The Advanced Technology QA Consortium (ATC)

ATC • AdvancedTechnologyConsortium
Providing support in quality assurance and data management for radiation therapy clinical trials

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1 INTRODUCTION

This poster is intended to inform caBIG Annual Meeting registrants of the latest developments by the Advanced Technology Consortium (ATC) for Clinical Trials Quality Assurance (QA) and the status of ATC supported radiation therapy clinical trials. More information can be found at ATC web site http://atc.wustl.edu.

ATC is 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), (4) Quality Assurance Review Center (QARC), and (5) Resource Center for Emerging Technologies (RCET – Univ. Florida Gainesville).

The overall mission of the ATC is to facilitate and support NCI sponsored advanced technology clinical trials, particularly those requiring digital data submission. We strongly believe that advanced medical informatics can create an environment in which clinical investigators can receive, share, and analyze volumetric, multimodality treatment planning and verification (TPV) 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 ATC mission is accomplished through the following coordination, service, and developmental efforts.

- COORDINATION EFFORTS AMONG QA CENTERS
  - Eliminate duplication of developmental effort and facilitate sharing of QA resources among cooperative groups.
  - Develop appropriate and uniform QA procedures and criteria for advanced technology trials across all cooperative groups.
- ATC SERVICE EFFORTS
  - Manage and facilitate
    - Credentialing of institutions
    - Protocol digital data submission
    - QA review of submitted data
    - Analysis of volumetric treatment planning data
  - Assist clinical trial cooperative groups in protocol development
    - Credentialing requirements
    - Target volume definitions
    - Quality assurance procedures
    - Data submission instructions
- ATC DEVELOPMENTAL EFFORTS
  - Electronic data exchange of digital planning data between protocol participating institutions and ATC QA Centers.
  - Web-based software tools to facilitate protocol digital data submissions and QA reviews by Study Chairs, RTOG Dosimetry Group, RPC, and QARC.
  - Archival treatment planning and QA databases that can be linked with the cooperative group's clinical outcomes database

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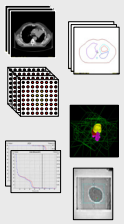
Question: What are the special requirements of advanced-technology radiotherapy clinical trials?
Answer: Digital Data Submission and Remote Review

- Protocol Compliant Data Set
  - Patient's Volumetric CT Data Set
  - All protocol-required contours
  - Volumetric 3-D dose distribution
  - Beam geometry – orientation and shape
  - Dose-Volume Histograms (DVHs) for full dose plan for all protocol ROIs
  - Digital films (DRRs or on-line images) optional
- Why not just collect the DVH data?
  - Loss of spatial Information in DVHs
  - Loss of fractionation information in DVHs
  - Variation in dose distributions throughout an organ may lead to different expectations of toxicity for some organs.
  - DVHs may not be adequate for developing dose-response models.
- Allows linkage of volumetric treatment planning data to clinical outcomes data

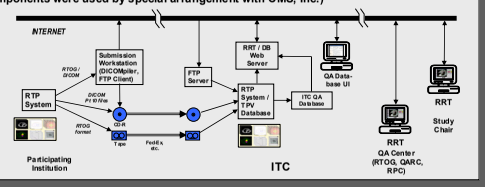


3 ATC'S ROLE IN DATA EXCHANGE FOR CLINICAL TRIALS QA

ATC developed the *RTOG Data Exchange Specification* and has assisted in the development of DICOM RT objects for the exchange of TPV data in cooperative-group clinical trials. ATC has sponsored a series of DICOM Implementers' Workshops to assist treatment planning system (TPS) manufacturers in implementing RT objects needed for clinical trials and has participated in development of Clinical Trials Identification modules (DICOM WG18). ATC interactions with TPS manufacturers have exposed several problems in interpretation/implementation of the DICOM standard resulting from complexity of DICOM RT objects and differences in design and capabilities of their software. A web-based *Remote Review Tool*, which allows visualization of images, structure sets, and dose distributions, has proven helpful to manufacturers in developing and verifying implementations. ATC DICOM Conformance Statement can be found at (http://atc.wustl.edu/resources).

4 ATC METHOD 1 DIGITAL DATA SUBMISSION REVIEW SYSTEM

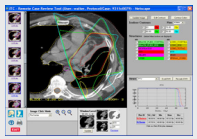
A system of software ("ATC Method 1") was developed at the Image-guided Therapy QA Center (ITC) to receive, process, and review volumetric digital radiation therapy treatment planning data (TPD) for ATC supported clinical trials. The system includes an FTP server for receiving TPD (in DICOM or RTOG data exchange format) from protocol participants, utilities for importing TPD into a local file format, and the web-based Remote Review Tool (RRT) for QA of ROIs, isodoses, DVHs, and dose statistics. (Proprietary software components were used by special arrangement with CMS, Inc.)

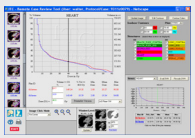


5 ATC METHOD 1 REMOTE REVIEW TOOL (RRT)

ATC data review capabilities include web-based tools, which allow visualization of images, structure sets, dose distributions and dose volume histograms. The ATC treatment planning-verification database represents the most comprehensive dataset available for patients treated with advanced technologies and will provide researchers the capability to access volumetric dose distributions, which can be evaluated with reference to segmented, volumetric patient image data and be correlated with the protocol outcomes to develop robust dose-response models.

The *Remote Review Tool* Features includes (1) CT Images (zoom, window/level); (2) Structure contours (review, editing); (3) Isodose contours; (4) Interactive DVH display; (5) Point-dose display; and (6) Measurement tool.





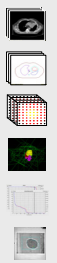
6 ATC METHOD 1 IMPLEMENTED AT QARC

The ATC Method 1 digital data submission and review system was recently ported to a Linux workstation at QARC. Software installation and maintenance were performed remotely at QARC by ITC personnel, with weekly teleconferences to coordinate the development effort. ITC software was adapted to better support the QARC QA process. QARC software was adapted to support RRT invocation directly from the QARC database user interface. The system is now in use for five COG, CALGB, and ACOSOG protocols; 29 cases from 15 institutions have been received and reviewed. This project demonstrated that ATC Method 1 can be implemented at other QA centers. However, the effort required was greater than anticipated as the tools must be tailored to each individual QA center's computer infrastructure/QA process.

7 ATC-Compliant Treatment Planning Systems

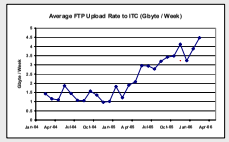
Treatment planning systems deemed to be *ATC-Compliant* as of 3/2006 are listed below. They are those with which ATC protocol participants have submitted *complete, reviewable* protocol data sets. Prospective users should consult the TPS manufacturer to verify the capabilities of the system they intend to use for protocol submissions. Exchange formats: D = DICOM-RT, R = RTOG Data Exchange (See http://atc.wustl.edu for current listing.)

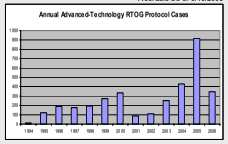
Treatment Planning Systems			Exchange Format	Treatment Modality				
Vendor	System	Version		3DCRT	IMRT	Seed Brachy	HDR Brachy	Protons
CMS	Focus/XiO	3.1	R	✓	✓	✓		
Elekta	RenderPlan 3D		R	✓				
	PrecisePlan	2.01	D	✓	✓			
Nomos	Corvus		R		++			
Nucletron	Helax TMS		R	✓	✓			
	TheraPlan Plus		R	✓				
	PLATO RTS	2.62	D	✓				
	PLATO BPS	14.2.6	D				✓	
Philips	Pinnacle[3]		R	✓	✓			
	AcqPlan	4.9	R	✓				
Resses Medical	Struta Suite CTPlan	4.0	R			✓		
RTek	PIPER	2.1.2	R			✓		
Varian	BrachyVision	6.5 (Build 11.67)	D				✓	
	Eclipse	7.1	D	✓	✓			
	VariSeed	7.1	D			✓		



8 RESULTS: Digital Data Submitted to ITC

Progress in the development of digital data submission capabilities of commercial treatment planning systems is reflected in annual submission of protocol case data sets (right) and average weekly submission to ITC's FTP server (left). Also reflected is continued growth in the number of institutions with demonstrated ability to submit digital data using ATC Method 1.



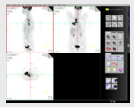


9 PROTOCOLS SUPPORTED BY ATC METHOD 1 (3/23/2006)

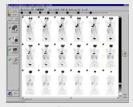
Protocol	Insts. Cred.	Cases Accrued	Accrual Goal	Status
RTOG 9406: Phase I/II Dose Escalation Study Using 3DCRT for Adenocarcinoma of the Prostate.	54	1084		closed
RTOG 9311: Phase I/II Dose Escalation Study Using 3DCRT in Patients with Inoperable NSCLC.	26	180		closed
RTOG 9803: Phase I/II Radiation Dose Escalation Study Applying 3DCRT in Supratentorial Glioblastoma Multiforme.	46	210		closed
RTOG 0022: Phase I/II Study of 3DCRT and IMRT for Oropharyngeal Cancer.	32	69		closed
RTOG 0225: Phase I/II Study of Conformal And Intensity Modulated Irradiation for Nasopharyngeal Cancer	36	68		closed
RTOG 0319: Phase I/II to Evaluate 3DCRT Irradiation Confined to Region of the Lumpectomy Cavity for Stage I/IIA Breast Carcinoma.	31	58		closed
RTOG 0117: Phase I/II dose intensification study using 3DCRT and concurrent chemotherapy for patients with inoperable, non-small cell lung cancer	47	38	73	open
RTOG 0126: Phase III randomize study of high dose 3DCRT/IMRT versus standard dose 3DCRT/IMRT in patients treated for localized prostate cancer.	127	841	1520	open
RTOG 0232: Phase III Study Comparing Combined External Beam Radiation & Transperineal Interstitial Permanent Brachytherapy with Brachytherapy alone	64	194	1520	open
RTOG 0234: A Phase II Randomized Trial of Surgery Followed by Chemoradiotherapy Plus C225 (Cetuximab) for Advanced Squamous Cell Carcinoma of the Head and Neck	42	12	230	open
RTOG 0236: Phase II Extracranial Stereotactic Radioablation in Treatment of Patients with Medically Inoperable Stage in NSCLC	7	38	52	open
RTOG 0321: Phase I/II Prostate: High Dose Brachytherapy and External Beam	15	91	110	open
NSABP B39/RTOG 0413: Phase III Partial Breast Irradiation (PBI cases)	277	507	1500	open
RTOG 0418: Phase II IMRT + / - chemo for post-op endometrial or cervical Ca	55	0	92	open 3/06
RTOG 0421: Phase III Trial for Previously Irradiated Head and Neck Cancer: Reirradiation with or without Chemo	37	6	240	open
RTOG 0438: Phase I Unresect. Primary Bil Hepatobil. Ca & Liver Mets Extracranial Stereotactic RT	1	0	18	open 11/05
RTOG 0521: Phase III Trial for localized High Risk Prostate Cancer: Androgen Suppression with Radiation vs. Radiation with Chemotherapy and Prednisone.	55	4	600	open 12/05
RTOG 0522: Phase III Trial Comparing Radiation and Cisplatin with/without Cetuximab for Advanced Head and Neck Cancer.	41	7	720	open 3/05
JCOG 0403: Phase II Study of Stereotactic Body Radiation Therapy in Patients with T1N0M0 Non-Small Cell Lung Cancer	13	67	165	open

10 Status of ATC PET Support for Advanced Technology Protocols

- PET Image Review for RTOG 0515
  - Institution submits PET DICOM Images and TP data to ITC using FTP or media.
  - ITC places (anonymized) PET data on ATC secure web server for download by Nuclear Medicine Chair or designate.
  - PET studies read (qualitatively) using eFilm or Syngo.
  - PET/CT image registration checked at ITC using FOCAL software.
  - TV contours evaluated using FOCAL with/without PET.
- PET/CT Fusion for RTOG 0522 (Quantitative PET)
  - PET data submitted to ACRIN Core Lab.
  - ACRIN checks PET images and uploads image data to CIP database.
  - ITC receives CT images, RT Structure sets, 3D Dose (DICOM, RTOG formats).
  - ITC-RTOG checks DICOM RT objects data integrity and upload data to CIP database.



PET scan (GE) downloaded and displayed on MIR NM Siemens Syngo software



PET scan (GE) downloaded and displayed on MIR NM eFilm software

CMS FOCAL software used to check image registration and review TV contours

11 caBIG In Vivo Imaging Workspace

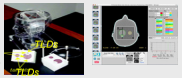
The ATC is one of the funded participants in the caBIG In Vivo Imaging Workspace. ATC members are participating in the following Special Interest Groups:
- Testbed SIG
- Standards and Interoperability SIG
- Software SIG

National Cancer Institute
caBIG™ cancer Biomedical Informatics Grid™

12 CREDENTIALING: RPC IMRT PHANTOM TEST

RPC tests ability of each RTOG institution to deliver IMRT by asking facility to:
- Scan RPC phantom (CT, MRI, etc.)
- Generate an IMRT plan according to defined protocol
- Deliver treatment to phantom
- Return phantom and dosimeters to RPC for evaluation.
- Submit digital planning data to the ITC

RPC uses ITC Remote Review Tool to analyze data



The RPC has considerable experience with the head and neck phantom, which to date has been irradiated 163 times at 128 institutions. Of particular note is the observation that roughly one-third of the first time irradiations fail to comply with the institution's own treatment plan using criteria of ±7%, ±4 mm. Repeat irradiations at institutions that fail initially show an improved pass rate.

A. MOLINEU *et al.* Anthropomorphic QA phantom for IMRT. Int. J. Radiation Oncology Biol. Phys., Vol. 63, No. 2, pp. 577–583, 2005

13 ATC METHOD 2 DIGITAL DATA SUBMISSION REVIEW SYSTEM

System of software referred to as *ATC Method 2* was developed by the Resource Center for Emerging Technologies (RCET) for supporting QA of cooperative group clinical trials within the ATC and includes the WebSys/NetSys client and server for secure data upload, /download, archiving of volumetric imaging and radiotherapy treatment planning data, a web-based Rapid Image Viewer (RIV) tool, and web-based tools for server administration. Testing of this method is now underway at ITC.

J. PALTA *et al.* Web-based submission, archive, and review of radiotherapy data for clinical quality assurance: a new paradigm. Int. J. Radiation Oncology Biol. Phys., Vol. 57, No. 5, pp. 1427–1436, 2003

14 ATC WEBSITE

The ATC has been active in the development of an infrastructure to facilitate the digital data submission and quality-assurance review of treatment planning and verification data for patients enrolled in advanced-technology radiation therapy clinical trials. The ATC web site (http://atc.wustl.edu) links to each of the ATC member web sites and provides information and resources for participating institutions and reviewers involved in these trials.

- Facility Questionnaire
- Dry Run Test Guides
- Data submission forms
- Data submission checklists
- QA Guidelines (by protocol)
- Protocol text

15 SUMMARY AND CONCLUSIONS

- The ATC is a team of radiation oncologists, clinical physicists, medical dosimetrists, imaging physicians and physicists, and information scientists, who play a key role in support of clinical trials, particularly in achieving institutional credentialing and protocol compliance for these advanced technology clinical trials requiring digital data submission.
- Volumetric 3D treatment planning digital data are collected, reviewed, analyzed, and stored in a TPV database that can be linked to clinical outcomes.
- Credentialing and QA processes for 3DCRT, IMRT, SBRT, HDR, and prostate brachytherapy multi-institutional clinical trials have been established to improve the consistency of treatment planning and delivery for these trials.
- The ATC is working to extend these capabilities to all cooperative groups planning to conduct advanced-technology clinical trials that require volumetric digital data submission.

16 ACKNOWLEDGEMENTS

The Advanced Technology QA Consortium is a team effort, supported by NIH U24 Grant CA81647, "Advanced Technology QA Center". The individuals listed below have made significant contributions to this work.

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