ATC Principal Investigator's Report ATC Evaluation Committee Meeting New Orleans, LA, January 15, 2009

> James A. Purdy, Ph.D. UC Davis Medical Center Sacramento, CA, USA

Supported by NIH U24 grant CA81647, "Advanced Technology QA Center"

- 1992 RTOG 3D QA Center established at Washington Univ. to support RTOG 3DCRT trials
- 1999-02: NCI funds 2 Advanced Technology QA Centers (WU ATC Consortium and UF RCET)
- 2002-07: RFA re-competed NCI U24 grant RCET folded into WU ATC Consortium U24 grant)
- 2007-12: RFA re-competed NCI U24 grant (WU ATC Consortium consists of ITC, RTOG RPC, QARC)









RFA-CA-07-503 OBJECTIVES

- 1. Eliminate duplication of infrastructure developmental efforts and facilitate sharing of QA resources among Coop. 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.
- Assist clinical trial cooperative groups in development of clinical trials protocols including: (a) credentialing requirements; (b) target volume definitions; (c) QA procedures; and (d) data submission instructions.

RFA-CA-07-503 OBJECTIVES

- 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 Study Chairs, Dosimetry Groups, the 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 DICOMRT.

Radiotherapy Data Collection for Advanced Technology Clinical Trials

Prior to 3DOG 9406

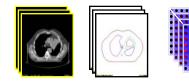


 Film, paper forms.

Postal

3DOG/RTOG 9406

to present

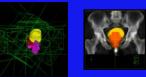


- Data objects for ATCsupported trials (typical patient accrual digital data set ~ 100 MB)
 - Volumetric, digital images (planning CT)
 - -Contours (TV, OAR)
 - -3-D dose distributions (fractionation)
 - -Treatment plans
 - -DVHs
 - -Treatment verif. images
- Participants must submit data digitally

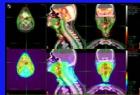
2008+ Protocols









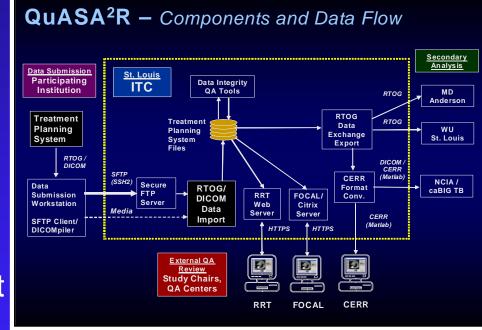


- Additional data objects needed for 2008 trials
 - Treat. plans (parameters for dose recalc.
 - Treatment verif. images (planar, kV CBCT, MV CT, Calypso,...)
 - Diagnostic imaging studies (pre- & post, MRI, MRS, PET/CT,...)

ATC Developmental Objectives

 Called ATC QuASA²R (Quality Assurance Submission, Archive, Analysis, and Review) system

 ATC(ITC) has embraced a flexible, modular architecture with emphasis on well-defined interfaces, which allows integration of commercial "offthe-shelf" and open-source software and focuses custom software development /enhancements on features not otherwise available.



 Approach enables stepwise implementation and upgrading of system components while providing continuous support of ongoing protocols.

Assisting the development of ATC Compliant Data Export from Commercial TP Systems has been (and is) a major focus of the ATC effort.

- ITC developed and maintains the RTOG Data Exchange format specification and has published a DICOM Conformance Statement to specify requirements for data submission.
- ITC participates in the DICOM standards process
 - WG-7 (Radiotherapy Objects) currently working on development of next-generation DICOM RT objects
 - WG-18 (Clin. Trials) Clin. Trials ID, de-identification profile

• ITC represents ATC as a Member of Integrating the Healthcare Enterprise (IHE) International, serving as follows:

- IHE-Radiation Oncology Technical Committee member
- IHE-RO Connectathon Test Committee member

 ITC works directly with TP system vendors to evaluate ATC compliance of data exported from new and updated software.

ATC Compliant Treatment Planning Systems

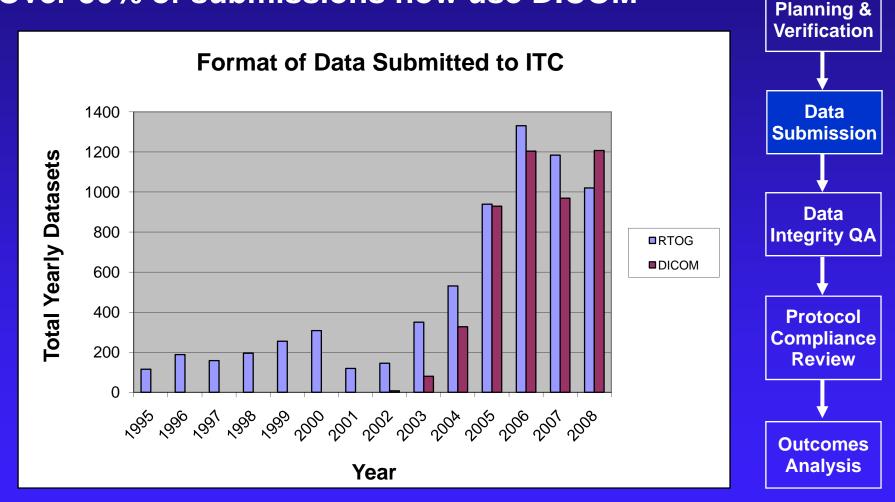
- 11 commercial TPS vendors (20 TPSs) have implemented ATC compliant export capability.
- Prospective users should consult the TPS manufacturer to verify the ATC-compliant data exchange capabilities of the TPS version they intend to use for protocol submissions.
- Please consult the ATC Protocols Page for additional credentialing requirements for ATCsupported protocols.

Treatment Planning Systems		Exchange Format	Treatment Modality					
Vendor	System	Version ¹	rormat	3DCRT	IMRT	Seed Brachy	HDR Brachy	Proton
Accuray	MultiPlan	1.5.2	D		~	•	·	
<u>CMS</u>	Focus/XiO	3.1	R	~	~	~		~
	XiO	4.3.1	D	\checkmark	~			
<u>Elekta</u>	RenderPlan 3D		R	~				
	PrecisePlan	2.01	D	1	~			
<u>Nomos</u>	Corvus		R		√ 2			
Nucletron	Helax TMS		R	~	~			
	TheraPlan Plus		R	\checkmark				
	Oncentra MasterPlan	1.5	D	~	~			
	PLATO RTS	2.62	D	~				
	PLATO BPS	14.2.6	D				\checkmark	
	SPOT-PRO	3.1-00	D			\checkmark		
Philips	Pinnacle ³		R	~	~			
	Pinnacle ³	8.0h	D	\checkmark	~			
	AcqPlan	4.9	R	\checkmark				
Prowess	Panther	4.41	D	~	~	~		
Rosses Medical	Strata Suite CTPlan	4.0	R			~		
<u>RTek</u>	PIPER	2.1.2	R			\checkmark		
TomoTherapy	Hi-ART	3.0 ³	D		\checkmark			
<u>Varian</u>	BrachyVision	6.5 (Build 7.1.67)	D				×	
	Eclipse	7.1	D	\sim	\checkmark			~
	VariSeed	7.1	D			1		

Exchange formats: **D** = DICOM RT Objects **R** = RTOG Data Exchange Format

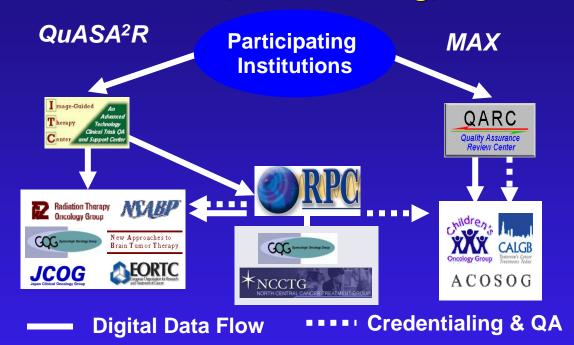
QuASA²R – *Data Submission*

•Over 50% of submissions now use DICOM



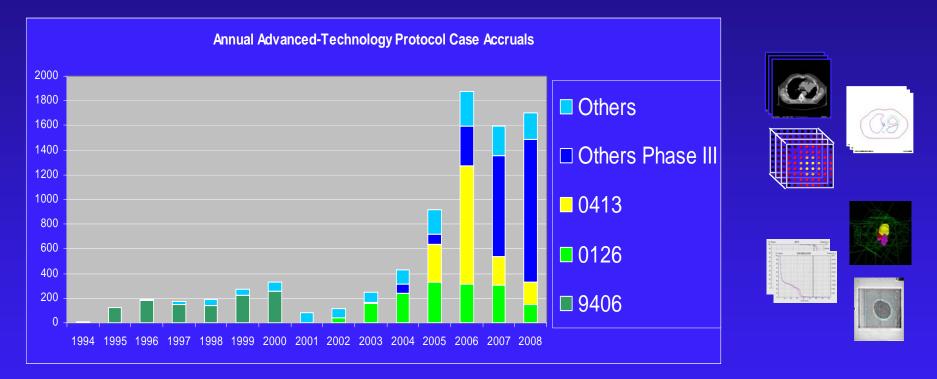
Treatment

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



- ATC effort has provided all U.S. Cooperative Groups the ability to submit case digital data (images/volumetric treatment planning data) to either ITC or QARC for quality assurance and outcomes analysis.
- 616 institutions submit to ITC: supporting 15 closed protocols (analysis) and 21 active protocols
- 20 commercial Treatment Planning Systems (11 vendors) ATC compliant
 10

As of December 31, 2008: <u>8274</u> Complete, Protocol-Case, Volumetric Digital Data Sets Submitted Over 14+ Year Period using ATC QuASA²R System



- 11 commercial TPS vendors (20 TPSs) have implemented ATC compliant export capability.
- 616 institutions able to submit digital RT data

ATC(ITC) Protocol Review Process

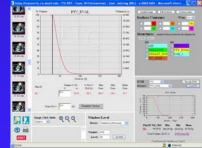
- Protocol specific digital treatment planning data are sent to ITC via SFTP or media.
- Protocol review process now clearly divided between ITC/RTOG
 - ITC is responsible for <u>Digital Data Integrity QA (DDIQA)</u> review which includes review for :
 - > completeness of protocol required elements
 - > format of data, spatial registration, dose scaling,
 - » possible data corruption; and
 - recalculation of all Dose Volume Histograms (DVHs).
 - Coop. Group is responsible for <u>Protocol Compliance QA</u> (PCQA) review which includes review of :
 - > TVs and OARs contours compliance
 - > protocol dose prescription and dose heterogeneity compliance by cooperative group specific reviewer(s) such as the Protocol Study Chair (SC) using QuASA²R's web-based *Remote Review Tool (RRT)*.

ATC Support of NSABP Clinical Trials

- NSABP B39/RTOG 0413 Partial Breast Irradiation (PBI) protocol has demonstrated value of ATC's digital data submission approach and the close collaboration needed in a demanding protocol.
- Multi-faceted case QA review process including protocol PIs and their designates, ITC personnel, and dosimetrists from RTOG and RPC.
- Three tiered review schema:
 - <u>Rapid Review</u>: Case must be approved by PI before patient can start treatment
 - <u>Timely Review</u>: First five cases are reviewed to ensure consistent quality of treatment
 - <u>Random Review</u>: Cases will be sampled and reviewed to maintain quality control.
 - All cases will eventually be reviewed
- Must allow 3 business days for a rapid review







ATC Support of NSABP Clinical Trials

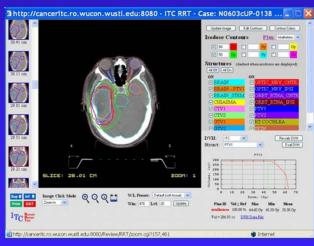
- Current accrual stands at 3219 (1208 3D, 300 Mammosite, 98 Multi-cath)
- Accrual goal is now 4300–early accrual skewed to low risk groups
- Accrual is now closed to low risk groups
- Accrual rate per year (PBI only)
 - 2005 302 (Accrual started in May)
 - 2006 933
 - 2007 233 (Opened to high risk patients only)
 - 2008 160 (Annualized based on 6/9/2008 statistics)
- Credentialing continues
 - 458 institutions credentialed (373 3DCRT, 274 Mammosite, 38 Multi-cath)
- ATC has participated in 3 workshops for PBI 2 at NSABP national meetings and 1 at an RTOG semi-annual meeting.
- ATC has also presented at 3 protocol breakout sessions at the NSABP national meeting.
- NSABP is currently looking to add a European institution to accrue to this protocol: St. Luke's hospital in Dublin, Ireland



ATC(ITC) Support of NABTT Clinical Trials

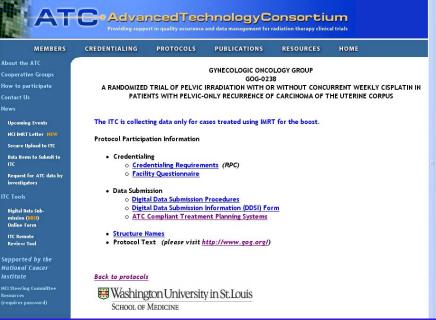
- NABTT: (ATC(ITC) is working with Dr. John Fiveash, M.D., Department of Radiation Oncology, Univ. of Alabama Birmingham)
 - Protocols are Phase I/II with maximum of 90-100 cases.
 - Credentialing involves planning a benchmark case and submitting data (same benchmark for all protocols)
 - QA for currently active study (NABTT 0603) to be done by Drs. J.
 Fiveash and Bob Lustig. ATC will identify this protocol as N0603.





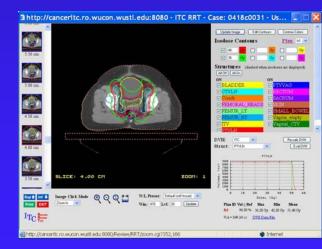
ATC(ITC/RPC) Support of GOG Clinical Trials

CCCC Gymee	wingte Decology Group
Home About GOG	Members Support Meetings/Education Publications Links FAQ
Mambar Assaud	News & Updates
GOG Administrative Office Four Fenn Center 1000 JFK Bivd Suite 1020 Philadelphia, PA 19103 Phone: 215-854-0770	Annual Metrics Annual Metrics Annual Metrics Add 19 ar 20 annu 10 0002 Clok here Help for Datasets, Families, and Florids Annual Metrics
GOG Statistical & Data Center Roswell Park Banalo, With Action Street Bhano, With Action Street Phone: 716-845-5702 Finance Office 2127 Espoy Cont Crothon, MD 21114 Phone: 410-721-7126	Cite angle for Acting information With a straight of the stra



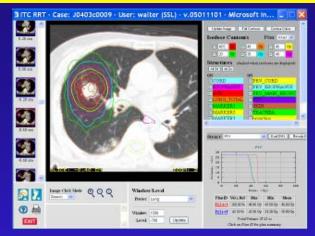
 GOG-0238:A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin In Patients with Pelvic-only Recurrence of Carcinoma of the Uterine Corpus

- First GOG protocol to use digital data submission of RT objects
- Supported by RPC and ITC



ATC(ITC) Support of JCOG Clinical Trials

 Study Closed: <u>JCOG 0403</u>: SBRT (48Gy in 4 fx over 4-8days) for medically inoperable Stage IA NSCLC, Endpoint: 3-yr overall survival, Sample size: 165



- Institutions participating in protocol JCOG 0403 submitted 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. Dr. Ishikura forwards submitted data to ITC in St. Louis for processing. Data are reviewed by Dr. Ishikura or his delegate using the ITC Remote Review Tool.
- 14 institutions were eligible to enroll patients and capable of digital data submission on JCOG 0403; 169 patients were registered to study.
- <u>JCOG 0702</u>: Phase I Dose Escalation Study of Stereotactic Body Radiation Therapy in Patients with T2N0M0 Non-Small Cell Lung Cancer (opened: 2008, accrual goals: 60; 14 institutions credentialed. 3 patients registered to study).

ATC(ITC) Support for EORTC Trials

- EORTC Protocol 22042: Adjuvant postoperative high-dose RT for atypical and malignant meningioma: a Phase-II and registration study;
- Damien C. Weber, MD (Study Coordinator) - Hopital Cantonal Universitaire De Geneve, Geneve
- Opened: 2007; accrual goals 64;
- 17 institutions credentialed; 3 patients registered to study.



EORTC Data Center Avenue E, Mounterlaan 83 / 11 Bravel 1200 Brazelles Rrigio - Bolgisso Tal 1: 22 2 774 16 11 Fax 1: 32 2 774 16 11 Fax 1: 32 2 773 15 L-mail : controlfeoricile Web : https//www.eortc.be

EORTC Radiation Oncology Group EORTC Brain Tumor Group

Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma: a Phase-II and observation study

> EORTC protocol 22042-26042 (EndraCT number 2005-005551-18)

 Institutions participating in EORTC protocol 22042 submit digital data representing CT images, structure sets, treatment plans, 3D dose distributions to ITC in St. Louis for processing and DDIQA. PCQA review performed by Dr. Weber or his delegate using the ITC Remote Review Tool.

ATC Supports CDRP

Institution	RTF#	Awarded site /mentor	Physician	Physicist	External Beam	Brachytherapy	Credentials
Rapid City Medical Center, Rapid City, South Dakota	1175	Awarded site	Dan <mark>Retereit.</mark>	Richard Crilly	Pinnacle	HDR-Nucletron Variseed- prostate seeds	0126 (IMRT), 0413 3D, 0413 Mammo, 0413 Multi, 0435 IMRT, 0522 IMRT
Riverview UW Cancer Center, Madison, WI	2850	Mentor site	James Welsh	Jeffrey Limmer	Pinnacle	LDR-Cs Pinnacle Variseed- prostate seeds	0126 (IMRT), 0225, 0234, 0236, 0421, 0521, 0522
Sanchez Cancer Center, Laredo Medical Center,	2905	Awarded site	Bobbie <mark>Bains,</mark>	Jessica Guajardo	Prowess,	Nucletron Plato	None
Cancer Ther & Research Center-Grossman (UTHSC San Antonio, TX)	1192	Mentor Site	Cheul Ha	Bill Salter	Prowess for 3D Corvus for IMRT	Prowess	0232, Passed H&N phantom, 0413 3DCRT, 0617, 0522
Daniel Freeman Memorial Hospital, Inglewood, CA	1322	Awarded site	David Kahn	Eric Frank	AcQPlan	Variseed, HDR- BrachyVision ABICUS	0232, 0413 Mammo, 0321,
USC/Norris Comprehensive Cancer Center	1966	Mentor Site	Oscar Streeter	Melvin <u>Astrahan</u>	Pinnacle	Varian Cad Plan	0522 IMRT, 0413 3DCRT
UPMC McKeesport Hospital, McKeesport, PA	1789	Awarded site	Susan <mark>Rakfal</mark>	Hungdheng Chen	Eclipse, Pinnacle	Prowess	0413 3DCRT, Approved H&N phantom
Washington Univ. Medical Center	1075	Mentor Site	Jeff Michalski	Dan Low	Pinnacle Eclipse	Nucletron Variseed Brachyvision	0117, 0126 (IMRT), 0225, 0232, 0234, 0236, 0413 Multi 0413 Mammo, 0413 3DCRT, 0421, 0521, 0522, 0617
New Hanover Regional Medical Center, Wilmington, NC	1948	Awarded site	Martin Meyerson	Scott Urguhart	Pinnacle	Variseed	0232, 0522 IMRT, 0413 3DCRT
Univ. of North Carolina Hospitals	2608	Mentor Site	Carolyn Sartor	Kathy Deschesne	PLUNC – in house sys.	Plato – HDR	0117, 0126 (Grandfathered)
Singing River Hospital Regional CC, Pascagoula, MS	2298	Awarded site	W. Sam Dennis	Dennis Wood	Eclipse	LDR ROCS, HDR Brachyvision, Variseed – prostate seeds	0126 IMRT, 0234 IMRT, 0413 3DCRT
University of Alabama, Birmingham, AL	2582	Mentor Site	Sharon Spencer	Richard <u>Ropple</u>	Eclipse	ROCS, Eclipse	0126 (IMRT), 0225, 0413 3D 0234, 0421, 0521, 0522

ATC(ITC) Support for Industry Trials

- ATC(ITC) Support for AstraZeneca Trials
 - RT QA for AstraZeneca ZD6474 (Tyrosine Kinase Inhibitor) Trial
 - Three institutions credentialed
- Discussions with Eli Lily have stopped
- Exploring possibility of setting up CRO at Washington University (Dr. Jeff Michalski, Dept. of Radiation Oncology)

ATC(ITC, QARC, RTOG) is working with caBIG/NCIA

National Cancer Institute CaBIG[™] cancer Biomedical Informatics Grid ™

 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.
- Continue to exploring projects with Ohio State Univ., QARC, ITC, ACRIN, RTOG, and CALGB
- Clinical Trial Tool Integration (CTTI Requirements (Saltz/FitzGerald)
- XIP-based Open Source Viewer (Saltz)

QRRO-ATC Project

Drs. Bosch and Matthews appointed to the QRRO *e-Data Committee* on Feb. 11, 2008.
QRRO *e-Data Committee* chaired by Christopher Rose, M.D. and Phillip Devlin, M.D. (Vice-Chair)

ATC is encouraging requests for secondary analysis using volumetric treatment planning data.

Data Request Form

Request for Use of ATC Data Form

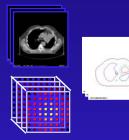
To:	Cooperative Group Chair and ATC, Principal Investigator
From:	
Affiliation	<u>.</u>
Date:	

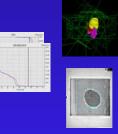
Protocol Study #(s):

All requests must be accompanied by a research plan for the proposed data use. The research plan must include: names of investigators; objectives; background; type of data requested; and data analysis description.

Specify what data is being requested:

Cooperative Group Approval: Xes	Date
ATC, P.I Approval: XeeNoSignature	Date
ATC, Sub-Contract P.I. Approval: Xes. No. Signature	Date





Head & Neck (IMRT, N=	Min	Мах	Avg		
PTV	D ₉₈	58.0	73.4	67.6	Gy
Spinal Cord	D _{mean}	32.8	44.8	39.6	Gy
Parotid	Dmean	21.2	50.3	32.4	Gy
Larynx	D_{mean}	3.9	57.7	32.9	Gy
Lung (3DCRT, N=158)	Min	Max	Avg		
PTV	D ₉₈	50.3	98.2	77.4	Gy
Spinal Cord	D ₂	0.1	60.1	26.0	Gy
Esophagus	Dmean	0.0	63.8	15.9	Gy
Heart	D _{mean}	0.0	45.3	10.5	Gy
Liver	Dmean	0.0	19.3	1.2	Gy
Brachial Plexus	D _{mean}	0.0	57.7	4.6	Gy
Lung	V ₂₀	5.3	46.6	21.2	%
Prostate (3DCRT, N=984	Min	Мах	Avg		
PTV	D ₉₈	52.2	81.6	75.0	Gy
Bladder	Dmean	4.9	75.9	37.7	Gy
Rectum	Dmean	12.9	72.5	42.7	Gy
Femoral Heads	D_{mean}	1.8	49.5	32.4	Gy

ATC WEB SITE Updated (http://atc.wustl.edu) Added FAQs



ATC Standing Committee (Coordination Efforts)

Appointed ATC Credentialing/QA Committee whose mission is: promote uniformity in credentialing/QA across cooperative groups (one of the specified goals of the ATC)

- credentialing requirements
- target volume definitions
- dose specification
- QA procedures
- data submission instructions
- assess clarity and correctness (i.e., "setting of the bar") of credentialing procedures.
- Membership
 - Marcia Urie (Chair)
 - Dave Followill (Co-chair)
 - Jim Galvin
 - Bill Straube

ATC Standing Committee (Coordination Efforts)

Appointed ATC Informatics Committee whose mission is to:

- Share pertinent information and provide input regarding the latest informatics technology available and/or used at the QA Centers/Cooperative Groups
- Periodically review and assess the ATC's informatics infrastructure and developmental schedule.

Membership

- Walter Bosch (Chair)
- Joe Deasy (Co-Chair)
- John Matthews
- Richard Hanusik
- Huy Duong
- Brenda Young (liaison ACRIN/RTOG)
- Joel Saltz (liaison caBIG)

ATC Standing Committee (Coordination Efforts)

 Appointed ATC Council of Industry Participants whose role will be to:

- provide input regarding the latest informatics technology commercially available
- periodically review and assess the ATC's informatics infrastructure and developmental schedule.
- Current Membership
 - Joel Goldwein, Elekta IMPAC (Chair)
 - AI Lawson CMS
 - Mike Courtney Philips
 - Damien Evans TeraMedica
 - Armin Langenegger Varian
 - Colin Sims Accuray
 - TBN -TomoTherapy

Change in ATC Leadership on July 1, 2009

- Year 11 (July 1, 2009-10): Beginning the 3rd year of the new funding period, Dr. Purdy, will step down as the Director of the Image-Guided Therapy Center (ITC) and as the P.I. for the ATC U24 grant.
- Drs. Bosch and Michalski will serve as co-PIs who will be responsible for the overall direction and coordination of the ITC/ATC efforts and for ensuring that the grant's goals are realized.
- Dr. Purdy will assist Drs. Bosch and Michalski in this effort as a co-investigator.

ACKNOWLEDGEMENTS

The Advanced Technology QA Consortium is a team effort, supported by NIH U24 Grant CA81647, "Advanced Technology QA Center". The individuals listed below have made significant contributions to this work.

NCI: James A. Deye, Ph.D. (Project Officer)

- ITC: James A. Purdy, Ph.D. (Principal Investigator), Walter R. Bosch, D.Sc., Jeff M. Michalski, M.D., William L. Straube, M.S., John W. Matthews, D.Sc., Joe Deasy, Ph.D. Roxana J. Haynes, R.N., Anna Eccher
- **QARC:** Thomas J. FitzGerald, M.D., Marcia M. Urie, Ph.D., Kenneth Ulin, Ph.D., Richard Hanusik
- **RPC:** Geoffrey S. Ibbott, Ph.D., David Followill, Ph.D., Andrea Molineu, M.S., Jessica Lowenstein, M.S., Irene Harris, B.S., CMD, Paola Alvarez, M.S., Joye Roll, B.S., CMD, Huy Duong, B.S.
- **RTOG:** Walter J. Curran, M.D., Jim Galvin, Ph.D., Elizabeth Martin, CCRP, Lorraine Quarles, Brenda Young