

1 The Advanced Technology Consortium (ATC) for Clinical Trials Quality Assurance (QA)

This brochure is intended to inform ASTRO Annual Meeting registrants of the latest developments by the ATC and the status of advanced technology clinical trials supported by the ATC. More information can be found at the ATC web site <http://atc.wustl.edu>.

The Advanced Technology Consortium (ATC) for Clinical Trials Quality Assurance (QA) is supported by a National Cancer Institute (NCI) U24 grant to Washington University. It 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). It capitalizes on the existing infrastructure and strengths of national QA programs. The overall mission of the ATC is to facilitate and support NCI sponsored advanced technology clinical trials, particularly those requiring digital data submission. This effort includes radiation therapy QA, image and radiation therapy digital data management, and clinical research and developmental efforts. Efforts are made to utilize each group's strengths and avoid duplication of existing programs. 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.



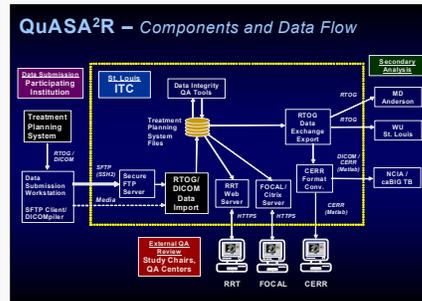
J.A. Purdy, Ph.D.
ATC Principal Investigator
September 21, 2008

2 ATC NIH U24 Grant Renewal

The Advanced Technology QA Consortium (consisting of ITC, RPC, QARC, and RTOG) administered through Washington University (P.I., J.A. Purdy, Ph.D.) completed the first year of the new grant on June 30, 2008. The funding period for the new grant is July 1, 2007 to June 30, 2012. The following ATC goals will be accomplished through coordination, service, and developmental 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 Cooperative Group study chairs and, QA Groups, RPC, and 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.

3 QuASA²R: Quality Assurance Submission, Archive, Analysis, and Review System



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

- 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.
- National / International QA resource for RT cooperative protocol groups
 - In active production at ITC and QARC
 - Supports collection, QA review and analysis of volumetric images and dosimetry

4 ATC Compliant Data Submission Software

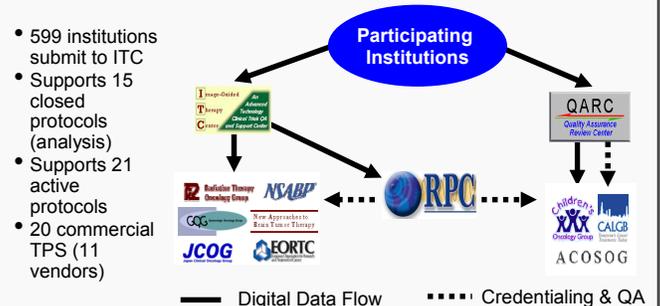
- ATC(ITC) maintains a list of commercial ATC Compliant Treatment Planning Systems (TPS) on the ATC website. These TPS can produce data in a format suitable for submission on ATC-supported protocols.
- ATC(ITC) continues to assist TPS manufacturers in developing ATC compliant data export capabilities and remains active in the development of the DICOM standard as well as IHE-RO profiles for improving the interoperable use of RT data.

Vendor	Treatment Planning Systems		Exchange Format	Treatment Modality			
	System	Version ¹		3DCRT	IMRT	Seed Brachy	HDR Brachy
Accuray	MultiPlan	1.5.2	D		✓		
CMS	FocusGTO	3.1	R	✓	✓	✓	✓
	XGO	4.3.1	D	✓	✓		
Elekta	RenderPlan 3D		R	✓			
	PrecisePlan	2.01	D	✓	✓		
Nomos	Corvus		R		✓	2	
	Nucletron				✓	✓	
Philips	TheraPlan Plus		R	✓	✓		
	Oncontra MasterPlan	1.5	D	✓	✓		
	PLATO RTIS	2.62	D	✓	✓		
	PLATO BPS	14.2.6	D			✓	
	SPOT-PRO	3.1.00	D			✓	
Philips	Pinnacle ³		R	✓	✓		
	Pinnacle ³	8.0b	D	✓	✓		
	AcqPlan	4.9	R	✓	✓		
Princess	Paathier	4.41	D	✓	✓	✓	
Kosses Medical	Strata Suite CTPlan	4.0	R	✓	✓		
RTek	PIPER	2.1.2	R	✓	✓		
Tomotherapy	Hi-ART	3.0 ³	D			✓	
Varian	BrachyVision	6.5 (build 1.1.47)	D			✓	
	Eclipse	7.1	D	✓	✓	✓	✓
	VarSeed	7.1	D			✓	

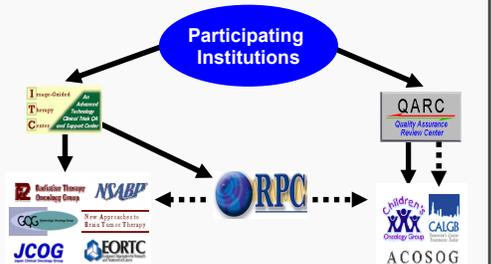
changing the way healthcare connects **Radiation Oncology** (See <http://atc.wustl.edu>)

5 ATC Support of Cooperative Groups (Electronic Submission, Credentialing, Dosimetry, QA)

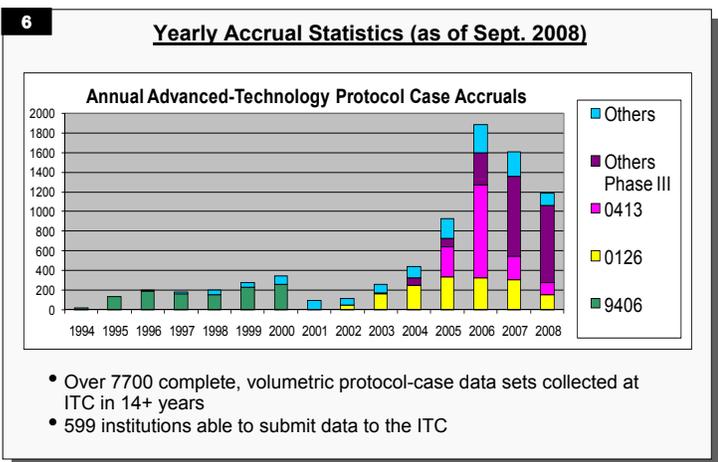
- The ATC effort has provided all U.S. Cooperative Groups the ability to submit images and volumetric treatment planning (TP) data to either ITC or QARC for QA and outcomes analysis in clinical trials utilizing advanced technology.
- The QuASA²R Clinical Trials QA System has proven to be extremely robust for support of clinical trials QA and encompasses mechanisms and software developed and maintained by the ITC for the submission, analysis, and review of clinical trials volumetric treatment planning data.



- 599 institutions submit to ITC
- Supports 15 closed protocols (analysis)
- Supports 21 active protocols
- 20 commercial TPS (11 vendors)



— Digital Data Flow Credentialing & QA



7 ATC Supports RTOG Protocols

The table below lists RTOG protocols supported by ATC and indicates the number of complete data sets (CT, Structures, 3D Dose, Plan) received by ITC as of July 2008.

Site	Protocol	Open	Data sets
Brain	9803 Brain 3DCRT	N	195
Breast	0319 Partial breast 3DCRT	N	53
	0413 Partial breast	Y	1483
GI	0529 Anal canal IMRT	N	63
	0822 Rectal IMRT	Y	8
	0436 Esophagus 3D	Y	1
	0438 Liver SBRT	Y	14
	0521 Prostate IMRT	Y	471
GU	9406 Prostate 3D	N	1062
	0126 Prostate 3D/IMRT	N	1426
	0232 Prostate seeds	Y	348
	0415 Prostate hypofract.	Y	512
	0521 Prostate IMRT	Y	471
	0526 Prostate seeds	Y	5
	0321 Prostate HDR	N	122
	0621 Prostate 3D/IMRT	Y	1
	0622 Prostate Bed 3D/IMRT	Y	0
	0534 Prostate Bed 3D/IMRT	Y	3
GYN	0418 Cervix IMRT	Y	90
	0417 Cervix Brachy	Y	6
	0022 Oropharynx 3DCRT/IMRT	N	68
	0225 Nasopharynx 3DCRT/IMRT	N	65
H/N	0234 H/N IMRT	N	79
	0435 H/N Palifermin	N	8
	0522 H/N 3DCRT/IMRT, PET	Y	582
	0615 Nasopharynx 3DCRT/IMRT	Y	19
	Lung	9311 Lung 3DCRT	N
0117 Lung 3DCRT		N	57
0236 Lung SBRT		N	52
0617 Lung 3DCRT/IMRT		Y	19
0618 Lung SBRT		Y	2
Sacoma	0623 Small Cell Lung 3DCRT	Y	2
	0515 Lung PET/CT target vol.	N	52
0630 Soft-Tissue Sarcoma	Y	0	

8 ATC Supports NSABP B39/ROG 0413

The Partial Breast Irradiation (PBI) protocol B39/0413 has demonstrated the value of ATC's digital approach and the close collaboration needed in a demanding protocol. Complete QA details are available at the ATC website <http://atc.wustl.edu> or the RPC website <http://rpc.mdanderson.org>.

- High volume, Multiple study groups, Multiple treatment modalities
- Credentialing involves both ITC and RPC and involves Benchmark tests (Downloadable CTs and structure sets)
- Multi-faceted review process including Pls from protocol and their designates, Dosimetrists from RTOG and RPC, and ITC personnel.

9 ATC Supports EORTC Protocol 22042-26042

- ITC is providing Data Integrity Quality Assurance services to the EORTC for Protocol 22042-26042 Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma: a Phase-II and registration study.

10 ATC Supports NABTT Protocols

- ITC is providing Data Integrity Quality Assurance services to the New Approaches to Brain Tumor Therapy consortium for NABTT Protocol 0603.
- Treatment planning data, submitted to ITC, are reviewed for Data Integrity and made available for Protocol Compliance QA review using the ITC Remote Review Tool.

New Approaches to Brain Tumor Therapy

11 ATC is working with caBIG and NCI

- ATC is one of the funded participants in the caBIG In Vivo Imaging Workspace.**
 - ATC members (ITC, RTOG, QARC) and ACRIN are actively participating in the In Vivo Imaging Workspace.
 - Continuing to explore caBIG IVI projects with Emory Univ. (Dr. Joel Saltz) and QARC
- PET/CT Fusion for RTOG 0522**
 - 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-ROG checks DICOM RT objects data integrity and uploads data to the National Cancer Imaging Archive

ITC provides RTOG 0522 Treatment Planning data (in DICOM and CERR formats) to the National Cancer Imaging Archive (NCIA)

12 ATC Supports JCOG 0403: Ph II Study of SBRT In Patients with T1N0M0 Non-Small Cell Lung Cancer

- Institutions participating in protocol JCOG 0403 submit digital data representing CT images, structure sets, treatment plans, 3D dose distributions, and DVHs to Dr. Satoshi Ishikura, Director of the Radiotherapy Support Center, Tokyo, JAPAN, who then uses the QuASA²R system to submit these data to ITC in St. Louis for processing.
- Data are reviewed by Dr. Ishikura or his delegate using the QuASA²R Remote Review Tool.
- Currently, 14 institutions are eligible to enroll patients and capable of digital data submission on JCOG 0403; 155 patients are registered to study.

13 Summary and Conclusions

- ATC is a "virtual entity" made up of the nation's major clinical trials QA centers, including the ITC, RTOG, RPC, and QARC. It capitalizes on the individual strengths of these QA programs, and plays a key role in achieving institutional credentialing and protocol compliance for advanced technology clinical trials requiring digital data submission.
- The ATC(ITC) developed QuASA²R system provides the most advanced medical informatics infrastructure currently in use anywhere in the world to support radiation therapy clinical trials digital data quality assurance.
- QuASA²R**
 - ... is based on practical experience in support of clinical trials QA,
 - ... provides secure data submission, analysis, and review of radiation therapy and imaging data,
 - ... has enabled the collection, review, and analysis of >5800 protocol case data sets, and
 - ... will continue to evolve using appropriate information technology to meet the QA needs of RT clinical trials.
- 11 treatment planning system vendors (20 different planning systems) have released ATC-compliant RTOG/DICOM export software.
- 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 regarding credentialing and QA processes for ATC supported protocols utilizing 3DCRT, IMRT, SBRT, HDR, and prostate brachytherapy.
- Volumetric 3D treatment planning digital data are collected, reviewed, analyzed, and stored in a database that can be linked to clinical outcomes; (over 7700 datasets thus far).
- 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.

14 Acknowledgements

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For more information, please visit <http://atc.wustl.edu>