

Principal Investigator's Report Advanced Technology QA Consortium

**RTOG Meeting – Philadelphia, PA
June 19, 2008**

**Walter R. Bosch, D.Sc.
Washington University in St. Louis
for
James A. Purdy, Ph.D.
UC Davis Medical Center, Sacramento, CA, USA**

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

ATC Specific Aims

ATC objectives are accomplished through developmental, coordination, service and educational specific aims.

- **Specific Aim 1 (Service)**: Maintain and manage the current electronic data submission of advanced technology protocol credentialing and case data.
 - ATC QuASA²R (Quality Assurance Submission, Archive, Analysis, and Review) system.
- **Specific Aim 2 (Developmental)**: Develop novel web-based remote-review tools that will enhance efficient & effective review of 3DCRT, IMRT, SRS, SBRT, particle, and brachytherapy protocols and address development of future protocol processes such as IGRT and ART.
 - Emphasis on web-based tools that achieve compatibility with existing software & electronic health record standards, and maintaining /developing archival multimodality ITPV, credentialing, and QA databases that can be linked with clinical outcomes database.



ATC Specific Aims

ATC objectives are accomplished through developmental, coordination, service and educational specific aims.

- **Specific Aim 3 (Coordination)**: Assist cooperative groups in the development and management of advanced technology clinical trials protocols including (a) tumor/target volume and organ at risk definitions; (b) credentialing requirements and evaluation criteria; (c) electronic data submission requirements/instructions; and (d) QA review procedures.
- **Specific Aim 4 (Educational)**: Serve as an educational resource to the nation's clinical trial cooperative groups and participating institutions for support of advanced technology radiation therapy clinical trials.



ATC Standing Committee

(Coordination Efforts)

- Dr. Purdy has 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)

- Dr. Purdy has 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)

- Dr. Purdy has 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)
 - Al Lawson - CMS
 - TBN - Philips
 - Damien Evans - TeraMedica
 - TBN - TomoTherapy
 - Armin Langenegger – Varian

ATC Developmental Objectives

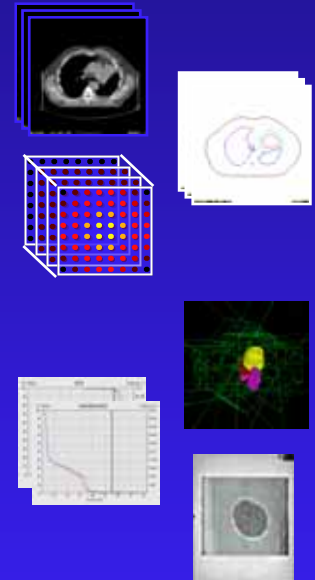
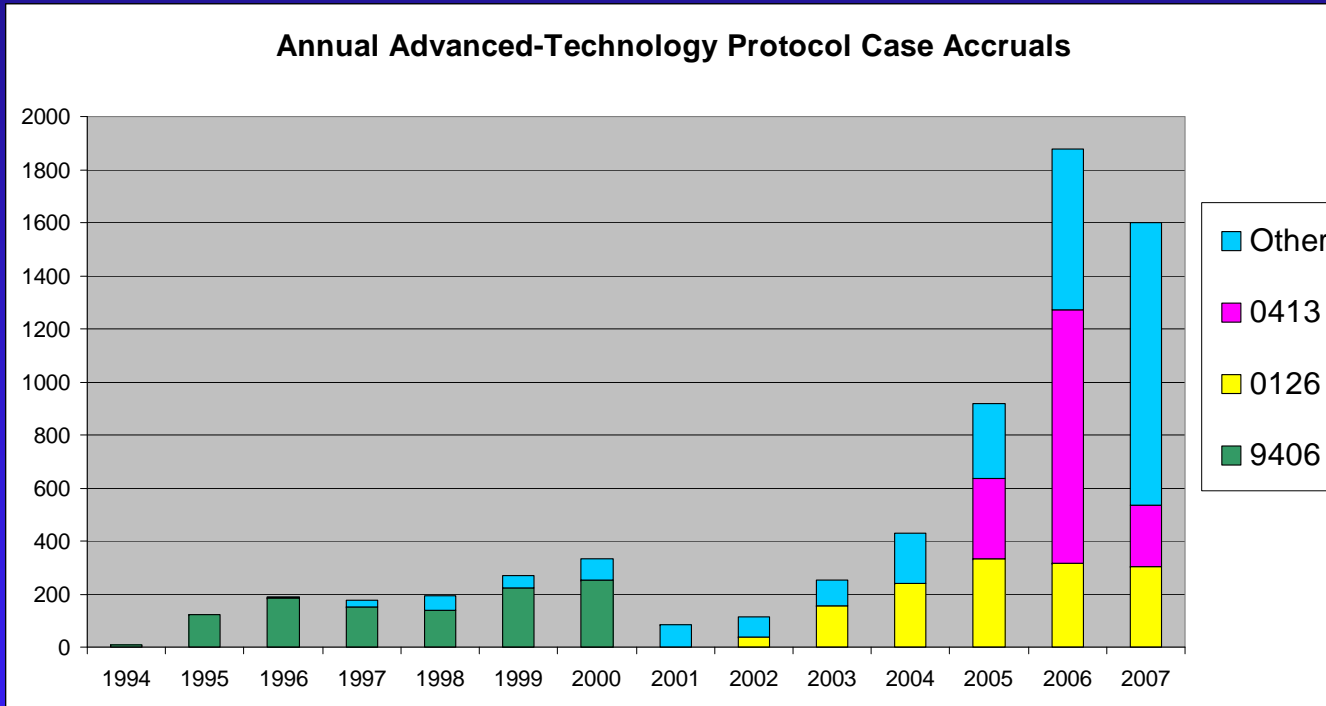
- Dr. Bosch will provide an update on development of the ATC *QuASA²R* (QuASA²R (Quality Assurance Submission, Archive, Analysis, and Review) system
- Development of QuASA²R is guided by:
 - the considerable experience and success of ITC computer scientists and QA personnel in supporting AT clinical trials,
 - recognition of QA tool needs for future protocols involving emerging technologies (e.g. IGRT, ART),
 - and compatibility with caBIG infrastructure.
- ITC has embraced a flexible, modular architecture with emphasis on well-defined interfaces, which allows integration of commercial “off-the-shelf” and open-source software and focuses custom software development/enhancements only on features not otherwise available.
- Approach enables stepwise implementation and upgrading of system components while providing continuous support of ongoing protocols.

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 ATC-supported protocols.

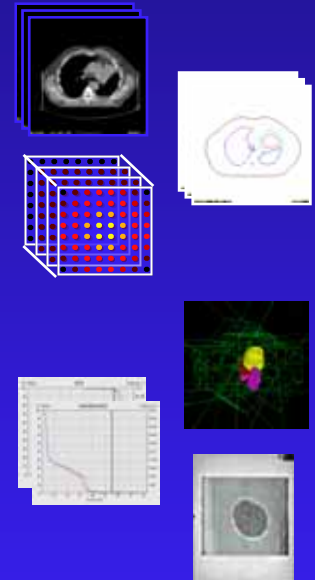
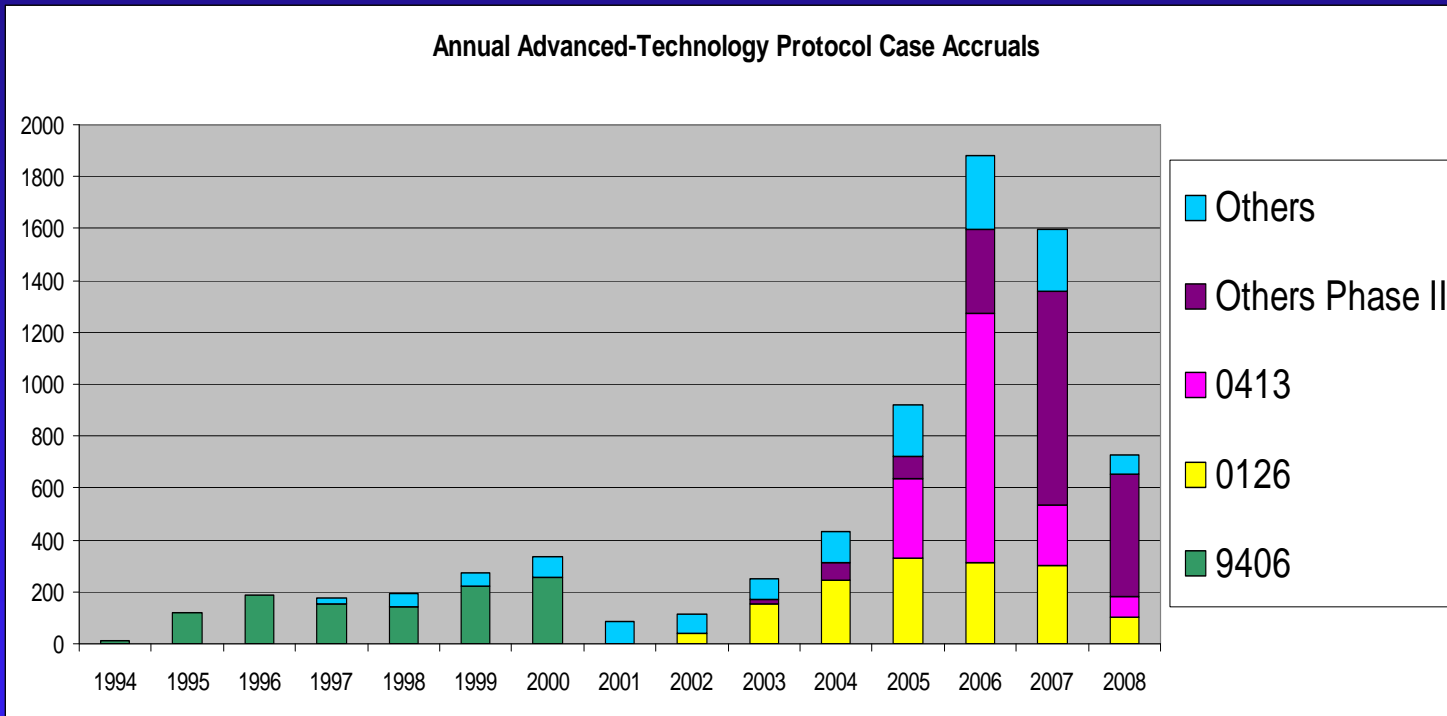
Treatment Planning Systems			Exchange Format	Treatment Modality				
Vendor	System	Version ¹		3DCRT	IMRT	Seed Brachy	HDR Brachy	Protons
Accuray	MultiPlan	1.5.2	D		✓			
CMS	FocusXiO	3.1	R	✓	✓	✓		✓
	XiO	4.3.1	D	✓	✓			
Elekta	RenderPlan 3D		R	✓				
	PrecisePlan	2.01	D	✓	✓			
Nomos	Corvus		R		✓ ²			
Nucletron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

- As of December 31, 2007: 6562 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.
- 553 institutions able to submit data

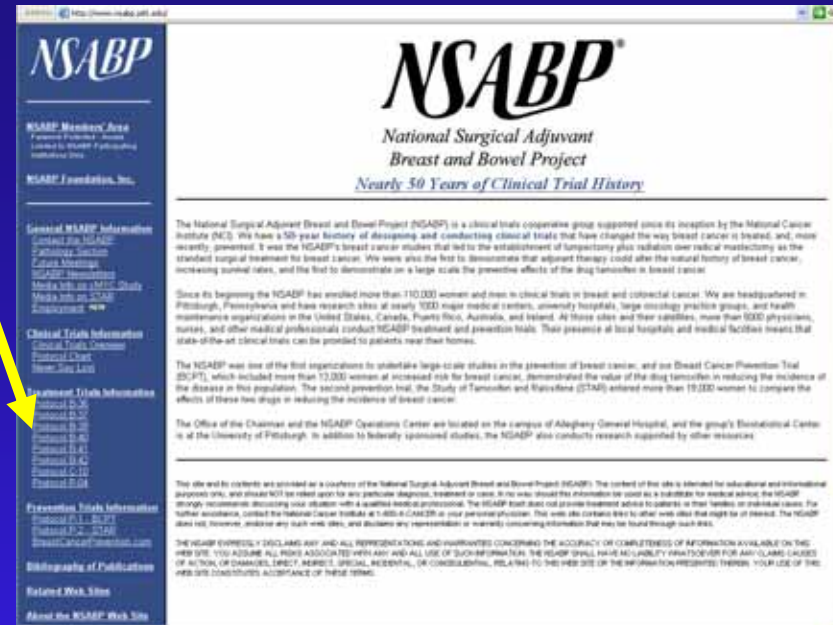
- As of June 9, 2008: 7302 Complete, Protocol-Case, Volumetric Digital Data Sets Submitted Over 14+ Year Period using ATC QuASA²R System



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

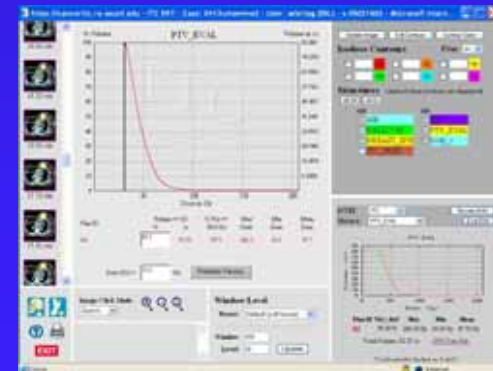
ATC Support of NSABP Clinical Trials

- NSABP B39/RTOG 0413 Partial Breast Irradiation (PBI) protocol has demonstrated the value of ATC's digital data submission approach and the close collaboration needed in a demanding protocol.
- Multiple study groups; Multiple QA Centers involved in credentialing and case QA review.
- High volume (1500 cases / 2 years)
- Multiple treatment modalities
- Institutions must be credentialled for at least one PBI technique before they can register a patient
- Benchmark tests (Downloadable CTs and structure sets)



ATC Support of NSABP Clinical Trials

- Multi-faceted case QA review process including PIs from protocol and their designates, Dosimetrists from RTOG and RPC, and ITC personnel.
- Three tiered review schema: Rapid Review, Timely Review and Random Review
 - Rapid Review: Case must be approved by PI before patient can start treatment
 - Timely Review: First five cases are reviewed to ensure consistent quality of treatment
 - Random Review: Cases will be sampled and reviewed to maintain quality control.
 - All cases will eventually be reviewed
- Institutions must allow 3 business days for a rapid review



ATC Support of NSABP Clinical Trials



- Current accrual stands at 3138 (1183 3D, 292 Mammosite, 95 Multi-cath)
- Accrual goal is now 4200—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 – 79 (As of 6/9/2008)
- 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

NEW APPROACHES TO BRAIN TUMOR THERAPY

Home
Objectives
Overview
Protocols
Protocol Status
Central Office
Institutions
Other Information
NABTT Map

For information on individual NABTT centers, please click on their name below.

Steps towards a cure...

N A B T T

NABTT INSTITUTIONS

- Cleveland Clinic, Cleveland, OH
- Emory University, Atlanta, GA
- Henry Ford Hospital, Detroit, MI
- Johns Hopkins University, Baltimore, MD
- Massachusetts General Hospital, Boston, MA
- Moffitt Cancer Center, Tampa, FL
- NCI Intramural Program, Rockville, MD
- University of Alabama, Birmingham, AL
- University of Pennsylvania, Philadelphia, PA
- University of Texas, San Antonio, TX
- Wake Forest University, Winston-Salem, NC

New Approaches to Brain Tumor Therapy
An NCI-funded CNS Consortium dedicated to improving the outcome for adults with primary brain tumors.

**The New Approaches to Brain Tumor Therapy
CNS Consortium**

Group Leaders: Stuart Grossman, Henry Brem

Member Institutions

- 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
- Wake Forest University

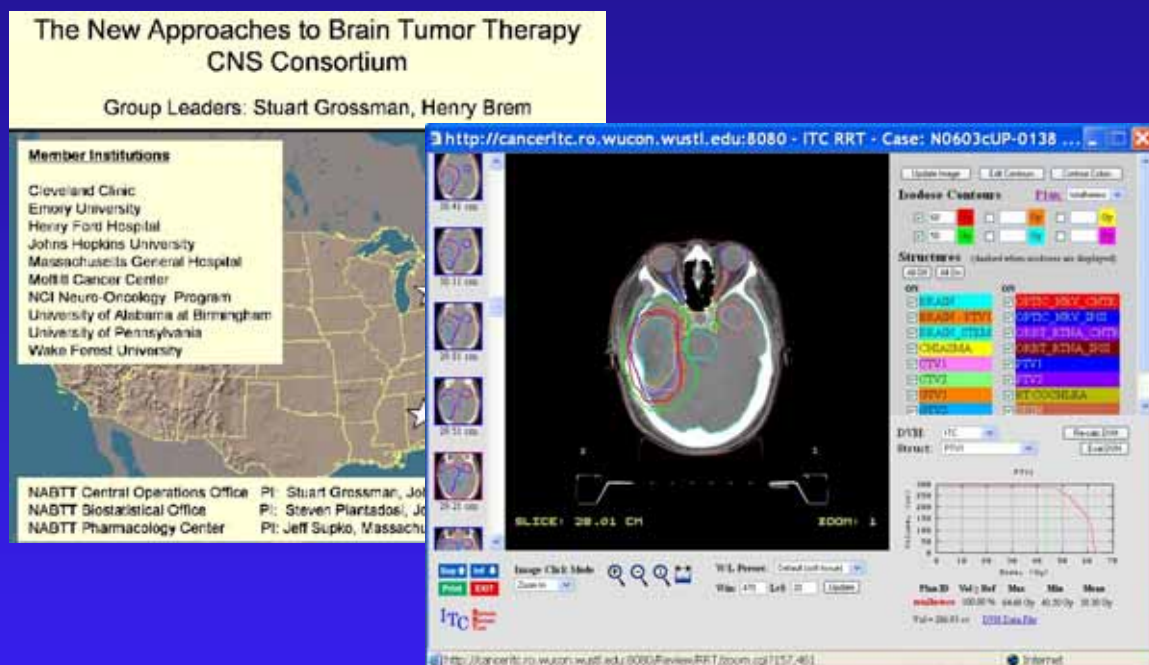


NABTT Central Operations Office PI: Stuart Grossman, Johns Hopkins University
NABTT Biostatistical Office PI: Steven Plantadosi, Johns Hopkins University
NABTT Pharmacology Center PI: Jeff Supko, Massachusetts General Hospital

- NABTT (ATC(ITC) is working with Dr. John Fiveash, M.D., Department of Radiation Oncology, Univ. of Alabama Birmingham)
 - 9-10 NABTT institutions are participating in these studies.
 - 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.

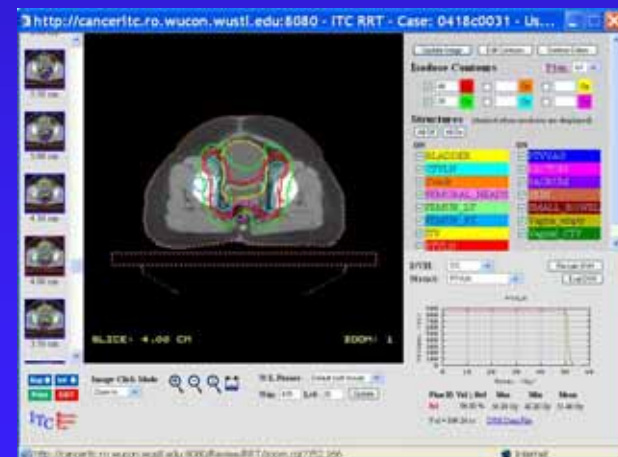
ATC(ITC) Support of NABTT Clinical Trials

- Thus far ATC(ITC) has received 9 benchmark case submissions which have passed DDIQA and PCQA.
 - MGH
 - UAB
 - Johns Hopkins
 - Moffitt
 - Penn
 - Cleveland Clinic
 - Emory
 - Wake Forest
 - Henry Ford
- NABTT personnel are invited on conference calls for updates of accrual and communications
- 1 case accrual has been submitted and reviewed using ATC(ITC) resources



ATC(ITC/RPC) Support of GOG Clinical Trials

- 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



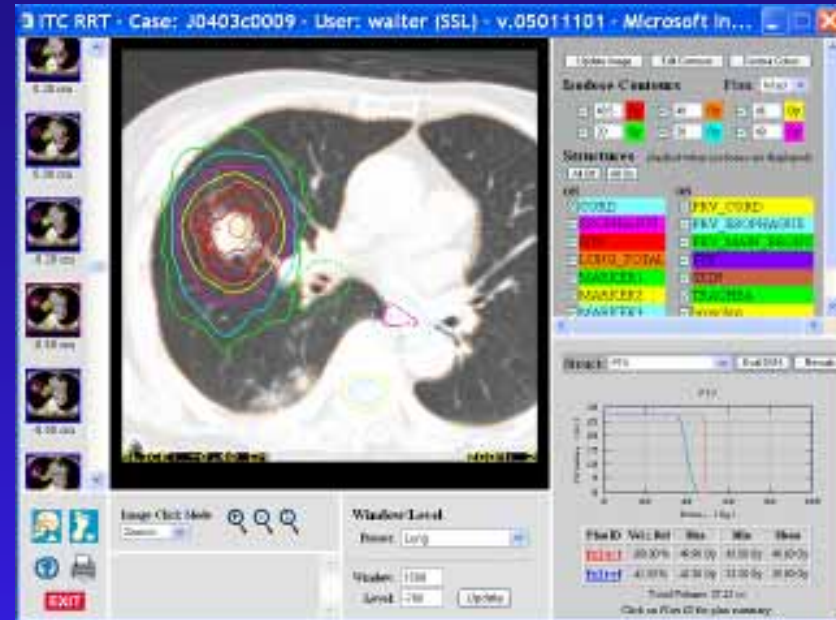
ATC(ITC/RPC) Support of GOG Clinical Trials

- ATC(ITC) will only receive data for patients that will undergo an IMRT boost treatment.
- Thus far 7 GOG institutions have met the credentialing requirements for IMRT on this protocol which include:
 - Pelvic or H&N phantom irradiation
 - Digital data submission to the ITC
 - IMRT Facility Questionnaire
 - Knowledge Assessment form
- Institutions have begun registering patients but to this point none have been registered for IMRT
- IMRT plans will be reviewed by RPC prior to the commencement of IMRT treatment (Rapid Review).
- Thus far 1 conference call has been held between the ATC and GOG. Others will be scheduled as necessary.



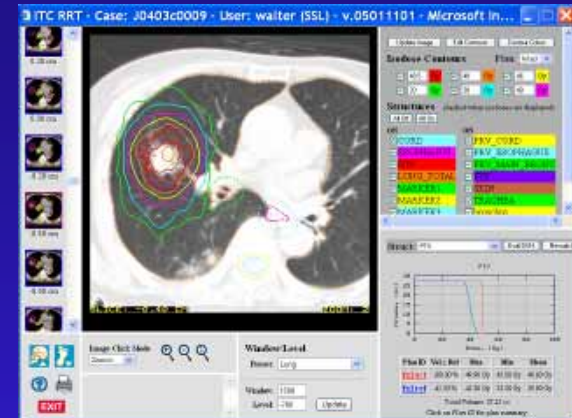
ATC(ITC) Support of JCOG Clinical Trials

- JCOG 0403: 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 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.
- Dr. Ishikura forwards submitted data to ITC in St. Louis for processing.
- Data are reviewed by Dr. Ishikura or his delegate using ATC QuASA²R's Remote Review Tool.
- 14 institutions are eligible to enroll patients and capable of digital data submission as of June 9, 2008.
- 144 patients are registered to study as of June 9, 2008.



ATC(ITC) Support of JCOG Clinical Trials

- There have been no major issues with receiving data from Japan for this clinical trial or with the review of these data utilizing QuASA²R's web based RRT.
- The input of Dr. Ishikura as a conduit for the digital data submission has almost certainly aided in the low level of issues in either communications or data quality.
- Minor issues include problems recalculating DVHs on a small subset of cases. The reason is not clear, but the problem has easily been resolved to this point.
- The ATC (ITC) is planning to undertake a second trial with the JCOG once the current trial is completed.



JCOG 0702

A PHASE I DOSE ESCALATION STUDY OF SBRT IN PATIENTS WITH T2N0M0 NON-SMALL CELL LUNG CANCER

- ✓ To define the recommended dose of SBRT for T2N0M0 NSCLC
- ✓ Primary endpoint, Grade ≥ 2 pneumonitis
- ✓ Sample size, 60+ pts (CRM)
 - Inoperable or 'unfit' for surgery
 - Accrual: 5 years

A PHASE I DOSE ESCALATION STUDY OF SBRT IN PATIENTS
WITH T2N0M0 NON-SMALL CELL LUNG CANCER

✓ Eligibility

- Pathologically proven NSCLC
- Stage IB
- Medically inoperable or unfit
- PS 0-2
- $\text{PaO}_2 \geq 60$ torr
- $\text{FEV}_{1.0} \geq 700$ ml
- Written informed consent

A PHASE I DOSE ESCALATION STUDY OF SBRT IN PATIENTS
WITH T2N0M0 NON-SMALL CELL LUNG CANCER

✓ Treatment

-4-6 MV X rays

-40-65 Gy in 4 fractions over 4-8 days

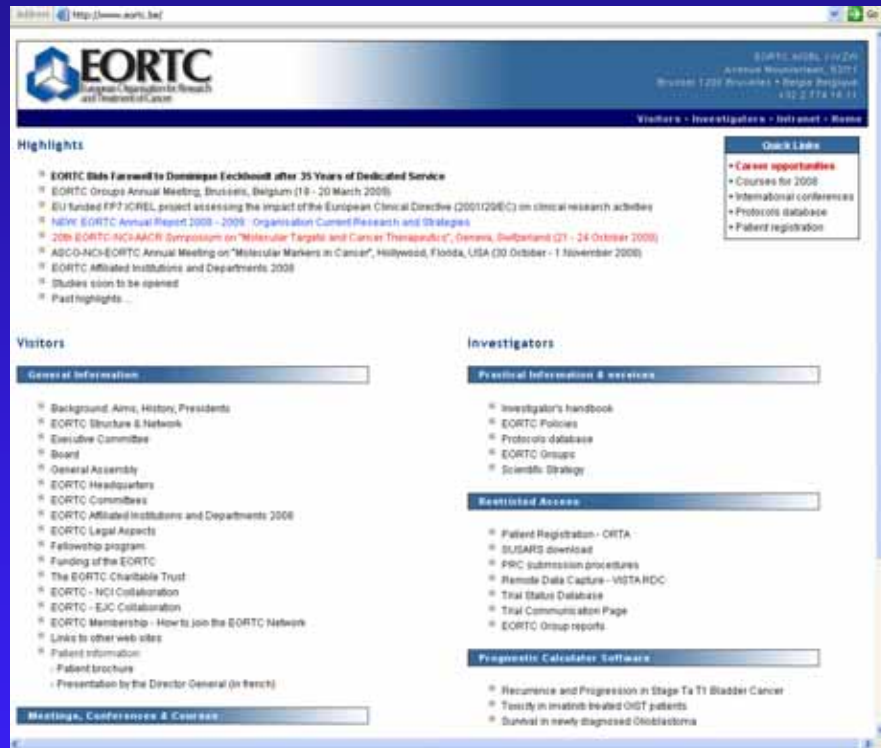
-prescribed to D_{95} of the PTV

-heterogeneity corrected dose

-algorithm, superposition

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



EORTC
European Organisation for Research and Treatment of Cancer

Address: Avenue Rockefeller, 1201
Brussels 1201, Belgium
Tel: +32 2 774 14 11

Visitors - Investigators - Helpdesk - Home

Highlights

- EORTC 8th Anniversary to Dominique Eeckhout after 35 Years of Dedicated Service
- EORTC Groups Annual Meeting, Brussels, Belgium (18 - 20 March 2008)
- EU funded FP7 JCREL project assessing the impact of the European Clinical Directive (2001/20/EC) on clinical research activities
- NEW: EORTC Annual Report 2008 - 2009: Organisation Current Research and Strategies
- 20th EORTC-NCI-AACR Symposium on "Molecular Targets and Cancer Therapeutics", Geneva, Switzerland (21 - 24 October 2008)
- AGCO-NCI-EORTC Annual Meeting on "Molecular Markers in Cancer", Hollywood, Florida, USA (30 October - 1 November 2008)
- EORTC Affiliated Institutions and Departments 2008
- Studies soon to be opened
- Past highlights ...

Visitors

General Information

- Background, Aims, History, Presidents
- EORTC Structure & Network
- Executive Committee
- Board
- General Assembly
- EORTC Headquarters
- EORTC Committees
- EORTC Affiliated Institutions and Departments 2008
- EORTC Legal Aspects
- Fellowship program
- Funding of the EORTC
- The EORTC Charitable Trust
- EORTC - NCI Collaboration
- EORTC - EJC Collaboration
- EORTC Membership - How to join the EORTC Network
- Links to other web sites
- Patient information
 - Patient brochure
 - Presentation by the Director General (in French)

Investigators

Practical Information & services

- Investigator's handbook
- EORTC Follows
- Protocols database
- EORTC Groups
- Scientific Strategy

Registered Access

- Patient Registration - ORTA
- SUSARs download
- FMC submission procedures
- Remote Data Capture - VISTA-HDC
- Trial Status Database
- Trial Communication Page
- EORTC Group reports

Prognostic Calculator Software

- Recurrence and Progression in Stage Tc T1 Bladder Cancer
- Toxicity in irradiated treated OIG patients
- Survival in newly diagnosed Oligoblastoma

Quick Links

- Career opportunities
- Courses for 2008
- International conferences
- Protocols database
- Patient registration

Meetings, Conferences & Courses



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EORTC protocol 22042 - 26042

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

Trial Status	Open
Dates	Date of activation: 17/12/2007
Data management at EORTC	Full
Phase	2
Randomized trial	No
Type	Adjuvant
Targeted sample size	EORTC Groups: - - All Groups: 77
Number of steps	1
Drug	
Study Staff	Damien C. Weber (Study Coordinator) - Hopital Cantonal Universitaire De Geneve, Geneve Laurence Collette (Statistician) - EORTC, Brussels Sarah Morren (Data Manager) - EORTC, Brussels Denis Lacombe (Coordinating Physician) - EORTC, Brussels Nadège Gosselin (Project Manager) - EORTC, Brussels, nadège.gosselin@eortc.be , +32 2 7741000
Type of cancer	Brain
Participating Groups	EORTC Radiation Oncology Group(Coordinating Group) EORTC Brain Tumor Group
Currently authorized centers	Hospital Germans Trias i Pujol (Badalona - Barcelona), Spain - Inst. 391 Hopital Cantonal Universitaire De Geneve (Geneve, Switzerland) - Inst. 451
Protocol summary	Link provided by NCI/POD
Full protocol in PDF (requires password)	22042.pdf

[Back to Protocol section](#)

- Damien C. Weber (Study Coordinator) - Hopital Cantonal Universitaire De Geneve, Geneve
- Laurence Collette (Statistician) - EORTC, Brussels

- Sarah Morren (Data Manager) - EORTC, Brussels
- Denis Lacombe (Coordinating Physician) - EORTC, Brussels
- Nadège Gosselin (Project Manager) - EORTC, Brussels

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



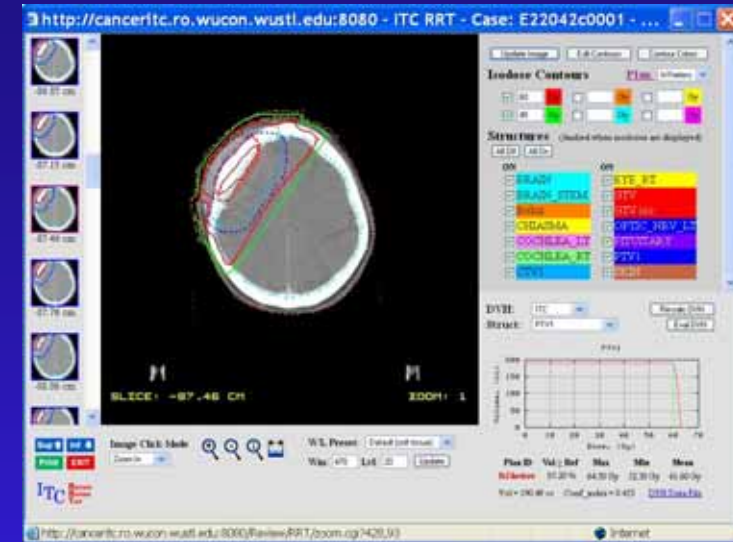
- **EORTC Protocol 22042**

- Sample size: 70, ~10 institutions
- ATC(ITC) performs digital data integrity QA (DDIQA); Dr. Weber performs PCQA.
- Institutional credentialing is underway (3)
- 1 case accrual



ATC(ITC) Support for EORTC Trials

- Benchmark cases have been submitted from 3 institutions.
 - Addenbrooke's Hospital, Cambridge University Hospitals NHS Trust, (Cambridge, England)
 - Institut Català d'Oncologia (Barcelona, Spain)
 - Hôpitaux Universitaires de Genève (Geneva, Switzerland)
 - All passed (but not on first try) DDIQA & PCQA.
 - No issues have been noted with communications or time zones or submitting data via SFTP from Europe.
- Several other institutions have been given SFTP accounts and are preparing for submitting the benchmark cases.
 - Centre Leon Berard (Lyon, France)
 - Hôpital Jules Courmont - Centre Hospitalier Lyon Sud (Lyon, France)
 - University Clinic Leipzig (Leipzig, Austria)
 - Università di Torino (Torino, Italy)
 - Marmara University Hospital (Istanbul, Turkey)
- ATC(ITC) has received 1 case accrual that has also passed DDIQA review and PCQA review



ATC Supports CDRP

Status of all CDRP sites is periodically reviewed – June 9, 2008

Institution	RTF#	Awarded site / mentor	Physician	Physicist	External Beam	Brachytherapy	Credentials
Rapid City Medical Center, Rapid City, South Dakota	1175	Awarded site	Dan Peterreit	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 Bains	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 Astrahan	Pinnacle	Varian Cad Plan	0522 IMRT, 0413 3DCRT
UPMC McKeesport Hospital, McKeesport, PA	1789	Awarded site	Susan Rakfal	Hungcheng 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 Urquhart	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 Popple	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 Lilly 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



- 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)

ATC Posters/Presentations at 2008 Meetings

- AAPM, July 27-31, Houston, TX
 1. QuASA²R - a digital data Quality Assurance Submission, Archive, Analysis, and Review system for advanced technology clinical trials in radiation therapy (Bosch, et al. Poster Session)
 2. Update on Digital Data Integrity Quality Assurance for Multi-Institutional Advanced Technology Clinical Trials (Straube, et al. Poster Session)
 3. Improvements to the Computational Environment for Radiotherapy Research Open-source Software System (Wu, et al. Poster Session)
- ASTRO, Sep 21-25, Boston, MA
 1. Impact of Protocol Complexity on Digital Data Integrity Quality Assurance for Clinical Trials Requiring Digital Data Submission (Straube, et al. Poster Session)

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: _____

Date: _____

Protocol Study #(\$): _____

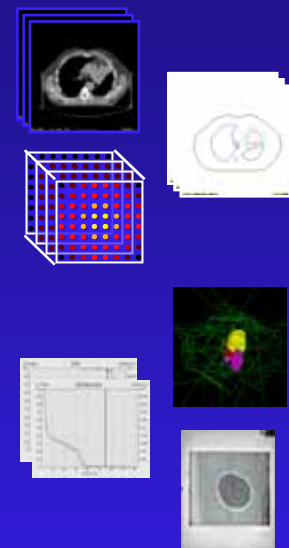
All requests must be accompanied by a research plan for the proposed data use. The research plan must include: names of investigators; objectives; background; type of data requested; and data analysis description.

Specify what data is being requested:

Cooperative Group Approval: Yes No Signature _____ Date _____

ATC, P.I Approval: Yes No Signature _____ Date _____

ATC, Sub-Contract P.I. Approval: Yes No Signature _____ Date _____



Head & Neck (IMRT, N=64)		Min	Max	Avg	
PTV	D ₉₈	58.0	73.4	67.6	Gy
Spinal Cord	D _{mean}	32.8	44.8	39.6	Gy
Parotid	D _{mean}	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	D _{mean}	0.0	63.8	15.9	Gy
Heart	D _{mean}	0.0	45.3	10.5	Gy
Liver	D _{mean}	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	Max	Avg	
PTV	D ₉₈	52.2	81.6	75.0	Gy
Bladder	D _{mean}	4.9	75.9	37.7	Gy
Rectum	D _{mean}	12.9	72.5	42.7	Gy
Femoral Heads	D _{mean}	1.8	49.5	32.4	Gy

Action Items (Administration/Collaboration) – March 28, 2008

1. ATC subcontractors to submit Progress Report to Dr. Purdy by April 1, 2008 (FitzGerald, Curran/O'Meara, Ibbott)
2. Confirm dates for ATC meetings:
 - June 19 at RTOG Semi-Annual Mtg (O'Meara/Purdy)
 - TBD at RPC (Ibbott/Purdy)
 - TBD-ATC Evaluation Committee; Jan. 15, 2009 at RTOG Semi-Annual Mtg (Deye/O'Meara/Purdy)
 - TBD-ATC Steering Committee; TBD at RTOG QA Office (Deye/O'Meara/Purdy)
3. Prepare response to ATC Steering Committee input (Purdy)
4. Have high quality (increased number) of ATC Posters/Presentations at 2008 AAPM/ASTRO Meetings (all)
5. Draft response to AAPM Newsletter article (Purdy, et al.)
6. Continue to promote requests to ATC for secondary analysis using volumetric treatment planning data archived at ITC. (Purdy, Deasy, Michalski, Deye)
7. Establish ATC collaborative effort with Quality Research in Radiation Oncology (QRRO) project (Purdy/Bosch/Wilson/Rose/Devlin/Deye)

Action Items (Informatics Infrastructure) – March 28, 2008

1. Develop strategy to integrate commercial solutions with ATC Informatics Infrastructure enterprise solutions (ATC IT committee)
2. Evaluate suitability of QARC's MAX for all ATC centers (Bosch, Hanusik, Ulin, Sharma)
3. Implement developmental/equipment purchase schedule for QuASA²R (Bosch, Purdy)
4. Evaluate PLUNC functionality for incorporation into ATC informatics infrastructure (Deasy, Cheney)
5. Harden/deploy/test grid enabled CERR (Saltz, Sharma, Deasy, Bosch)
6. Modify CERR to display (submitted) DRRs (Deasy, Ulin, Bosch)
7. Develop procedure/process for synchronization of changes made to CERR (particularly as it relates to QA of clinical trials) (Deasy)
8. Develop online access for routine DVA data extraction by coop groups (Deasy, Winter, Sadek, Bosch)
9. Develop (or use commercial TPS) Monte Carlo QA tool for dose recalculation to TV and OARs (Deasy, Ibbott, Followill, Xiao, Galvin)
10. Develop data submission tool (anonymized) for QuASA²R (Bosch, Matthews, Deasy)
11. Need to streamline DICOM view (server side viewer needed). (Bosch, Matthews, Deasy)

Action Items (Credentialing/QA) – March 28, 2008

1. Refine/Develop proton beam credentialing and case remote QA review strategy
 - a. *QARC Proton Questionnaire to be updated (Urie, Galvin).*
 - b. RPC to evaluate use of prostate phantom for proton QA (Ibbott, Gillin, Deye)
 - c. Proton centers to provide feedback to ITC on adequacy of Remote Review Tool for case review (Bosch, Urie, J. Michalski, Coen, Choi, Liao)
2. Review credentialing process and produce summary for next meeting (ATC QA Credentialing Committee)
3. Refine/Develop strategy for support of IGRT, ART, multimodality imaging protocols (Galvin, Xiao, Michalski, Deasy, Bosch, Purdy, Ulin, Urie, et al.)
4. Develop standard names for target volumes and Organs at risk for ATC supported protocols. (Bosch, Michalski)
5. ATC put together a collaborative working group (CWG) whose deliverable would be a "white paper" that took the approach of the NCI IRAT initiative, but focused on radiation oncology protocols focus on what is needed to make quantitative imaging one of the key structural components of an RT clinical trial. (Jeraj, Gillin, Cao, J. Balter)

Action Items (Data Mining) – March 28, 2008

1. RTOG 0522/NCIA Project: Assess feasibility of accessing/using the RTOG 0522 dataset (DICOM RT data objects as well as advanced imaging, FDG-PET/CT in treatment assessment manner) components as a reference data set. This is a significant and high priority as it will open up possibilities for future data mining through the ATC capabilities. Goal is to have a report of the findings (vis a vis availability, cohesiveness, use-friendliness, etc) by the June RTOG meeting. (Jeraj, Gillin, Deasy, Bosch)

ATC Future Meeting Dates

1. Oct. 2, 2008: ATC Steering Committee, at RTOG HQ, Philadelphia, PA
2. Oct. 3, 2008: ATC Meeting at RTOG HQ QA, Philadelphia, PA
3. Jan. 15, 2009: ATC Evaluation Committee, RTOG Semi-Annual Meeting, New Orleans, LA
4. Spring, 2009: ATC Meeting at RPC, Houston, TX
5. Fall, 2009: ATC Meeting at QARC, Providence, RI

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