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

Principal Investigator's Report
Advanced Technology QA Consortium

RTOG Meeting – Toronto, Ontario
June 22, 2006

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"Advanced Technology QA Center"

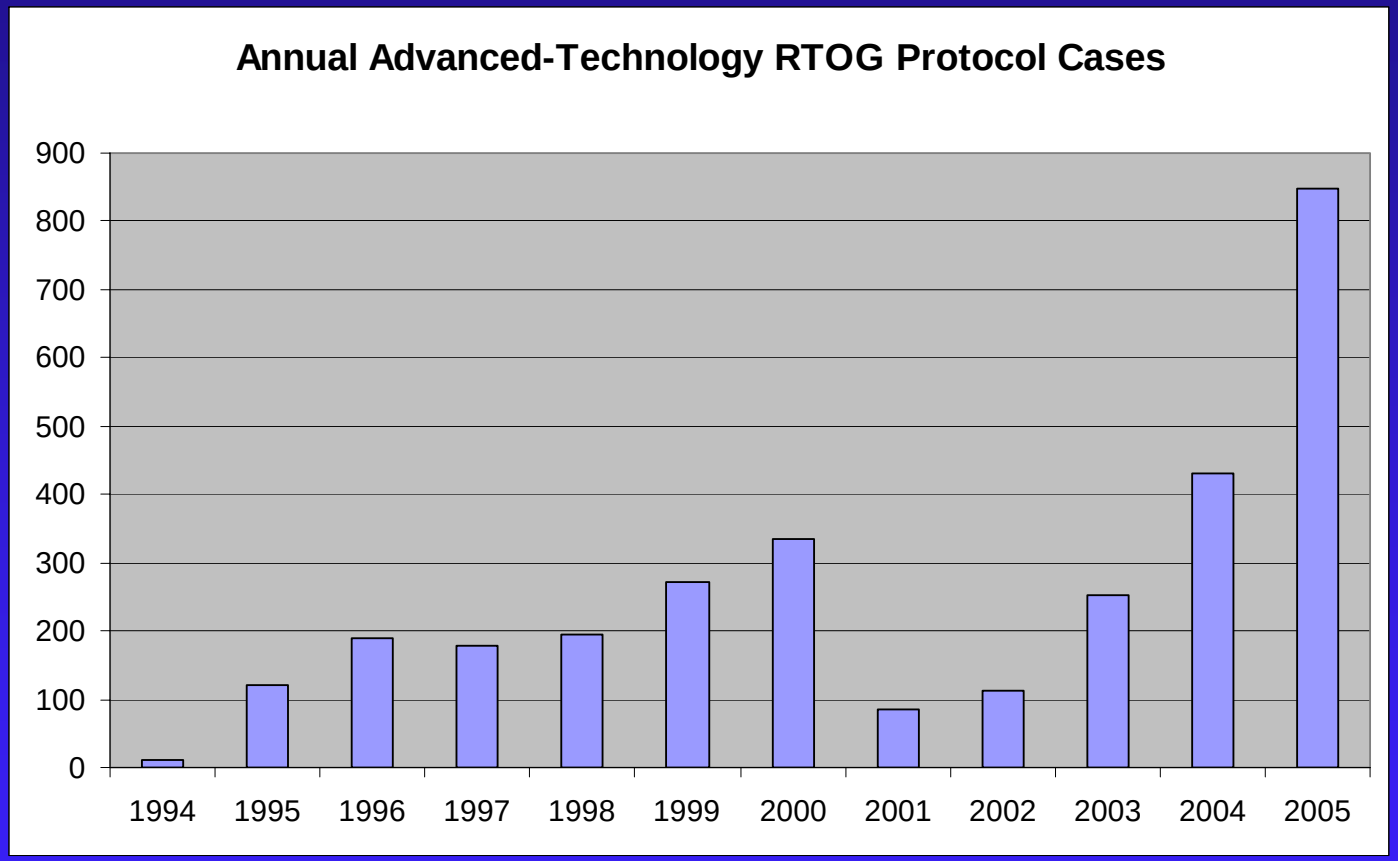
P.I.'s Report

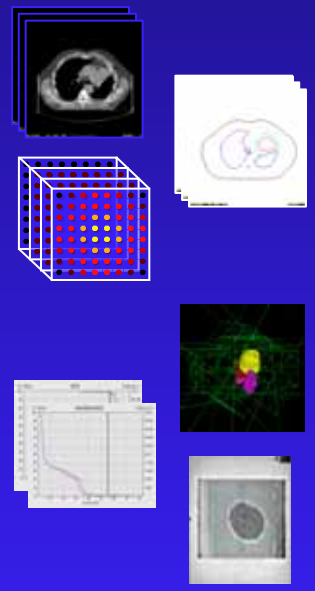
- Welcome
- Approval of minutes from June 7, 2006 ATC Teleconference
- Changes at ITC-WU
- Update on ATC Service activities
- Update on potential interactions with other cooperative groups
- ATC IMRT Task Group
- 2006 Scientific/Professional Meetings
- Update on caBIG In Vivo Imaging Workspace
- ATC Website
- Challenges/Opportunities
- Schedule of future ATC Teleconferences and meetings
- ATC Steering Committee Response

Update on Changes at ITC - WU

- ITC/WUCON Network Re-configuration (discussed during ITC report)
- Workload at ITC
  - Hired new CRA (Anna Eccher, QA Data Coordinator)
- Admin support change (Kathy Feurer)
- ITC 21 CFR 11 effort on-going
- Awaiting Yr08 Award Statement

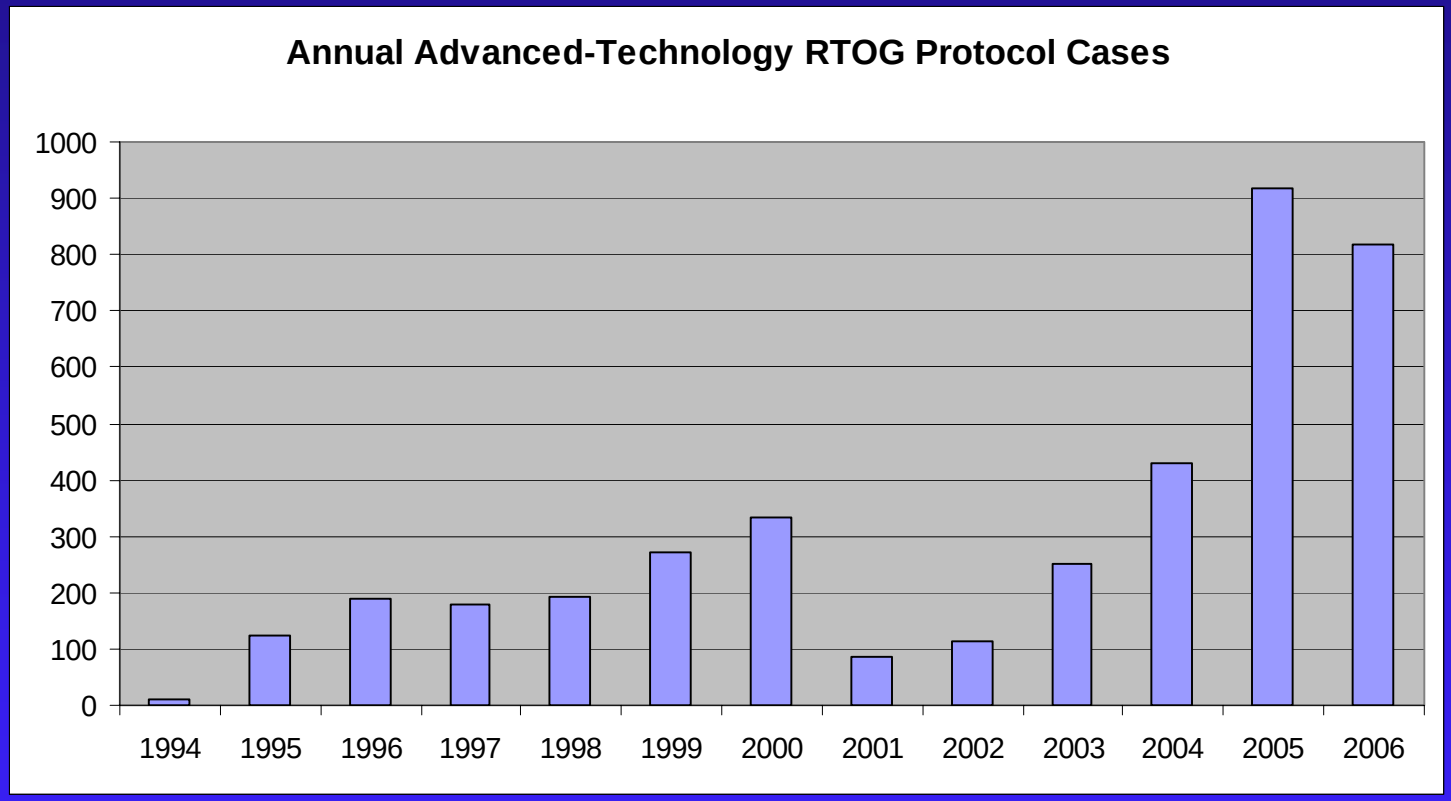
- **Jan 19 2006 ATC Mtg: 3026 Complete, Protocol-Case, Digital Data Sets Submitted Over 12 Year Period using ATC Method 1***

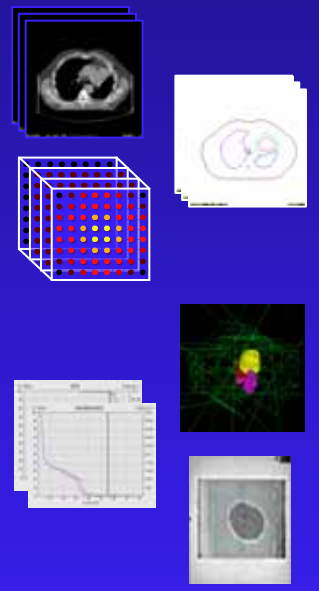




- **15 commercial RTP systems have implemented export capability**
- **331 institutions able to submit data**

- **June 22 2006 ATC Mtg: 3913 Complete, Protocol-Case, Digital Data Sets Submitted Over 12 Year Period using ATC Method 1***





- **15 commercial RTP systems have implemented export capability**
- **418 institutions able to submit data**

ATC Compliant Treatment Planning Systems
(as of June 22, 2006)

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	✓				
Rosses Medical	Strata Suite CTPlan	4.0	R			✓		
RTek	PIPER	2.1.2	R			✓		
Varian	BrachyVision	6.5 (Build 7.1.67)	D				✓	
	Eclipse	7.1	D	✓	✓			
	VariSeed	7.1	D			✓		

D = DICOM RT Objects R = RTOG Data Exchange Format

ITC Work With Vendors/Users Toward ATC Compliance

- CMS XIO 4.3.1 was released in early June; this version has DICOM export which was Vendor Complete as last tested. No data from a clinical site has been received by ITC using XIO 4.3.1 DICOM export.
- Simuplan TPS (Simuplan, S.L.), a MAC based TPS for mammosite, submitted DICOM test data 11May2006 (CT, RS, RP, and RD). Only the CT was readable by the Merge library. Simuplan asked for more specifics, but Dr. Matthews has not yet been able to follow-up because of his focus on WUCON reconfiguration efforts.
- ITC has received TomoTherapy Hi-Art digital data from UC Davis using Tomo Research Workstation and is reviewing for ATC compliance.

Proton Data Beam Data Exchange with ITC

- MDACC
  - Varian Eclipse
- MGH
  - CMS Xio

14 RTOG Digital Data Protocols (June 22, 2006)

Protocol	Description
9406	Ph I/II 3DCRT Prostate Dose Escalation
9311	Ph I/II 3DCRT Lung Dose Escalation
9803	Ph I/II 3DCRT GBM Dose Escalation
0022	Ph I/II 3DCRT/IMRT Oropharynx
0319	Ph I/II 3DCRT Partial Breast
0117	Ph I/II 3DCRT/chemo Lung
0126	Ph III 3DCRT/IMRT Prostate
0225	Ph I/II 3DCRT/IMRT Nasopharynx
0232	Ph III Ext Beam/TIPPB Prostate
0234	Phase II Randomized Trial of Surgery Followed by Chemoradiotherapy Plus C225 (Cetuximab) for Advanced Squamous Cell Carcinoma of H&N
0236	Ph II SBRT Lung
0321	Ph I/II HDR/Ext Beam Prostate

WHITE = open protocols BLUE = closed protocols

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14 RTOG Digital Data Protocols (June 22, 2006)

Protocol	Description
00415	Phase III Rand Conventional Fx 3DCRT/IMRT vs Hypo Fx 3DCRT/IMRT in Prostate Ca
0418	Phase II IMRT + / - chemo for post-op endometrial or cervical Ca
0421	Phase III Trial for Previously Irradiated Head and Neck Cancer: Reirradiation with or without Chemo
0438	Phase I Unresect. Primary Bil Hepatobil. Ca & Liver Mets Extracranial Stereotactic RT
0515	Phase II NSCLC Volume definition+/- PET
0521	Phase III localized High Risk Prostate Cancer: Androgen Suppression with Radiation vs. Radiation with Chemotherapy and Prednisone
0522	Phase III Trial Comparing Radiation and Cisplatin with/without Cetuximab for Advanced Head and Neck Cancer

WHITE = open protocols BLUE = closed protocols

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1 NSABP/RTOG ATC Supported Open Protocols (June 7, 2006)

Protocol	Description	Institutions Credentialed	Cases Accrued	Accrual Goals
NSABP B39 RTOG 0413	Phase III Partial Breast Irradiation	322(264/189/32)	1446 (488/158/62)	3000

WHITE = open protocols

6 COG/CALGB/ACOSOG/ECOG QARC ATC Supported Open Protocols (June 22, 2006)

Cooperative Group	Protocol
COG	ACNS0121
COG	ACNS0126
COG	ACNS0331
CALGB	99809
ACOSOG	Z5031
ECOG	E2303

WHITE = open protocols

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1 JCOG ATC Supported Open Protocols (June 7, 2006)

Protocol	Description	Institutions Credentialed	Cases Accrued	Accrual Goals
JCOG 0403	Phase II Study of SBRT in Patients with T1N0M0 Non-Small Cell Lung Cancer	13	67	165

WHITE = open protocols

Update on Potential Interactions with other Cooperative Groups

- **EORTC:**
  - **Dr. Bernard Davis will step down as QA Physics coordinator of the EORTC Radiotherapy Group. This will take effect at the next group's meeting in the autumn.**
  - **Successor is Dr Edwin Aird, Chief Physicist at the Mount Vernon Hospital in the UK.**
  - **Collaboration with the ATC will continue as planned regarding the QA of the atypical meningioma study (No. 22042-26042) chaired by Dr Damien Weber of Geneva University Hospital. He and the physicist Giovanna Di Pasquale will be looking after the QA for the EORTC, together with Philip Poortmans and Edwin Aird, responsible for clinical and physics QA of the EORTC RTGroup.**
  - **Data integrity QA will be performed by the ITC as in RTOG, NSABP, and JCOG studies.**

Update on Potential Interactions with other Cooperative Groups

- NABTT (Dr. John Fiveash, M.D., Department of Radiation Oncology, University of Alabama-Birmingham) – No activity
- JCOG: Agreed to 2nd protocol support
- TROG – No activity

CDRP-ATC

- Singing River is now credentialed for 0413 3DCRT and working on 0126 using IMRT;
- UPMC/Mckeesport is credentialed for 0413 using 3DCRT.
- Several of the mentoring institutions are grandfathered into many of the new RTOG protocols that opened recently using IMRT.

New Issues – How do we handle the continuing increase in ATC service efforts?

- Need a more formal mechanism as to how we decide which clinical trials are supported by ATC funding.
  - In the past, ITC encouraged all comers (mostly RTOG, JCOG, …)
  - ATC must optimize use of all resources.

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ATC Task Group: Guidelines for use of IMRT for intra-thoracic treatments

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ATC Guidelines for Use of IMRT for Intra-Thoracic Treatments
May 31, 2006

Preamble:

The Advanced Technology Consortium (ATC) has helped to develop general guidelines (*Int. J. Radiat. Oncol. Biol. Phys. 59 (2004):1257-1262*) for protocols that incorporate Intensity Modulated radiation Therapy(IMRT) as a radiation therapy treatment technique option. These have been communicated to all clinical trial groups by the National Cancer Institute (NCI)and they clearly state that respiratory motion can cause far more problems for IMRT treatments than for traditional treatments. Because the delivery of IMRT is dynamic as is the effect of breathing motion, the interplay between the two may result in non-reproducible dose distributions due to the variability in how subfields are added. In addition, other patient motions may have significant effects on the summation of subfields whose intensities are based on a static image. Thus extra care is required in the

ATC Task Group: Guidelines for use of IMRT for intra-thoracic treatments

(comments from M. Gillin, Ph.D.)

1. There is a typo in item 1 A period after the word immobilization.
2. Item 2 - Peter Balter and I have a disagreement about "entire volume". One of us believes that it is the entire lung, while the other believes that it is the PTV. Perhaps clarification is needed. In the list of techniques, should gated acquisition be mentioned?
3. Item 3 - Should ITV be mentioned here? This concept does appear in the footnote. MDACC is a big user of ITV, which we define as an explicit structure of the unions of the CTVs. These guidelines avoid the issue of the expansion of the GTV to the CTV. Perhaps this is wise.
4. Item 4 - Should the expansion of the CTV to the PTV be a function of the set up/immobilization systems, e.g. Vac-loc + wing board and weekly port film = 10 mm expansion, full body immobilization + PF = 5 mm expansion, any immobilization + daily kV imaging = 3 mm expansion.

ATC Task Group: Guidelines for use of IMRT for intra-thoracic treatments
(comments from M. Gillin, Ph.D.)

5. Item 6 - The criteria of acceptability for the RTOG is a great question for the Med Phys Committee to consider.
6. Item 8 - A proposed addition "and should include common labels for each structure to be used across all institutions and protocols".
7. Item 10 - How should CT guided setups be documented?
8. Item 11 - Is it time to require DICOM-RT format for this data exchange or is RTOG still valid? As opposed to "representative slices" can the entire plan be submitted and let the QA center extract what it needs?
9. If I understand this properly, as a consequence of this guideline, the doses being delivered for these protocols may be different than historical doses. Should this possible change be recognized?

2006 Scientific Meetings

- ATC Workshop (Special Interest Session) held at AAMD Annual Meeting on June 6, 2006, in Vancouver, BC, Canada.
  - Held as breakout session while main program held in another room.
  - First session involved Eclipse (8:30 - 9:30); second session involved Pinnacle (10:00-11:00); third session involved Rahd and Nucletron (11:00-12:30)
  - Bill Straube presented an overview of ATC and digital data submission to the groups prior to each session and then vendors demonstrated TPS digital data submission UI's.
  - All Vendors brought equipment to demonstrate their submission.
  - All vendors plan on putting together information for the ATC website.
  - ATC should plan to do another workshop at the next AAMD Annual meeting to be held in New Orleans.

2006 Scientific Meetings

- AAPM Annual Meeting to be held July 30-Aug. 3, 2006, in Orlando, Florida.
  - ATC Brochure will be distributed using MDACC booth
  - Abstracts
    - Testing of ATC Method 2 for Supporting QA of Cooperative Group Advanced Technology Clinical Trials Requiring Digital Data Submission (ITC/RCET/NCIC)
    - Implementation of ATC Method 1 for Clinical Trials Data Review at the Quality Assurance Review Center (ITC/QARC)
    - Digital Data Integrity QA for Multi-Institutional Clinical Trials (ITC)
    - ITC Assists Developers of ATC Compliant DICOM Export for Clinical Trials (ITC)
    - Implementation of MINERVA/PEREGRINE as a Possible ATC Review Tool (ITC-UCD, Idaho National Laboratory, Idaho Falls, ID, Montana State University, Bozeman, MT)

2006 Scientific Meetings

- ASTRO Annual Meeting to be held Nov. 5-9, 2006, in Philadelphia, PA.
  - ATC Brochure will be distributed using NCI booth
  - Abstracts
    - A Review of the Activities of the ITC in Support of RTOG Advanced Technology Clinical Trials (ITC/RTOG for poster discussion session)

ATC-caBIG In Vivo Imaging Workspace

- ATC is one of the funded participants in the caBIG In Vivo Imaging Workspace. ATC members are participating in the following Special Interest Groups (SIGs) Teleconferences:
  - Testbed SIG
  - Standards and Interoperability SIG
  - Software SIG
- ATC members will participate in the upcoming In Vivo Imaging Workspace face to face meeting to be held in Rockville, MD on July 20-21, 2006.

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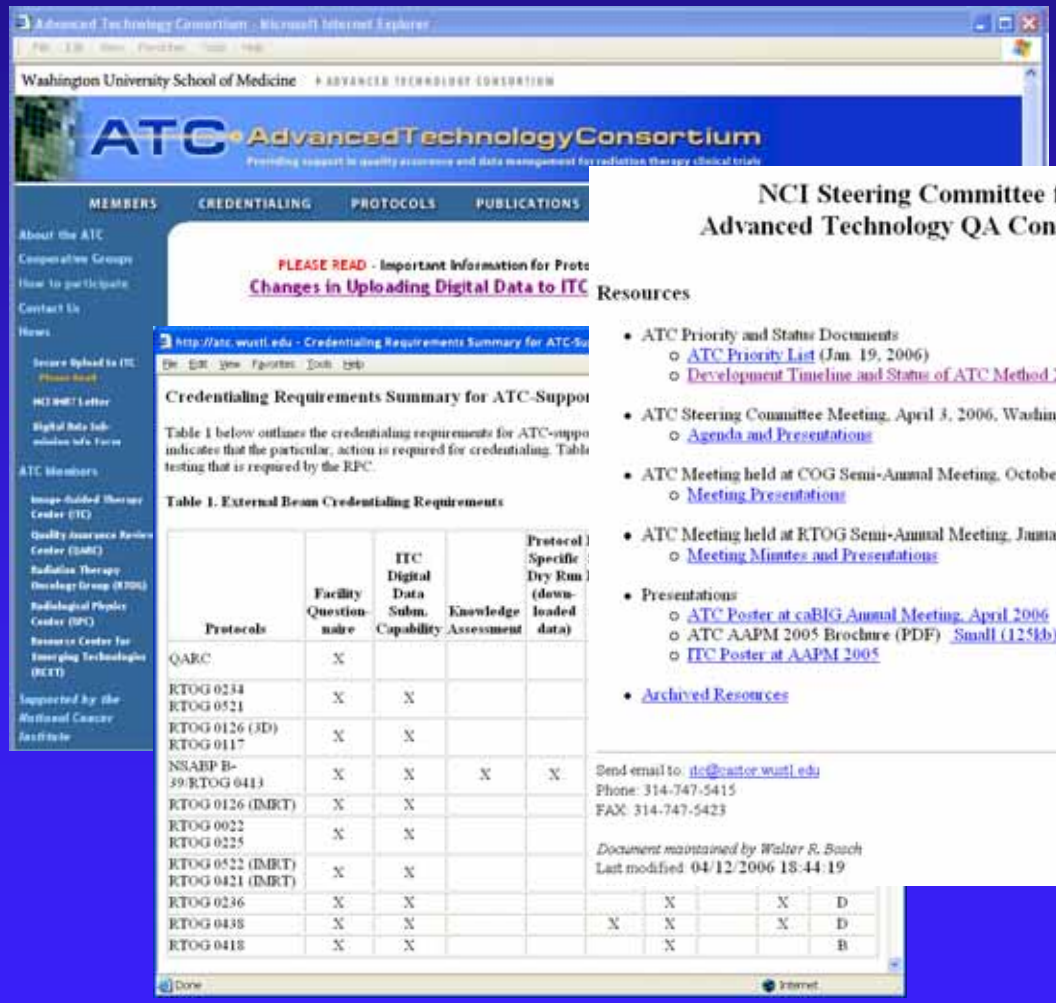
ATC WEB SITE (*http://atc.wustl.edu)*



- Steering Committee
  - Priority Lists
  - Timeline for ATC Method 1 at QARC
  - Timeline for ATC Method 2 at ITC (at NCIC)
- Publication Page
- Table of credentialing requirements for RTOG studies

Can ATC serve a broader educational mission?

Challenges/Opportunities: ATC Supported Clinical Trials

- Developing a more formal mechanism as to how it is decided as to which clinical trials are to be supported by ATC funding.
- ATC compliant stereotactic radiosurgery or radiotherapy RTP systems
- PET (quantitative) data import and image fusion QA
- 4-D CT (several 100 MB)
- Image-Guided RT (EPID, MV and kVp Cone beam CT, Helical Tomotherapy megavoltage CT)
- Adaptive Radiation Therapy (Daily Confirmation/Adjustment using On-Board Imaging)

Challenges/Opportunities: ATC Supported Clinical Trials

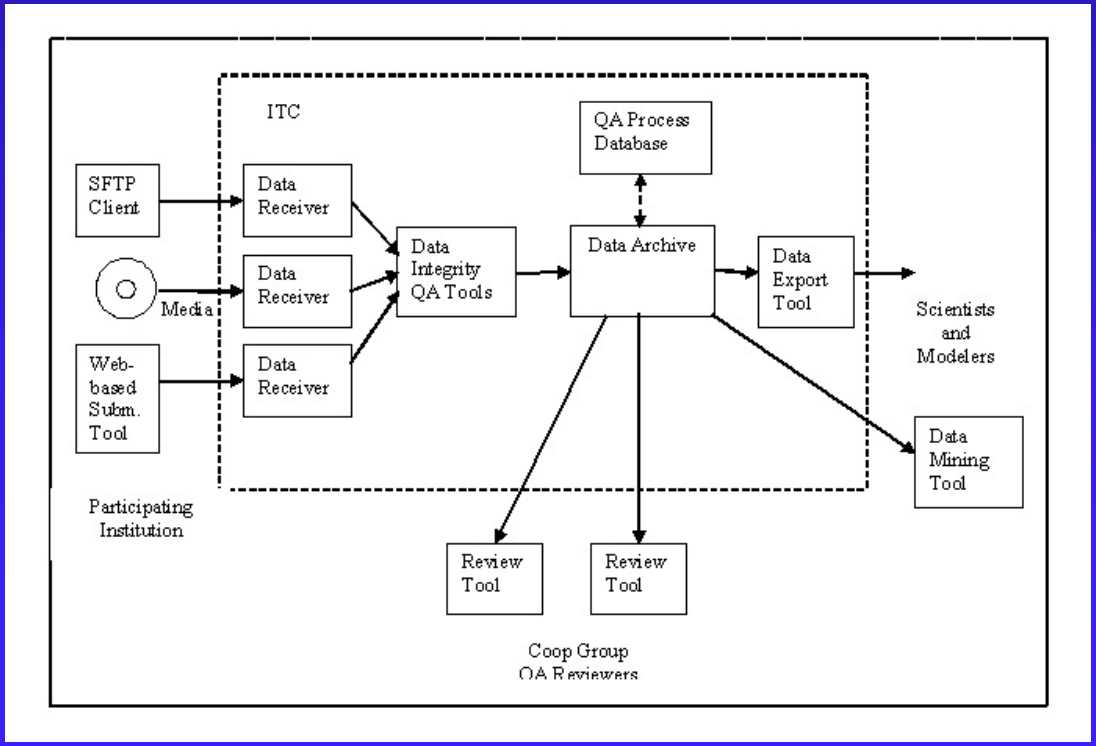
- Increased use of ATC Method 1 at QARC
- Successful implementation of ATC Method 2a at ITC and 2b at NCIC
- Move of ATC effort toward integration with industry informatics efforts
- caBIG compliant software
- RTOG Grant Renewal/ATC Grant Renewal 2007

Move of ATC effort toward integration with industry informatics efforts

- We are beginning planning for a new information infrastructure utilizing the lessons learned by the ITC and the RCET in clinical trials QA software development.
- Ideas being discussed for the new system design include:
  - using a more modular architecture with well-defined interfaces to enable integration of a heterogeneous mix of commercial-off-the-shelf, open-source, and custom software components
  - facilitate testing and maintenance of system components
  - allow step-wise implementation and upgrading of system components.

Move of ATC effort toward integration with industry informatics efforts

- A block diagram of the new architecture being considered is shown below. Around the core of the system are components for data submission, case review, outcomes analysis/data mining, and data export.



Future ATC Teleconferences and Meetings

- Next ATC Teleconference is scheduled for July 5, 2006.
- caBIG In Vivo Workspace Meeting July 20-21 in Rockville, MD
- AAPM Annual Meeting, July 30-Aug. 3, 2006, Orlando, Florida
- ATC Meeting at Fall COG Semi-annual meeting Oct. 5-6, Los Angeles, CA
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ATC Steering Committee Response

- The ATC has matured significantly and evolved into the premier image-based therapy clinical trials resource for NIH and the NCI. From a high level perspective, this modest entity has a remarkable record of achievement in a relatively short time. Some of these accomplishments include:
  - **A central role in defining and implementing DICOM/RT, an image interchange standard with extensions for radiation therapy. Without such a standard, it would be exceedingly difficult and awkward to capture treatment plans from disparate systems at various clinical sites and to unify these data into a meaningful collection. This was accomplished by direct interfaces with industry and insistence by ATC, enforced by medical physics organizations' attention to the issue so manufacturers today adhere to the standard and support its implementation on their products.**