

# **Principal Investigator's Report Advanced Technology QA Consortium**

**RTOG Meeting – Philadelphia, PA  
June 21, 2007**

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**Supported by NIH U24 grant CA81647,  
“Advanced Technology QA Center”**

# Agenda

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- 4:00 PM: Project Officer Report (Deye)
- 4:10 PM: P.I.'s Report (Purdy)
- ATC grant proposal update
  - Meetings/Teleconference schedule
  - Exploration of ways in which ATC effort could become synergistic with Quality Research in Radiation Oncology (QRRO) effort (Purdy, Jean Owen)
- 4:30 PM: RTOG Service Report (focusing on current problems/issues regarding service provided by ITC and RPC in support of AT protocols): (Martin, Galvin)
- 4:55 PM: RPC Service Report (focusing on current problems/issues regarding service provided by ITC and RTOG in support of AT protocols): (Ibbott, Followill)
- 5:20 PM: ITC Service Report (focusing on current problems/issues regarding service provided by RPC and RTOG in support of AT protocols): (Straube, Bosch, Purdy)
- 5:45 PM: RTOG Medical Physics Committee Report pertaining to ATC (Gillin) -Status of Dose Calculation Algorithm/Heterogeneity Corrections use for Lung Clinical Trials (Ibbott, Followill, Gillin)
- 6:00 PM: RTOG IGRT Committee Report pertaining to ATC (Michalski) -IGRT QA Guidelines (Galvin, Michalski)
- 6:15 PM: Update on RTOG informatics infrastructure pertinent to ATC (Galvin, Young)
- 6:30 PM: Report on CERR developments in support of RTOG and RPC (Deasy)
- 6:45 PM: Discussion; New Business
- 7:00 PM: Adjourn

# P.I.'s Report

## *ATC Grant Proposal Update*

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- 12/01/2006 - Application entered into system
- 12/04/2006 - Scientific Review Group review pending.
- 03/06/2007 - Scientific Review Group review completed: Council review pending. - WU-ATC score was the best
- 04/02/2007 - Scientific Review Group review pending.
- 04/16/2007 - Scientific Review Group review completed: Council review pending. WU-ATC score was the best (Also, best ever received)
- 06/20/2007 - Council review completed - Awaiting notification.

## Goals for our ATC grant will be accomplished through these *coordination, service, & developmental objectives*:

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- Eliminate duplication of infrastructure developmental efforts and facilitate sharing of QA resources among Coop. Groups.
- Help insure that appropriate and uniform QA procedures and criteria for advanced technology trials are developed across all Coop. Groups.
- Facilitate/help manage the uniform credentialing of institutions for AT protocols.
- Facilitate/manage digital data protocol submission.
- Facilitate/manage the QA review of submitted data.
- Further development of methods for rapid analysis of volumetric TP data.

## Goals for our ATC grant will be accomplished through these coordination, service, & developmental objectives: (cont'd)

- Assist Coop. Groups in development of protocols including: (a) credentialing; (b) TV definitions; (c) QA procedures; and (d) data submission instructions.
- Develop, implement, and maintain innovative methods for electronic exchange of digital planning data between participating institutions and between QA Centers.
- Develop, implement, and maintain innovative web-based software tools to facilitate protocol digital data reviews by Coop. Groups and QA Centers.
- Develop, implement, & maintain archival TP and QA databases linked with Coop. Groups' clinical outcomes databases.
- Achieve compatibility with existing software and electronic health record standards, including the Cancer Bioinformatics Grid (caBIG) and DICOM RT.

# P.I.'s Report

## *ATC Meetings/Teleconference schedule*

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- Want to explore new approach
  - Face to Face meetings at QA Centers
  - Monthly Tcons for involved QA Centers
  - Perhaps hold Quarterly Tcons for all ATC members?

# P.I.'s Report

## *ATC - QRRO*

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- Exploration of ways in which ATC effort could become synergistic with Quality Research in Radiation Oncology (QRRO) effort (Purdy, Jean Owen)

# Introduced new acronym for ATC Method 1



The ITC developed QuASAR 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.

## QuASAR

- ... 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 >5400 protocol case data sets, and
- ... will continue to evolve using appropriate information technology to meet the QA needs of RT clinical trials.

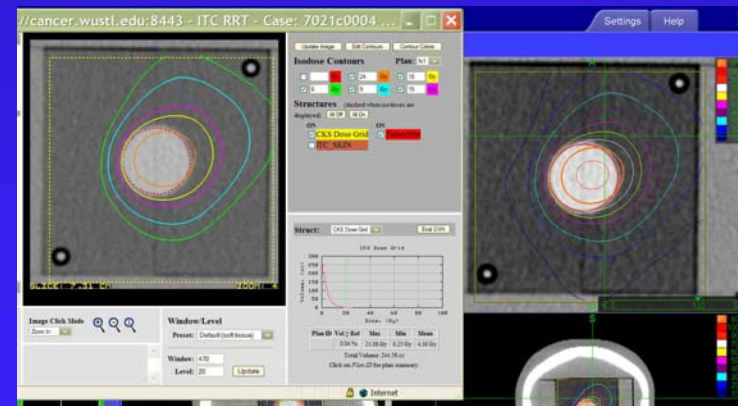


# Mission Critical: ITC Digital Data Exchange Development Efforts

- Maintain requirements for clinical trials data submissions
  - RTOG Data Exchange Format Spec.
  - ATC DICOM Conformance Statement
- Assistance to TP vendors
  - Hosted 6 Digital Data Exchange and DICOM Technical Workshops (1995–2004) for TP vendors
  - Assist individual TPS manufacturers in implementing ATC compliant export capabilities
  - Organize 2004 ATC/AAPM/NEMA DICOM Demonstration
  - Participated in DICOM WG-18 (Clinical Trials)
  - Actively involved in IHE-RO Initiative (DICOM interoperability) and DICOM WG-7 (development of next-generation DICOM RT Objects)

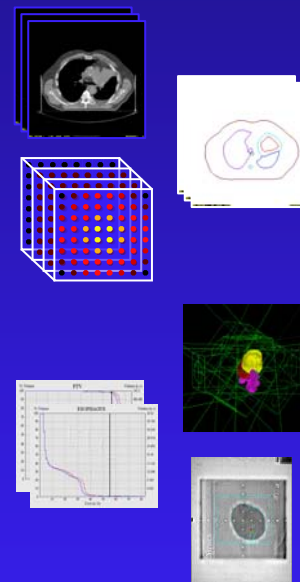
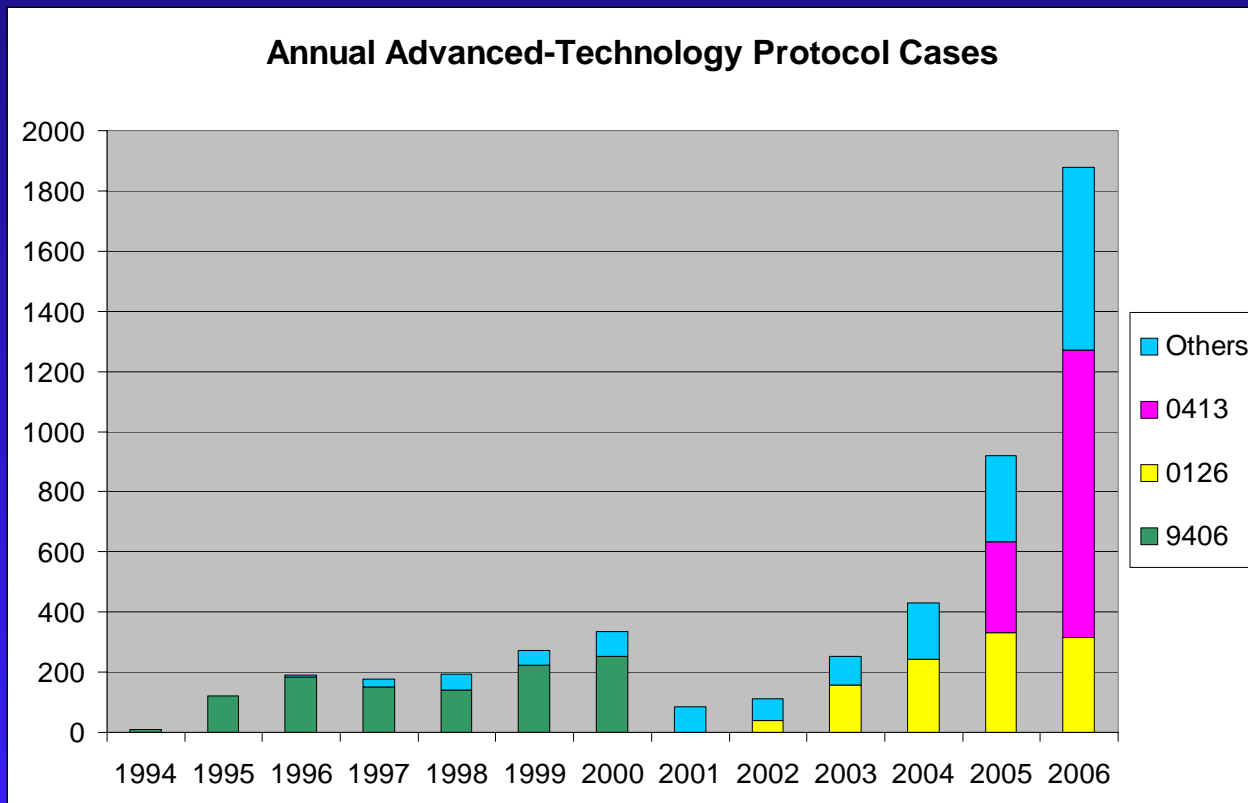
Vendor	System	Version <sup>1</sup>	Exchange Format	Treatment Planning Systems			Treatment Modality		
				3DCRT	IMRT	SBRT <sup>2</sup>	Seed Brachy	HDR Brachy	Protons
<a href="#">CMS</a>	Focus/XiO	3.1	R	✓	✓	✓	✓		✓
	XiO	4.3.1 <sup>3</sup>	D	✓	✓				
<a href="#">Elekta</a>	RenderPlan 3D		R	✓					
	PrecisePlan	2.01	D	✓	✓	✓			
<a href="#">Nomos</a>	Corvus		R		✓ <sup>4</sup>				
<a href="#">Nucletron</a>	Helax TMS		R	✓	✓				
	TheraPlan Plus		R	✓					
	PLATO RTS	2.62	D	✓					
	PLATO BPS	14.2.6	D						✓
<a href="#">Philips</a>	Pinnacle <sup>3</sup>		R	✓	✓	✓			
	AcqPlan	4.9	R	✓					
<a href="#">Rosset Medical</a>	Strata Suite CTPlan	4.0	R					✓	
<a href="#">RTek</a>	PIPER	2.1.2	R					✓	
<a href="#">TomoTherapy</a>	Hi-ART	3.0 <sup>5</sup>	D		✓				
<a href="#">Varian</a>	BrachyVision	6.5 (Build 7.1.67)	D						✓
	Eclipse	7.1	D	✓	✓	✓			✓
	VariSeed	7.1	D					✓	

Table of ATC Compliant TP Systems (see <http://atc.wustl.edu>)



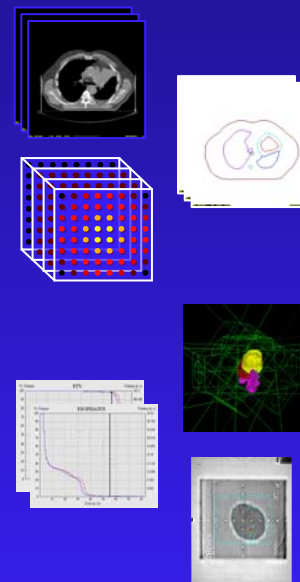
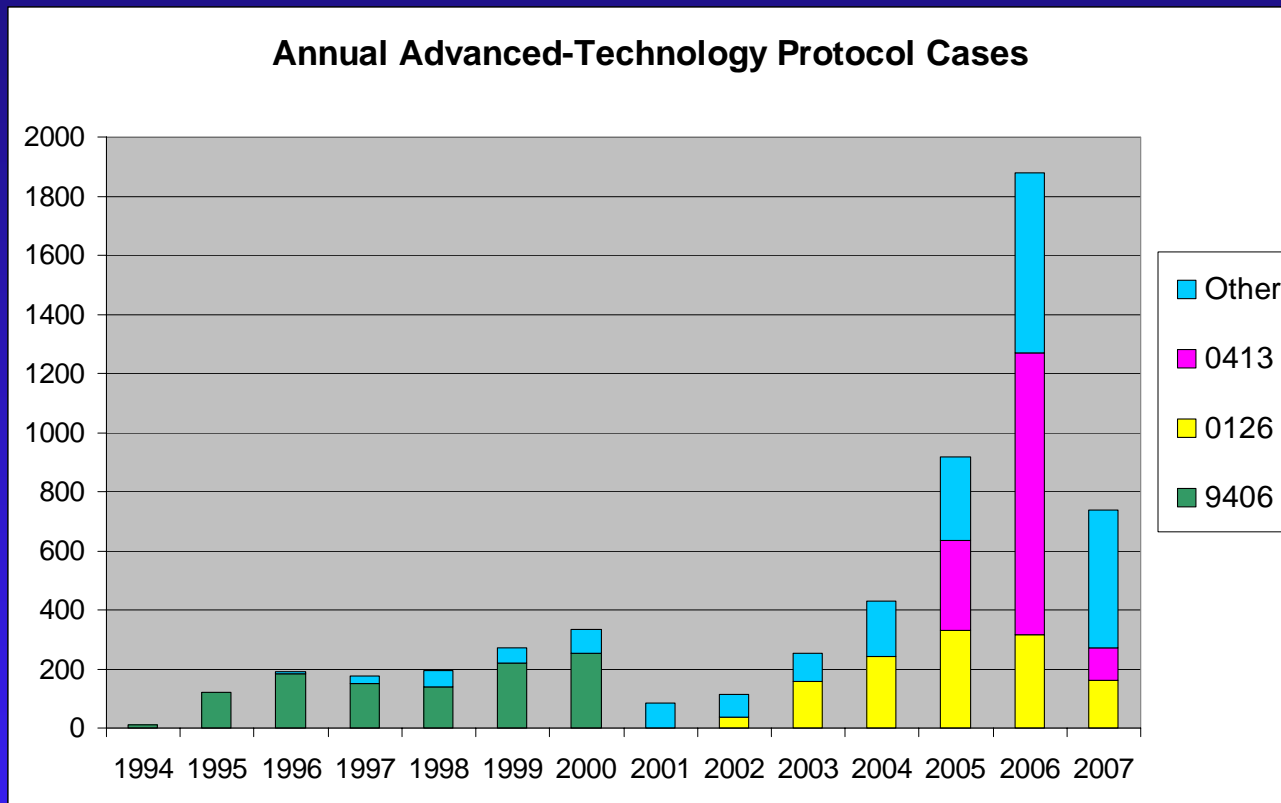
Screen capture showing comparison of RRT (left) and CyberKnife iso-dose displays

- **Service Objective: January 2007 ATC Mtg: 4974 Complete, Protocol-Case, Volumetric Digital Data Sets Submitted Over 13 Year Period using QuASAR**



- **8 commercial TPS vendors (15 TPSs) have implemented ATC compliant export capability.**
- **486 institutions able to submit data**

• **Service Objective: June 12, 2007 ATC Mtg: 5706 Complete, Protocol-Case, Volumetric Digital Data Sets Submitted Over 13 Year Period using QuASAR**



- **9 commercial TPS vendors (16 TPSs) have implemented ATC compliant export capability.**
- **523 institutions able to submit data**

# Data Integrity QA Prior to Review for Protocol Compliance

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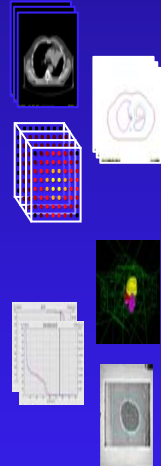
- Experience shows approximately 25% of data sets received require some intervention to be reviewable.
- Data QA Concerns
  - Completeness
    - ◆ Are required objects present & interpretable?
  - Identification
    - ◆ Are case, plan, structure IDs consistent?
  - Consistency
    - ◆ Are images, structures, doses spatially registered?
    - ◆ Are doses properly scaled?
    - ◆ Are DVHs calculated in a consistent manner?



# Service Objective: Digital Data Integrity QA for protocol cases using QuASAR

**Table 2: 2007 - Protocol Case Digital data submissions per protocol and the number of problems encountered that required human intervention by the ITC personnel.**

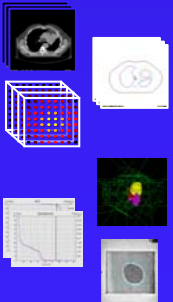
Protocol	# of cases Digitally Submitted	Problems Requiring Human Intervention	% of cases requiring human intervention
0117	27	4	14.8
0126	111	34	30.6
0232	49	4	8.2
0234	3	0	0
0413	159	41	25.8
0415	107	22	20.6
0417	0	0	0
0418	32	5	15.6
0435	1	1	100
0438	3	1	33.3
0521	67	39	58.2
0522	118	19	16.1
0529	15	3	20
<b>TOTAL</b>	<b>692</b>	<b>173</b>	<b>25</b>



# Service Objective: Protocol Data Submission for Credentialing - DDIQA

**Table 4:** 2007 - Credentialing submissions per protocol and the number of problems encountered that required human intervention by the ITC personnel.

Protocol	# of cases Digitally Submitted	Problems Requiring Human Intervention	% of cases requiring human intervention
0117			0
0126	10	5	50
0232	13	1	7.7
0413	83	29	34.9
0415	3	0	0
0435	1	0	0
0521	3	0	0
0522	39	12	30.8
<b>TOTAL</b>	<b>152</b>	<b>47</b>	<b>30.9</b>

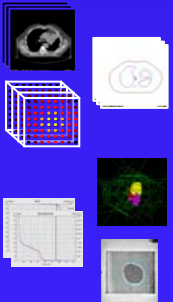


# Service Objective: Phantom Data Submission for Credentialing - DDIQA

**Table 5:** Phantom submissions per phantom type and the number of problems encountered that required human intervention by the ITC personnel since March 2006.

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Phantom	# of Submissions	Problems Requiring Human Intervention	% of cases requiring human intervention
H&N	164	42	26
Pelvis	46	18	39
Lung	14	7	50
Liver	3	0	0
<b>TOTAL</b>	<b>227</b>	<b>73</b>	<b>32</b>



# Protocol Compliance Review

- Protocol compliance review consists of:
  - review of target volume and organ at risk contours compliance by the specific RTOG Protocol Study Chair (SC) using QuASAR's web-based *Remote Review Tool (RRT)*; and
  - review of protocol dose prescription and dose heterogeneity compliance by RTOG HQ Dosimetry Group using the RRT.
  - Scores entered by ITC
- Despite strong continued efforts by all, we continue to fall behind
  - No accountability to Membership Evaluation and QA Committees
  - Need Coop. Group to enforce timeliness





# ATC(ITC) Working with NABTT

- NABTT (Dr. John Fiveash, M.D., Department of Radiation Oncology, University of Alabama Birmingham)
- QA plan agreed upon. Latest is posted to the NABTT and ATC websites.

The screenshot shows a web browser window displaying the NABTT website. The address bar shows "http://www.nabtt.org". The page title is "NEW APPROACHES TO BRAIN TUMOR THERAPY". The main heading is "The New Approaches to Brain Tumor Therapy CNS Consortium". Below the heading, it lists "Group Leaders: Stuart Grossman, Henry Brem". A section titled "Member Institutions" lists the following: Cleveland Clinic, Emory University, Henry Ford Hospital, Johns Hopkins University, Massachusetts General Hospital, Moffitt Cancer Center, NCI Neuro-Oncology Program, University of Alabama at Birmingham, University of Pennsylvania, and Wake Forest University. A map of the United States is shown with stars indicating the locations of these institutions. At the bottom, there is contact information for the NABTT Central Operations Office, Biostatistical Office, and Pharmacology Center, along with the names and affiliations of the Principal Investigators (PIs): Stuart Grossman (Johns Hopkins University), Steven Plantadosi (Johns Hopkins University), and Jeff Supko (Massachusetts General Hospital).

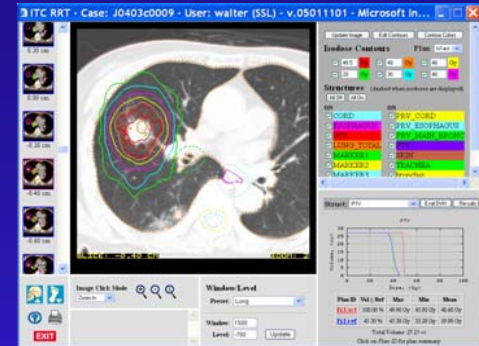
# ATC Working with EORTC

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- ATC(ITC) is working with the EORTC to provide data integrity QA for the upcoming EORTC Protocol 22042 “Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma: a Phase-II and registration study”.
- Testing of data submission (using SFTP) and review (using RRT) are currently underway.
- Waiting on signed agreement regarding protection of patient data.

# ATC(ITC) 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 forwards these data to ITC in St. Louis for processing.
- Data are reviewed by Dr. Ishikura or his delegate using the ITC Remote Review Tool.
- Currently, 14 institutions are eligible to enroll patients and capable of digital data submission on JCOG 0403; 106 patients are registered to study.

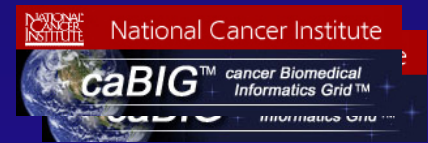


# ATC(ITC) is Supporting Industry Clinical Trial

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- ITC support of the AstraZeneca protocol has begun.
  - Three institutions credentialed
  - Case studies have been submitted

# ATC is working with caBIG/NCIA

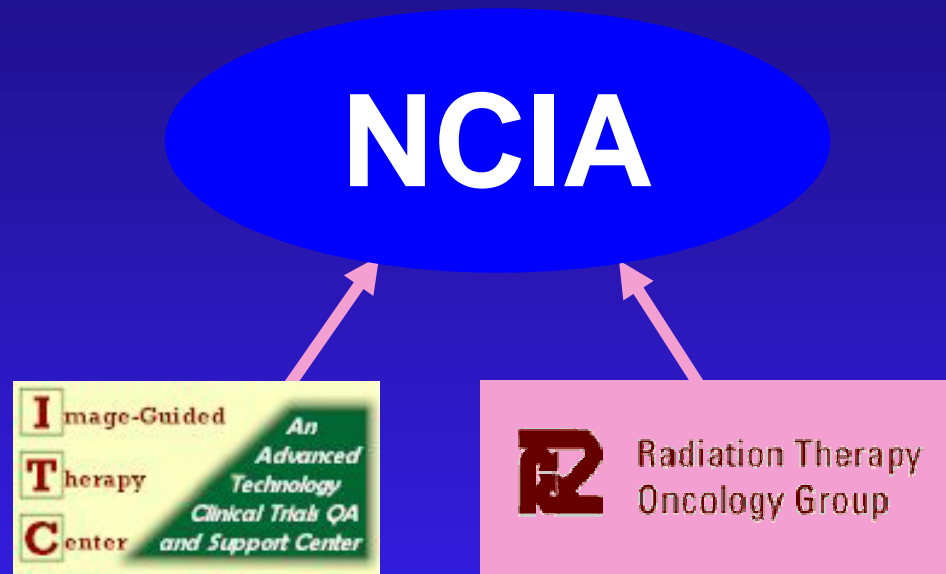


- ATC is one of the funded participants in the caBIG In Vivo Imaging Workspace.
  - ATC members (ITC, RTOG, QARC) and ACRIN are actively participating in the Testbed Special Interest Group (SIG).
  - Exploring project with Ohio State Univ., QARC, ITC, and CALGB
  - Working with OSU on RSNA demonstration project “Application of caGrid® Middleware to Facilitate Quality Assurance for Advanced Technology Radiation Therapy Clinical Trials”
    - ◆ Volumetric CT images, target-volume/organ-at-risk (TV/OAR) contours, treatment plans, and 3D dose distributions submitted by study participants converted to Matlab format using CERR.
    - ◆ CERR datasets are then used for distributed protocol compliance review of image segmentation and dosimetry.
    - ◆ To facilitate distributed review of the CERR datasets, a secure grid-based infrastructure is used for distribution of data sets and collection of reports

# RTOG 9406 NCIA Dataset Project

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Proposed addition of 3DOG/RTOG 9406 treatment planning and outcomes data set to the National Cancer Imaging Archive



- Treatment Planning Data
  - DICOM RT
  - CERR
- Histories, Staging, and Outcomes Data
  - Forms
  - CDEs



# ATC (ITC, RTOG) Posters/Presentations at 2007 ASTRO Annual Meeting

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- A Survey of the ITC Volumetric Treatment Planning Data Archive Supporting RTOG Advanced Technology Clinical Trials: W. R. Bosch, W. L. Straube, J. W. Matthews, J. M. Michalski, J. O. Deasy, B. Young, E. O'Meara, W. J. Curran, J. D. Cox, J. A. Purdy.
- Dosimetric Evaluation of Heterogeneity Corrections for RTOG 0236: Hypofractionated Radiotherapy of Inoperable Stage I/II Non-Small Cell Lung Cancer: Y. Xiao, W. L. Straube, W. R. Bosch, R. D. Timmerman, J. Galvin.
- Dose-volume analyses of grade  $\geq 2$  late rectal toxicity among patients treated on protocol RTOG 94-06: S.L.Tucker, L. Dong, W.R. Bosch, J. Michalski, K. Winter, R. Mohan, Kuban, M.R. Cheung, A.K. Lee, J.D. Cox
- Fit of a Generalized Lyman Normal-tissue Complication Probability (NTCP) Model to Grade  $> 2$  Late Rectal Toxicity Data from Patients Treated on Protocol RTOG 94-06: S. L. Tucker, L. Dong, W. R. Bosch, J. Michalski, K. Winter, A. K. Lee, M. R. Cheung, D. A. Kuban, J. D. Cox, R. Mohan
- Variation in the Definition of Clinical Target Volumes for Postoperative Conformal Radiation Therapy of Prostate Cancer: J. M. Michalski, C. Lawton, I. El-Naqa, M. A. Ritter, T. Pisansky, C. N. Catton, R. K. Valicenti, M. J. Seider, H. M. Sandler, W. Bosch.

# ATC Workshop (Special Interest Session) held at 2007 AAMD Annual Meeting

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- Held as breakout session from main program
- 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.



# DATA REQUESTS

## ATC Supported Clinical Trials

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- 06/13/07 - Andrew Jackson Ph.D., Department of Medical Physics, Memorial Sloan Kettering Cancer Center.
  - From the ATC-ITC, we request (for each patient treated under RTOG 9311) Dose Volume Histograms (% volume, absolute dose – calculated with tissue inhomogeneity corrections) for paired lungs only or for the two lungs separately and the paired lungs if available, together with the absolute volumes of these structures.
  - From the ATC-RTOG, we request each patient's RTOG acute and late lung complication grade, time of diagnosis of complication and follow-up time, adjuvant chemotherapy status (yes/no) from patients treated under RTOG 9311.

# DATA REQUESTS

## ATC Supported Clinical Trials

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- 06/14/07 - Lyndon S. Hibbard, PhD, CMS Research, CMS, Inc., St. Louis, MO,
  - From the ATC-ITC, we request data in the RTOG Protocol 9406 (“A Phase I/II Dose Escalation Study ... Adenocarcinoma of the Prostate”). We are particularly interested in the CT images and anatomy structure contours to develop programs to automatically segment the prostate (GTV) and critical organs.

# ATC - PLaNUNC

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- I have been in discussion with Dr. Ed Chaney regarding possible collaborations regarding use of PLaNUNC within QuASAR system.
- Ed indicated he would be pleased to work with ATC in any way we think might be helpful.
- About to enter the final year of R01 and main focus is on final validation of their convolution/superposition algorithm, and implementation of a multi-image handling tool for ART/IGRT.
  - The tool will be able to load, register, segment, and compare many 10s of images at a time.
  - If the images are already segmented then the segmentations can be compared.
  - This is a big project because we are implementing multiple standard and cutting-edge registration and segmentation techniques.

# Challenges/Opportunities: ATC Supported Trials

- Developing a more formal mechanism as to how it is decided as to which clinical trials are to be supported by ATC funding.
- Multi-modality imaging (PET, MRI, MRS) target definition (data import) and subsequent image fusion QA;
- IGRT data submission and QA (EPID, daily MV and kV Cone beam CT, Helical Tomotherapy MV CT, US,...);
- QA review of the accuracy and quality of the institution's motion management methodology;
- Heterogeneous dose calculations (QA evaluation criteria);
- Outcome analysis tools (e.g., for protocols such as lung in which the dose data archived have either poor or no dose heterogeneity corrections);
- Proton beam therapy;
- ATC compliant data export for stereotactic specialized treatment systems (e.g., Elekta Gamma Knife);
- New processes such as adaptive radiation therapy (need deformable registration QA tools)
- Data sharing