

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

The Advanced Technology Consortium for Clinical Trials Quality Assurance (ATC) 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 RT-QA 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.

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ATC Co-Principal Investigators
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2 ATC Principal Investigator Transition

As of July 1, 2009, the beginning of the 3rd year of the current five-year finding period, Dr. Purdy has stepped down as P.I. of the ATC U24 Grant. Drs. Bosch and Michalski now serve as co-P.I.s, responsible for the overall direction and coordination of ITC/ATC efforts. Dr. Purdy continues to assist as a co-investigator.

3 ATC Grant Objectives

The following ATC goals will be accomplished through *coordination, service, and developmental objectives*:

- Eliminate duplication of infrastructure developmental efforts and facilitate sharing of QA resources among cooperative groups.
- Help to insure that appropriate and uniform QA procedures and criteria for advanced technology trials are developed across all cooperative groups.
- Facilitate/help manage the uniform credentialing of institutions for advanced radiotherapy trial protocols.
- Facilitate/manage digital data protocol submission.
- Facilitate/manage the QA review of submitted data.
- Further the development of methods for rapid analysis of volumetric treatment planning data.
- 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.
- Develop, implement, and maintain innovative methods for electronic exchange of digital planning data between institutions participating in clinical trials and between QA Centers.
- 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.
- Develop, implement, and maintain archival treatment planning and QA databases that can be linked with the cooperative groups' clinical outcomes databases.
- 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.

4 QuASA²R (Quality Assurance, Submission, Archive, Analysis, and Review) Clinical Trials QA System

The QuASA²R system developed by the ITC (has been extremely successful 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.

- QuASA²R developed by the ITC through the ATC.
- 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.
- 25 active protocols, 19 closed protocols (7 cooperative groups/sponsors)



- 634 institutions
- 22 commercial TPS (11 vendors)

5 Data Submission Software

- A list of ATC Compliant commercial Treatment Planning Systems (TPS) can be found on the ATC website. These TPS can export 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.

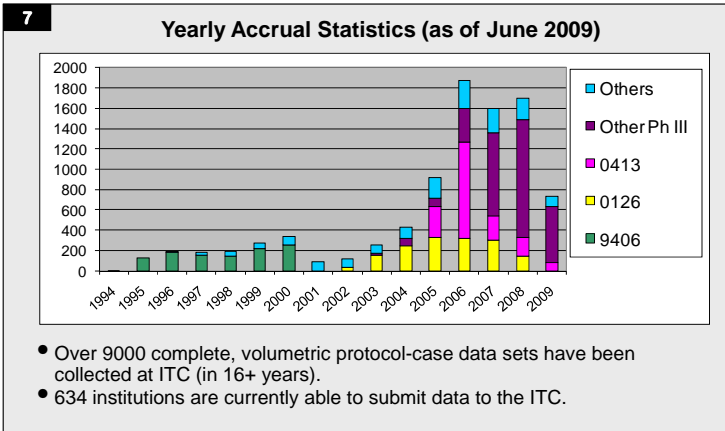
Vendor	System	Version ¹	Exchange Format		Treatment Modality		
			3DCRT	IMRT	Seed Brachy	HDR Brachy	Protons
Accuray	MultPlan	1.5.2	D		✓		
BrainLAB	iPlan	4.1.2	D	✓	✓		
Elekta	CMS Focus/GO	3.1	R	✓	✓		✓
	CMS XGO	4.3.1	D	✓	✓		
	RendezPlan 3D		R	✓	✓		
	PrecisePlan	2.01	D	✓	✓		
Nomos	Corvus		R	✓	✓		
	Nucletron						
	Helax TMS		R	✓	✓		
	TheraPlan Plus		R	✓	✓		
	Oncentra	1.5	D	✓	✓		
	MasterPlan	3.1	D	✓	✓		✓
	PLATO RTS	2.62	D	✓	✓		
	PLATO BPS	14.2.6	D	✓	✓		✓
	SPOT-PRO	3.1-00	D	✓	✓		
Philips	Pinnacle ²		R	✓	✓		
	Pinnacle ²	8.0h	D	✓	✓		
	AcqPlan	4.9	R	✓	✓		
Prevision	Pathfinder	4.41	D	✓	✓		
Rosin Medical	Stata Suite CTPlan	4.0	R	✓	✓		
RTek	PIPER	2.1.2	R	✓	✓		
TomoTherapy	Hi-ART	3.0 ³	D	✓	✓		
Varian	BrachyVision (base 1.1.1)	6.5	D	✓	✓		✓
	Eclipse	7.1	D	✓	✓		✓
	VarSeed	7.1	D	✓	✓		✓

(See <http://atc.wustl.edu>)



6 Abstracts at AAPM 2009 Supported By ATC Grant

- SU-FF-T-320** The Radiological Physics Center's Annual TLD Machine Calibration Audit and Its Impact On Clinical Trials - D. Followill, J. Lowenstein, L. Palmer, G. Ibbott
- SU-FF-T-370** Evaluation of An Anthropomorphic Pelvis Phantom for Proton Therapy, R Grant, G Ibbott, N Sahoo, S Tucker, X Zhu, D Followill
- SU-FF-T-444** Validation and Benchmark of a Source Model for a Varian 6 MV Photon Beam Using Monte Carlo Calculations S Davidson, J Cui, S Kry, M Vicic, J Deasy, R White, G Ibbott, D Followill
- MO-A-BRC-1** Credentialing for Clinical Trials: The Role of the RPC G Ibbott
- MO-FF-A3-5** Tools and Methods for Consensus Generation From Experts' Contours for Radiotherapy Structure Definition, A Apte, J Deasy, W Bosch, I El Naqa



8 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 2009.

Site	Protocol	Open	Data sets
Brain	9803 Brain 3DCRT	N	195
	0825 Glioblastoma	Y	4
Breast	0319 Partial breast 3DCRT	N	53
	0413 Partial breast	Y	1605
GI	0529 Anal canal IMRT	N	62
	0436 Esophagus 3D	Y	46
	0438 Liver SBRT	Y	20
	0822 Rectal IMRT	Y	46
	9406 Prostate 3D	N	1062
GU	0126 Prostate 3D/IMRT	N	1466
	0232 Prostate seeds	Y	416
	0321 Prostate HDR	N	122
	0415 Prostate hypofract.	Y	808
	0521 Prostate IMRT	Y	521
	0526 Prostate seeds	Y	16
	0534 Prostate Bed 3D/IMRT	Y	68
	0621 Prostate 3D/IMRT	Y	18
	0622 Prostate Bed 3D/IMRT	Y	3
	0712 Bladder	Y	3
	GYN	0418 Cervix IMRT	N
0417 Cervix Brachy		Y	6
0022 Oropharynx 3DCRT/IMRT		N	68
0225 Nasopharynx 3DCRT/IMRT		N	65
0234 H/N IMRT		N	85
H/N	0435 H/N Palifermin	N	17
	0522 H/N 3DCRT/IMRT, PET	N	817
	0615 Nasopharynx 3DCRT/IMRT	Y	43
	0619 H/N Post-op IMRT	Y	2
	Lung	9311 Lung 3DCRT	N
0117 Lung 3DCRT		N	60
0236 Lung SBRT		N	55
0617 Lung 3DCRT/IMRT		Y	90
0618 Lung SBRT		Y	10
0623 Small Cell Lung 3DCRT		Y	4
Sacoma	0515 Lung PET/CT target vol.	N	52
	0630 Soft-Tissue Sarcoma	Y	15

RTOG
RADIATION THERAPY ONCOLOGY GROUP

9 ATC Supports NSABP B39/RTOG 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 PIs from protocol and their designates, Dosimetrists from RTOG and RPC, and ITC personnel.

NSABP

10 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.

EORTC
European Organisation for Research and Treatment of Cancer

11 ATC Supports GOG Protocols

ITC is providing Data Integrity Quality Assurance services to Gynecologic Oncology Group for GOG protocols 0238, 0249, and 0258. 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.

GOG
Gynecologic Oncology Group

12 ATC is working with caBIG and NBIA

- ATC is one of the funded participants in the caBIG In Vivo Imaging Workspace.**
 - ATC members (ITC, RTOG, QARC) and ACIN are actively participating in the In Vivo Imaging Workspace.
 - Continuing to pursue caBIG IVI projects with Emory Univ. (Dr. Joel Salz) and QARC
- PET/CT Fusion for RTOG 0522**
 - PET data submitted to ACIN Core Lab.
 - ACIN 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 uploads data to the National Biomedical Imaging Archive

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

NATIONAL CANCER INSTITUTE
caBIG™ Cancer Biomedical Informatics Grid™

13 ATC Supports JCOG 0702: Ph I Dose Escalation Study of SBRT In Patients with T2N0M0 Non-Small Cell Lung Cancer

- Institutions participating in protocol JCOG 0702 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 0702; 9 patients are registered to study.

JCOG
Japan Clinical Oncology Group

14 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.
- 11 treatment planning system vendors (22 different planning systems) have released ATC-compliant RTOG/DICOM export software.
- Volumetric 3D treatment planning digital data are collected, reviewed, analyzed, and stored in a database that can be linked to clinical outcomes; (over 9000 datasets thus far, from more than 630 institutions worldwide).
- 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 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.

15 ACKNOWLEDGEMENTS

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