Principal Investigator's Report

Advanced Technology QA Consortium Steering Committee Meeting April 6, 2005

James A. Purdy, Ph.D.

Supported by NIH U24 grant CA81647



Agenda

•	9:00 AM:	Welcome by Project Officer (J. Deye)
•	9:15:	ATC P.I. Report (J. Purdy)
•	9:45 :	QARC subcontract summary - T.J Fitzgerald
•	10:00:	RTOG subcontract summary - W. Curran (or designee)
•	10:15:	RPC subcontarct summary - G. Ibbott
•	10:30:	RCET subcontract summary - J. Palta
•	10:45	BREAK
•	11:00	CIP review (RIDER, MIRC/RSNA) - G. Becker
•	11:20	ca Image workspace - C. Jaffe
•	11:40	ACRIN review – T. Caldwell
•	12:00	e-Chart Vendor perspective - J. Goldwein (IMPAC medical)
•	12:15	Working lunch (split into at least 2 sub-groups to examine themes for the integration of the ATC into the broader framework of data archiving and retrieval in support of clinical trials)
•	2:15	Reunite groups to report out major areas for future development of ATC efforts
•	3 pm	ADJOURN

ATC OVERVIEW



ATC HISTORY

- April 1992 RTOG funded 3DQA Center at WU-St. Louis to provide QA for RTOG 3DCRT trials.
 - I felt then, as I do now, review of target volumes using 3D tools for QA of 3D clinical trials is essential and thus digital data submission is key.

ATC HISTORY

- May 1993 RTOG & 3DQA Center (later changed name to ITC) awarded NCI grant for Operation/ Statistical Center for prostate dose escalation study (3DOG, became RTOG 94-06).
- April 1999 NCI funded two U24 grants "Advanced Technology QA Centers"
 - ITC (with sub-contracts to RTOG, RPC, and QARC)
 - Resource Center for Emerging Technology (RCET) at the University of Florida

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

ATC HISTORY

 In July 2002, NCI consolidated two AT Center grants and funded a single U24 grant to the Washington University Image-Guided Therapy QA Center (P.I. J.A. Purdy) with sub-contracts to the following centers:



- Radiation Therapy Oncology Group (RTOG)
- Radiological Physics Center (RPC M.D. Anderson Cancer Center)
- Quality Assurance Resource Center (QARC)
- Resource Center for Emerging Technologies(RCET – Univ. of Florida in Gainesville)
- UC Davis Medical Center (2004)





AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE



Radiological Physics Center





ATC's MISSION

Developmental efforts:

- electronic data exchange of digital planning data between ATC QA Centers and protocol participating institutions;
- web-based software tools to facilitate protocol digital data submissions and QA reviews by RTOG, QARC, and RPC;
- archival treatment planning & QA databases that can be linked with the cooperative group's clinical outcomes database.

Service efforts:

- assist Coop. Group's in protocol development, manage/facilitate protocol digital data submissions, credentialing, QA review, and data analysis.

 $^{\circ}$ C – April 2005



ITC's MISSION

- Facilitate the submission and review of volumetric, digital treatment planning data for multi-institutional, advanced technology clinical trials.
 - Receive and process digital treatment planning data for ATC supported protocols via FTP and CD/tape media (~ 1.3 Gb/wk)
 - Facilitate web-based review of target/OAR volumes and dosimetry using ITC Remote Review Tool.
 - Support the development and implementation of standards for digital data exchange (DICOM, RTOG Data Exchange) through assistance to TPS manufacturers, hosting ATC DICOM workshops, and participation in DICOM and IHE working groups.
 - Maintain ATC web site to disseminate information regarding credentialing and participation in advanced technology trials.

Data Exchange: ATC Methods 1/2/3

ATC Method 1

- Developed by: ITC
- Status: in production at ITC supporting clinical trials: RTOG (7 open, 5 closed), NSABP (1), JCOG (1); now installed at QARC, training underway
- **Data Objects:** CT/MR Images, Structure contours, 3D doses, Plan/Source specifications, DVHs, Tx verification images, Diagnostic images, Screen captures
- **Formats:** DICOM Images/RT objects, RTOG data exchange, JPEG (screen captures)
- Transport: FTP, storage media (CD, 4mm/8mm tape)
- Submission SW: FTP client, ITC DICOMpiler, CD-burner
- Review: web browser/ITC Remote Review Tool

ATC Method 2

- **Developed by:** RCET (WebSys/NetSys); ITC (RRT)
- **Status:** In development and testing at ITC and RCET as of 3/2005
- **Data Objects:** CT/MR Images, Structure contours, 3D doses, Plan/Source specifications, DVHs, Treatment verification images, Diagnostic images
- Formats: DICOM Images/RT objects, RTOG data exchange
- Transport: HTTP/Secure Object Archiving Protocol
- Submission SW: WebSys client
- Review: web browser/ITC Remote Review Tool for treatment planning data; web browser/Rapid Image Viewer applet for diagnostic, treatment verification images

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ATC Method 3

- **Developed by:** RCET; Implemented by NCIC
- **Status:** near production at NCIC CTG for MA.20
- **Data Objects:** 2-D screen captured images, Scanned documents
- Formats: variety of image formats (GIF, JPG, SGI, XWD, PNG, TIFF, BMP) converted to DICOM objects and JPEG
- **Transport:** HTTP/Secure Object Archiving Protocol to NetSys server at NCIC CTG (Kingston, Ontario, Canada)
- Submission SW: NetSys client; Irfan View (pub. domain) to annotate and de-identify images
- Review: web browser/Rapid Image Viewer applet

April 2005 m I2

Study Groups

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Cooperative Groups With Clinical Trials Served by the ATC

- RTOG 12 protocols (5 completed; 7 open)
- JCOG 1 protocol
- NSABP 1 protocol
- COG developmental work with QARC involving 2 protocols

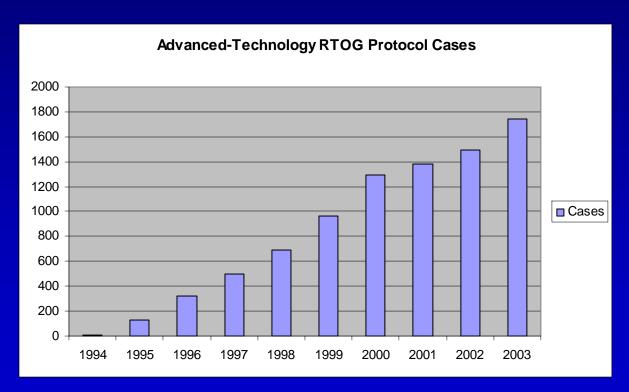


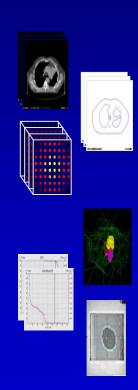
Protocols



Last Year's ATC Steering Committee Meeting

 Over 1700 complete digital data sets (RTOG Protocols) submitted over last 10 year period

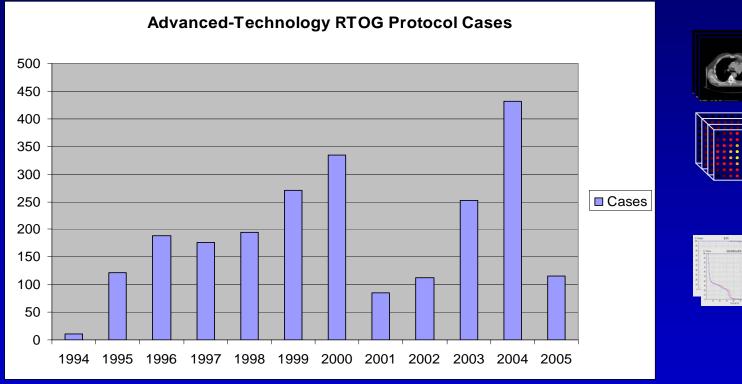


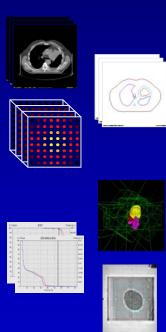


- 11 commercial RTP systems have now implemented ATC export capability
- 121+ institutions are able to submit complete data sets



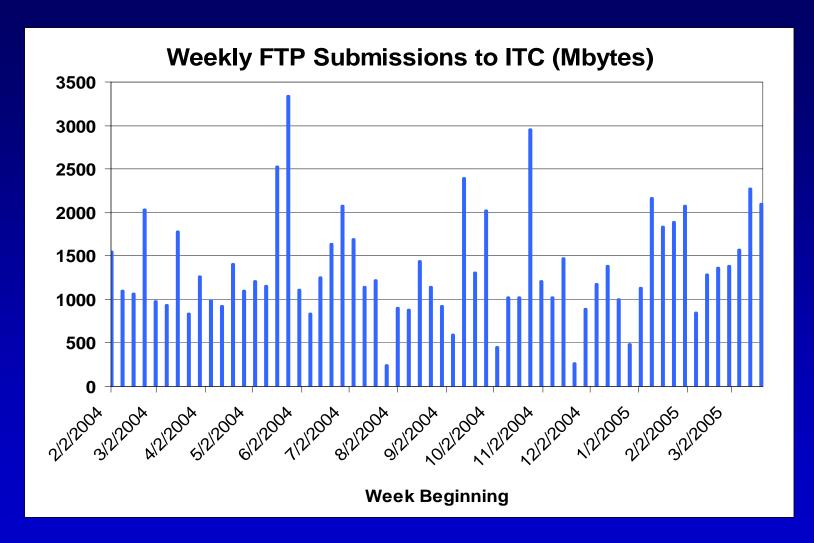
2312 Complete Digital Data Sets Submitted Over 11+ Years



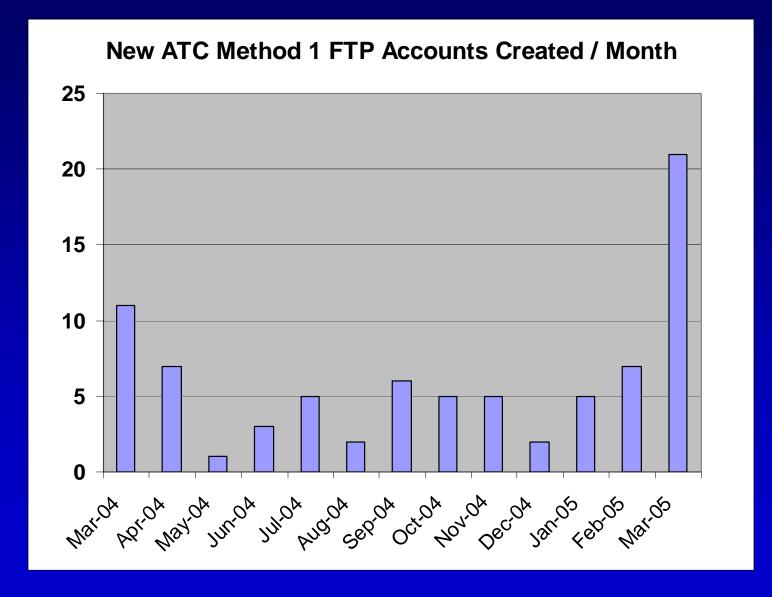


- 15 commercial RTP systems have implemented export capability (see http://atc.wustl.edu)
- 190 institutions are able to submit data (3/31/05)



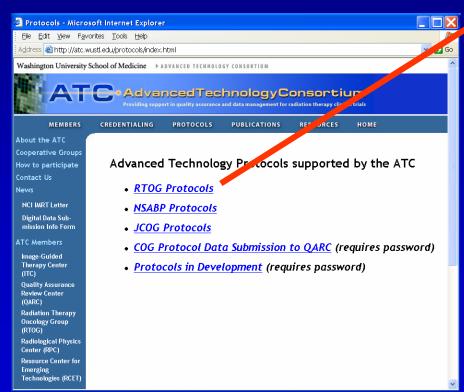


Average rate of FTP data submission to ITC is 1.35 GB/week (15 users, 28 data sets).





Protocol Documents on ATC Web Site http://atc.wustl.edu

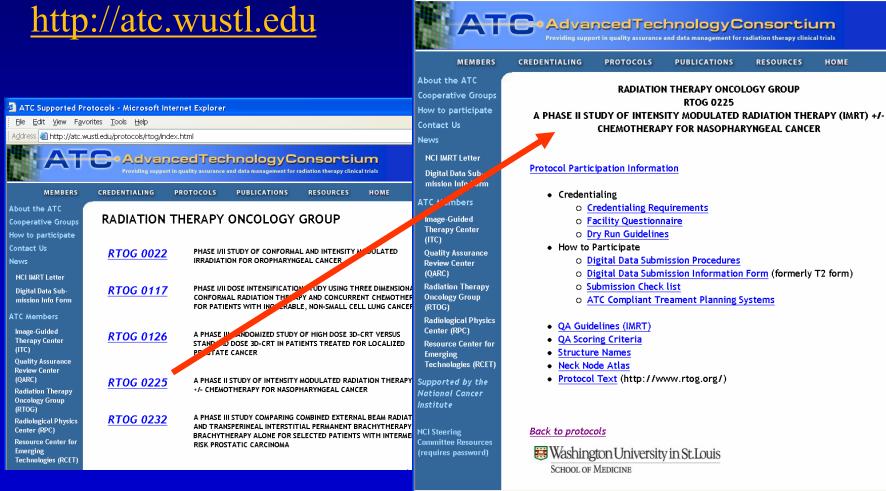




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Protocol Documents on ATC Web Site (2) http://atc.wustl.edu



Protocol 0225 - Microsoft Internet Explorer
File Edit View Favorites Tools Help

Address 🙆 http://atc.wustl.edu/protocols/rtog/0225/0225.html

Washington University School of Medicine > ADVANCED TECHNOLOGY CONSORTIUM

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✓ → Go

BLUE = closed protocols WHITE = open protocols

ATC-Supported Protocols (3/31/2005)

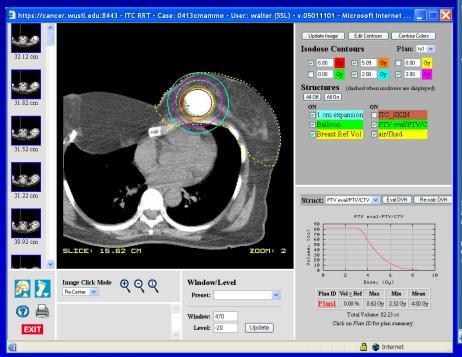
Protocol	Description	# Institutions	# Cases
RTOG 9406	Ph I/II 3DCRT Prostate Dose Escalation	54	1084
RTOG 9311	Ph I/II 3DCRT Lung Dose Escalation	27	180
RTOG 9803	Ph I/II 3DCRT GBM Dose Escalation	46	210
RTOG 0022	Ph I/II 3DCRT/IMRT Oropharynx	31	69
RTOG 0319	Ph I/II 3DCRT Partial Breast	31	58
RTOG 0117	Ph I/II 3DCRT/chemo Lung	40	23
RTOG 0126	Ph III 3DCRT/IMRT Prostate	117 (36 IMRT)	510 (64 IMRT)
RTOG 0225	Ph I/II 3DCRT/IMRT Nasopharynx	32	44
RTOG 0232	Ph III Ext Beam/TIPPB Prostate	52	99
RTOG 0236	Ph II SBRT Lung	4	7
RTOG 0321	Ph I/II HDR/Ext Beam Prostate	3	1
NSABP B-39/ RTOG 0413	Ph III Partial Breast Irradiation	5	1
JCOG 0403	Phase II SBRT Lung	13	19

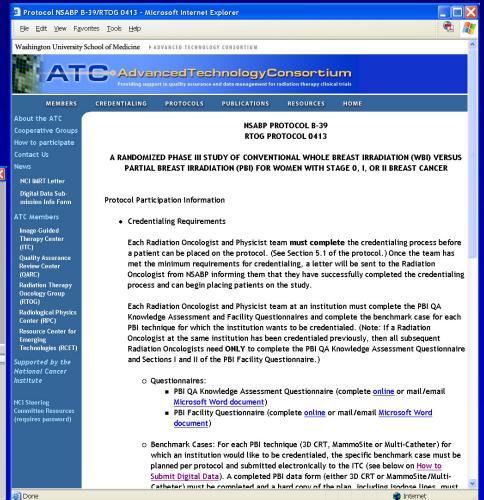
TOTAL 190 2312



A RANDOMIZED PHASE III STUDY OF CONVENTIONAL WHOLE BREAST IRRADIATION (WBI) VERSUS PARTIAL BREAST IRRADIATION (PBI) FOR WOMEN WITH STAGE 0, I, OR II BREAST CANCER

- High volume (1500 cases / 2 years)
- Multiple study groups
- Multiple treatment modalities
- Benchmark test
- Rapid review





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Review Process – Review Categories

- Rapid Review First case put on PBI arm for a particular modality (Mammosite®, Multi-Catheter or 3DCRT)
- Timely Review First 5 cases put on PBI arm for a particular modality.
- Random Review
- All Cases will eventually be reviewed
- Multi-faceted review process including PIs from protocol and their designates, Dosimetrists from RTOG and RPC, and ITC personnel.



Review Process

- Case Registered by institution
- Notification sent by NSABP to ITC that case has been randomized to the PBI arm.
 - Information about institution
 - whether the case is rapid review, timely review or random review
- Institution is notified about the Rapid Review process by ITC via email



Review process- workflow at ITC

- Registration sent to ITC
- Case registered in QA and Event tracking databases-labeled as rapid review, etc
- Institution submits digital data to ITC
 - Institution is required to submit DDSI
 - Rapid Review is indicated on DDSI
 - Email sent to ITC and digital pagers that case is Rapid Review



Review Process - Workflow

- Digital Data is processed by ITC and prepared for review via the RRT
- Dosimetrists (RPC for HDR, RTOG for 3D) are notified that case is ready for Dose Volume Analysis Review
- Dosimetry Review is completed using Review forms and RRT
- PI is notified that Case is ready for review
 - PI is given institution contact information
 - Only the PI will communicate information to the institution which could have an effect on patient care.

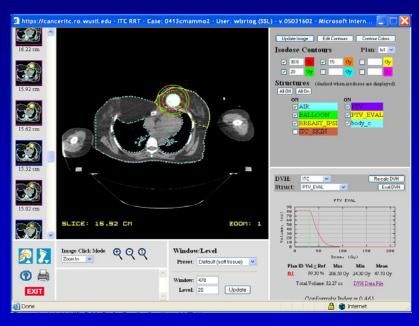


Review process-workflow

- Institution is notified by the PI that the patient can be treated.
- Institution moves into timely review category.
- After 5 acceptable timely reviews the institution moves to Random Review Category.



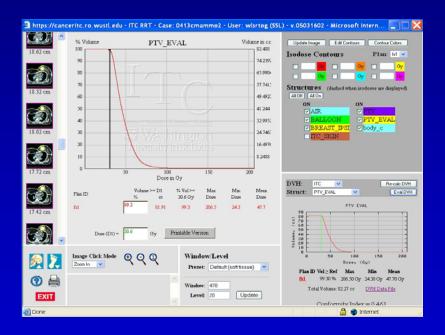
TV/OAR Review - Currently on paper soon to be on line



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		Image-Guided Th	erapy Center [ITC]
Proto	ocol B39 Organs at Risk,	Target Volume QA Re	view for Mammosite
Patie	nt Initials:		Physician:
Institu			
Moda	ality:	Dose Level #:	
	W	Mark	Comments
	<u>Item</u>	QA Score*	<u>Comments</u>
1.	PTV_EVAL	□ 1 □ 2 □ 3	
2.	Trapped air/fluid	□1 □2 □3	
3.	Ipsilateral Breast	□1 □2 □3	
4.	Skin/Unspec. Tissue	□ 1 □ 2 □ 3	
5.	CT Data Score	1 1 1 2 1 3	
6.	Balloon Symmetry	1 1 1 1 1 1 1	
	r protocol; inor corrections made and/or rec	juested, evaluable as is;	
3 - ma	ajor corrections required, uneval	luable as is	
11.	Other Comments:		
-			
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			Date of Review:
			Date of Neview.



DVA Review – Currently on paper soon to be on line

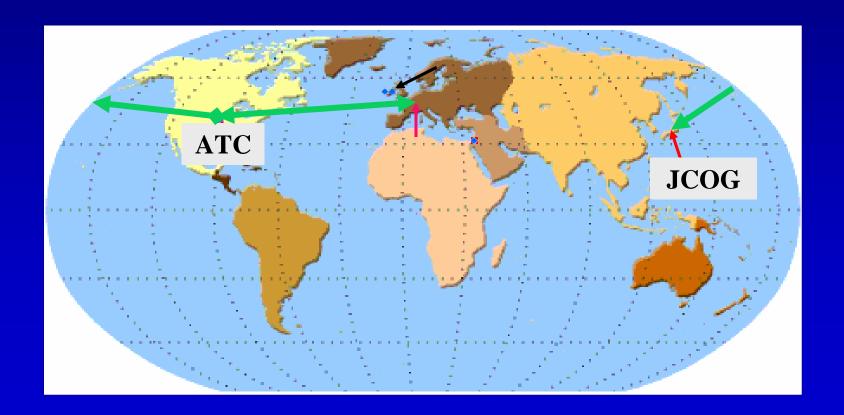


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Target Volum		Percent Volume ne Receiving		% Ve trapped air/flu	by	Min Dose (Gy)	Do	ean ose Gy)	Coverage Score			
PTV_EVAL		:	30.6									
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B. DOSE H	ETER		Y(DH)	And C	ONF					_		
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V200 is defi	ined as t		%				_		Mean Dose (Gy)	Score	Criter 1	ia 2
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PTV_EVAL						30.6		1		-		-	100		
B. DOSE HETE Volume (cc V150 V200 Dose Heterogeneity 1 V150 is direct as the V200 is defined as the	V150/20 ormal bre rormal bre	Hetero	ics, 3: V15 est or abo est or ab	Score (90200 = 50 (90 0 = 68 Oy (SIS (Se	rrocc e app	endix II					Cri	iteria 2			
Ipsilateral Breast		11 11			17	18.7				- 1	< 609	4 65%			
Overall Case Score fo	e DVA:														
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JCOG





JAPAN CLINICAL ONCOLOGY GROUP PROTOCOL JCOG 0403 A PHASE II STUDY OF STEREOTACTIC BODY RADIATION THERAPY 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 at the National Cancer Center Hospital East, Kashiwa, JAPAN.
- Dr. Ishikura forwards these data to the ITC for processing.
- Data are reviewed by Dr. Ishikura or his delegate using the ITC Remote Review Tool.



JAPAN CLINICAL ONCOLOGY GROUP PROTOCOL JCOG 0403

• The table below lists the 13 institutions eligible to enroll patients and capable of digital data submission on JCOG 0403. (One other institution, which is eligible to enroll patients but NOT capable of digital data submission, has been exceptionally allowed to participate in the study.)

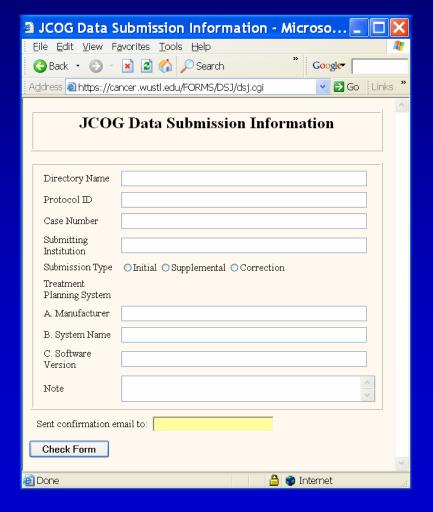
Institution	Location	RTP System	Approval Date
Hiroshima University	Hiroshima, Japan	Philips Pinnacle3	Nov 5, 200
Hokkaido University	Sapporo, Japan	CMS FOCUS/Xio	Aug 11, 2004
Institute of Biomedical Research and Innovation	Kobe, Japan	CMS FOCUS/Xio	Aug 6, 200
Keio University	Tokyo, Japan	CMS FOCUS/Xio	Nov 2, 200-
Kitasato University	Sagamihara, Japan	Philips Pinnacle3	Dec 27, 200-
Kyoto University	Kyoto, Japan	Varian Eclipse	Aug 25, 2004
Kyushu University	Fukuoka, Japan	Varian Eclipse	Nov 24, 200
Nihon University	Tokyo, Japan	CMS FOCUS/Xio	Oct 21, 200-
Sapporo Medical University	Sapporo, Japan	CMS FOCUS/Xio	Sep 27, 200-
Tohoku University	Sendai, Japan	Varian Eclipse	Oct 1, 200
Tokyo Metropolitan Komagome Hospital	Tokyo, Japan	CMS FOCUS/Xio	Sep 3, 200
Tokyo Women's Medical University	Tokyo, Japan	CMS FOCUS/Xio	Dec 27, 200
University of Yamanashi	Tamaho, Japan	CMS FOCUS/Xio	Jul 29, 2004

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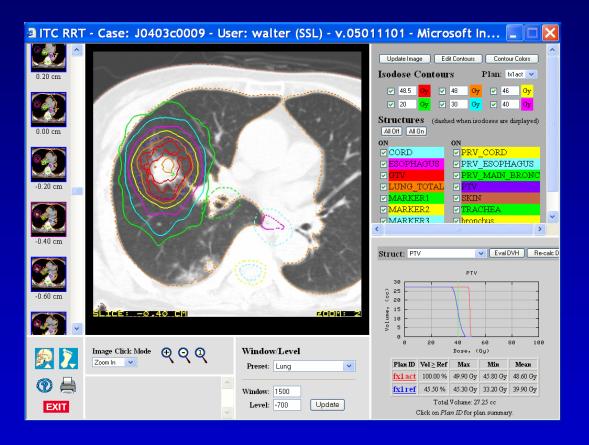
JAPAN CLINICAL ONCOLOGY GROUP PROTOCOL JCOG 0403

 Dr. Ishikura uses the online JCOG Data
 Submission Information form on the ATC web site to announce the submission of data to the ITC FTP server.





JAPAN CLINICAL ONCOLOGY GROUP PROTOCOL JCOG 0403



• As of 3/31/2005, 19 SBRT data sets have been received and prepared for review using the RRT.

TC – April 2005

Data Exchange Vendors



ATC Activities in Support of Digital Data Exchange for Clinical Trials QA

- Pioneering development of RTOG Data Exchange Specification for exchange of treatment planning data in cooperative-group clinical trials
- Participation in the development of DICOM RT objects via DICOM WG7
- Participation in the development of DICOM Clinical Trials Identification modules in DICOM WG18
- Developed ATC DICOM Conformance Statement (http://atc.wustl.edu/resources), which lists the DICOM Information Objects used to submit images and radiotherapy TP data for ATC-supported clinical trials and gives specific requirements for attributes of these objects.
- Sponsorship of a series of DICOM Implementers' Workshops to assist manufacturers in implementing the RT objects needed for clinical trials
- Planning and coordination of ATC/NEMA/AAPM DICOM Connectation at AAPM 2004
- Participation in IHE-RO planning and technical committees

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ATC Compliant Treatment Planning Systems Per Modality

Treatment planning systems deemed to be *ATC Compliant* as of January 20, 2005 are listed in the table below. They are those with which ATC protocol participants have submitted *complete*, reviewable protocol data sets.

Treatment Planning Systems		Exchange	Treatment Modality					
Vendor	System	Version*	Format	3DCRT	IMRT	Seed Brachy	HDR Brachy	Protons
<u>CMS</u>	Focus/XiO	3.1	R	\checkmark	\checkmark	\checkmark		
<u>Elekta</u>	RenderPlan 3D		R	✓				
	PrecisePlan	2.01	D	\checkmark	\checkmark			
Nomos	Corvus		R		++			
Nucletron	Helax TMS		R	✓	✓			
	TheraPlan Plus		R	✓				
	PLATO RTS	2.62	D	\checkmark				
	PLATO BPS	14.2.6	D				\checkmark	
Philips	Pinnacle ³		R	✓	✓			
	AcqPlan	4.9	R	✓				
Rosses Medical	Strata Suite CTPlan	4.0	R			1		
<u>RTek</u>	PIPER	2.1.2	R			\checkmark		
<u>Varian</u>	BrachyVision	6.5 (Build 7.1.67)	D				✓	
	Eclipse	7.1	D	\checkmark	✓			
	VariSeed	7.1	D			\checkmark		

Exchange formats for submission of ATC Protocol Data: D = DICOM RT Objects R = RTOG Data Exchange Format

ATC – April 2005



TPS Vendors Achieving ATC Compliant Status Since April 2004

DICOM RT Objects

Nucletron	Plato BPS	9/22/04
Varian	BrachyVision	1/21/05

RTOG Data Exchange Format

Rosses	CTPlan	12/22/04
RTek (Univ. of Rochester)	PIPER	12/28/04



BrachyVision screen capture showing MammoSite® plan derived from ATC PBI benchmark data set.

C – April 2005



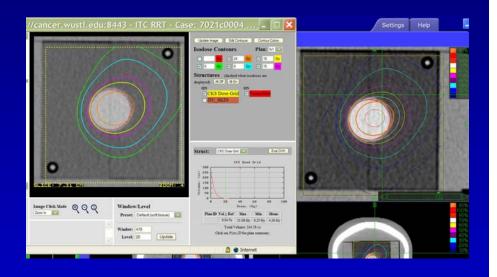
TPS Vendors Achieving "Vendor Complete" Status Since April 2004

DICOM RT Objects

TomoTherapy	Hi-Art	6/22/04
Accuray	CyberKnife	1/27/05
Nucletron	Oncentra (OTP)	3/14/05
CMS	XiO	3/22/05

RTOG Data Exchange Format

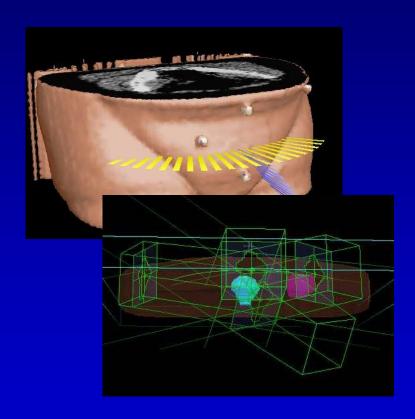
BrainLab	BrainScan	3/30/05



Screen capture from AccuRay (1/18/05) showing comparison of RRT (left) and CyberKnife iso-dose displays for test data set.

BrainLab BrainScan

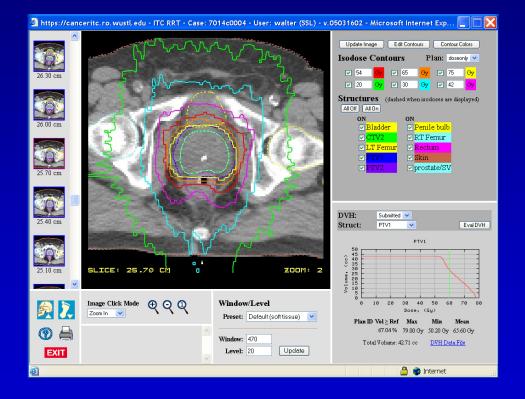
- Early work on DICOM export for Novalis was far from complete at AAPM 2004
- Efforts redirected to implement RTOG export for BrainScan
- Intensive correspondence with Dr. John Matthews Dec 2004 Mar 2005
- "Vendor complete" and ready for clinical test 3/30/2005



Screen capture from BrainScan (3/30/05) amd ITC 3D view showing comparison of arc plans for test data set.

TomoTherapy Hi-ART

- Vendor Complete since 6/22/2004
- Dry Run submitted (passed 3/16/2005) by clinical site
- TomoTherapy is not yet prepared to release software with DICOM export
- DICOM export is anticipated in Beta release near end of 2005.





Other Progress by TPS Vendors Working with ITC to Develop ATC Compliant Export Capability

- Siemens Dosimetrist Workspace/Konrad
 nearly vendor complete, 7/2004
- 3DLine **Ergo** nearly vendor complete, 1/25/2005
- NAS (Nomos) **Corvus** anticipated "2005 Q2 release," 3/18/2005
- Philips (ADAC) **Pinnacle 3** dose export not yet implemented, 9/14/2004

PET/CT

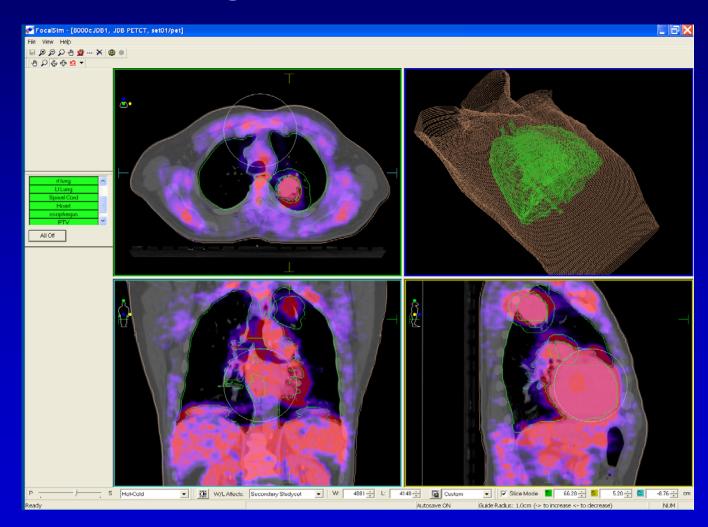
PET/CT Fusion for Target Volume Evaluation

- Test of PET/CT data import and review, using
 - DICOM PET Image files (single frame per object), and
 - Treatment planning CT and target volume contours DICOM (CT, RTSS) or RTOG Data Exchange.
- QA Process
 - Import TP data using ATC Method 1 utilities and send patient dataset to ITC's Focal Workstation
 - Send DICOM PET images directly to ITC's Focal workstation.
 - Register CT and PET studies using maximum mutual information auto-registration in Focal.
 - Compare display of registered images with hardcopy/screen captures from fusion workstation of submitting institution

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PET/CT Fusion for Target Volume Evaluation

- PET Images(DICOM) fromSiemens imager
- Treatment planning data in DICOM or RTOG format
 - CT Images
 - RT Structure
 Set including
 targets and
 organs-at-risk





PET/CT Fusion for Target Volume Evaluation

PET Images (DICOM) from GE imager



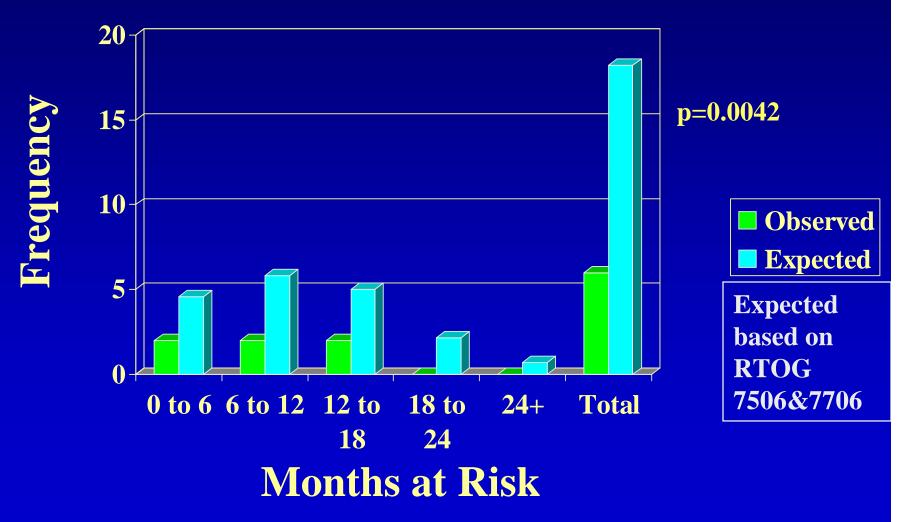
(Images provided courtesy of M. Gillin.)



DATA MINING

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RTOG 9406 Dose Level V (78 Gy, 2Gy/fx), Disease Group 1, Late Grade 3+ Toxicity



J. Michalski, K. Winter, et al, presented at 2003 ASTRO



SUMMARY AND CONCLUSIONS

- The ATC continues to pioneer the submission of digital TPS data for clinical trials by fine-tuning the established Method 1 (FTP upload), while completing the development, testing, and deployment of Methods 2 and 3.
- The ATC is working with RTP manufacturers and urging them to give the highest priority to implementing digital data submission capability on their systems.



SUMMARY AND CONCLUSIONS

- ATC has provided the RTOG the unique ability to conduct 3DCRT, IMRT, SBRT, HDR, and prostate brachytherapy multi-institutional clinical trials in which volumetric 3D treatment planning digital data is collected, reviewed, analyzed, and linked to clinical outcomes.
- This past year ATC has been successful in extending this capability to JCOG and NSABP.
- With the implementation of ATC Method 1 at QARC, we are now in a position to extend these capabilities to most other cooperative-groups.



SUMMARY AND CONCLUSIONS

- ATC Method 3 anticipated to "go live" at NCIC in support of MA.20 April-May
- ATC Method 2 development and testing at ITC and RCET will continue
- ATC will continue to support data mining requests and the development of data mining tools