagnostic imaging data. Diagnostic imaging data (CT, MR, US, PET) submitted to the ITC via SFTP or media can be anonymized and prepared for secure download from the ITC web server by reviewers with assigned user accounts. Downloaded image sets are then displayed on the reviewer's PC using DICOM viewer software, e.g., K-Pacs (http://www.k-pacs.net).

To support 3D evaluation of multiple image series (CT-CT and multi-modality) along with treatment planning information, the ITC has implemented a CMS FOCAL Broadband review system as part of the QuASA^{2}R system. Treatment planning data (in DICOM or RTOG Data Exchange format) are imported into a CMS-based file system using the same process as for the RRT. DICOM image data are sent to a DICOM receiver (Storage SCP) on the FOCAL server. The FOCAL application then allows fusion of the DICOM image data with treatment planning data sets.

Data Analysis

The ITC has developed scripted data analysis tools to extract dose-volume statistics for correlation with outcomes in RTOG clinical trials and which have resulted in numerous publications as posted on the ATC website. The ITC has also supported secondary analysis involving correlation of dosimetric information from treatment planning data sets with clinical outcomes. In one case, the RRT was used to delineate normal structures not originally defined in the protocol. DVHs computed for these new structures were compared with outcomes [8]. The ITC has also performed bulk export of protocol data sets in RTOG Data Exchange format to two other investigators that has led to two successful NIH R01 grants [9, 10].

RESULTS AND DISCUSSION

The ATC QuASA^{2}R system has been continually refined and updated and is actively in production use at the ITC to support the submission and review of digital data for RTOG protocols (14 closed, 21 active), and NSABP (1 active), JCOG (1 active, 1 closed) protocols (as of November 2008). In addition, this system has been implemented at QARC for review of volumetric treatment planning data for several COG, CALGB, and ACOSOG protocols [11]. Data sets collected include CT planning images, OAR/TV contours, beam geometry/seed locations, 3D dose distributions, DRRs, and scanned films as either DICOM (images and RT objects) or RTOG data exchange format. In all, as of Oct. 2008, this system has enabled the collection and review of over 7700 volumetric protocol case data sets, over 4700 credentialing data sets, and hundreds of vendor test data sets.

The ATC QuASA^{2}R system has been used by the ITC to assist TPS developers in verifying that their DICOM implementations (CT, RT Structure Set, RT Dose, RT Plan, and RT Image) match ATC's conformance statement [12]. The ITC maintains a list of commercial ATC Compliant TPSs on the ATC website, which can produce data in a format suitable for submission to ITC or QARC on ATC-supported protocols. As of November 2008, 11 TPS vendors (20 TP systems) have achieved "ATC Compliant" status, meaning that a clinical user of the TPS has submitted to

the ITC a protocol compliant data set. The ITC continues to work with TPS vendors to evaluate data from new and updated versions of TPS software.

Work is currently underway at the ITC to extend the capabilities of the QuASA^{2}R system to support QA for a broader range of imaging and define requirements and develop technology for the next-generation QuASA^{2}R system. (See Appendix 1 for developmental time table). 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. To manage the collection and evaluation of these new data objects, the ITC is replacing the current imaging/treatment planning/verification (ITPV) database (which utilizes a commercial treatment planning vendor's (CMS) file format) with DICOM archive software supporting a tiered storage structure on a highly-redundant Network Attached Storage (NAS) hardware (Pillar Data Storage, San Jose, CA). The DICOM archive software, Evercore (TeraMedica, Milwaukee, WI) will provide storage for diagnostic imaging, DICOM RT, and meta-data related to the diagnosis, treatment, and outcomes assessment for protocol patients.

Updates to QA utilities that aid ITC staff in performing DDIQA continue to be implemented. An example is the integration of the open source software *Computational Environment for Radiotherapy Research* (CERR) for converting non-DICOM data received by the ITC to DICOM RT objects, for QA review, and for secondary data analysis [13]. CERR is now in regular use to prepare treatment planning data submitted for RTOG Protocol 0522 for inclusion in the National Cancer Imaging Archive (NCIA) as DICOM RT data objects. The 0522 protocol case data are reviewed both for DIQA and protocol compliance and are then converted to DICOM RT objects using CERR. DICOM objects and CERR (Matlab) files for these cases are then forwarded to the NCIA for correlation with PET/CT images collected for this protocol by ACRIN.

As a participant in the Cancer Bioinformatics Grid (caBIG) In Vivo Imaging Workspace, the ATC(ITC) has worked with Dr. Joseph Deasy and colleagues in the Bioinformatics and Outcomes Research (BIOR) Division of the Washington University Department of Radiation Oncology and Dr. Joel Saltz and colleagues (Ohio State University) to develop compatible interfaces between the QuASA^{2}R 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 [14].

SUMMARY AND CONCLUSION

The ATC's QuASA^{2}R system approach has demonstrated a robust track record in maintaining support for ongoing clinical trials while continuing to develop functionality for new treatment approaches and technologies such as image-guided radiation therapy (IGRT) and adaptive radiation therapy (ART). We employ a modular architecture that has allowed us to perform step-wise evolution/upgrading of the QuASA^{2}R system components using a mix of commercial-off-the-shelf, open-source and custom software components to support technological advances in radiation therapy clinical trials. The goal of this effort remains to create high quality archival multimodality imaging, treatment planning, credentialing, and QA databases for the advanced treatment modalities that can be linked with the cooperative group's clinical outcomes database.

The ATC's QuASA^{2}R system provides a robust infrastructure for digital data submission, archiving, and web-based QA review of RT objects. It has been the enabling technology that has allowed RTOG to uniquely conduct 3DCRT, IMRT, SBRT, HDR, and prostate seeds clinical trials that require volumetric digital data submission. It has greatly benefited TPS vendors in

developing/verifying implementation of digital data export. ATC(ITC) and RTOG databases are an important resource to facilitate future outcomes research.

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Appendix 1: Developmental timeline for updates to QuASA^{2}R

	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 2008 • Phase 1 is operational • Phase 2 is in progress
3	DICOM-based RT Archive (TeraMedica) • Support for wide range of imaging and RT datasets	Installed June 2008 • Prelim. Configuration • Testing 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
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 progress • Q/R tests with Evercore June 2008
7	QuASA2R / Commercial TPS Integration • Eclipse • Pinnacle • CMS	Begin Fall 2008
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)