Principal Investigator's Report
Advanced Technology QA Consortium

ATC Meeting Hosted by ITC
St. Louis, MO
March 27-28, 2008

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

New *ATC Grant*

ATC goals as specified in our ATC renewal application to be accomplished through the following ***service***, ***developmental***, ***coordination***, **and educational objectives**:

1. Eliminate duplication of infrastructure developmental efforts and facilitate sharing of QA resources among cooperative 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 RT trials.
4. Facilitate/manage digital data protocol submission.
5. Facilitate/manage the QA review of submitted data.
6. Further development of methods for rapid analysis of volumetric treatment planning data.
7. Assist clinical trial Coop. Groups in development of clinical trials including: (a) credentialing requirements; (b) TV definitions; (c) QA procedures; and (d) data submission instructions.
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, 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 caBIG and DICOM RT.

ATC Progress Report
Specific Aims (Service Effort)

- **Specific Aim 1**: 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.

ATC Progress Report
Specific Aims (Developmental Effort)

- **Specific Aim 2**: Develop novel web-based remote-review tools that will enhance the efficient/effective review of 3DCRT, IMRT, SBRT, and brachytherapy protocols. Design of these tools will address development of future protocol processes such as image-guided radiation therapy (IGRT) and adaptive radiation therapy.
  - Tools/interfaces designed by multidisciplinary team of experts in clinical trials QA.
  - *QuASA²R* is modular in architecture to promote efficient design, testing, and implementation of tools and subsystems. Starting from a DICOM-based ITPV data archive with well-defined interfaces,
  - Developmental approach will (a) allow selective re-use and adaptation of existing components, (b) enable integration of heterogeneous mix of commercial-off-the-shelf, open-source, and custom software components; (c) facilitate testing, maintenance of system components, and (d) allow step-wise evolution/upgrading of the *QuASA²R* system to support technological advances in RT clinical trials.
  - Emphasis will be on development/improvement of web-based tools that achieve compatibility with existing software & electronic health record standards, including caBIG and DICOM RT, and maintaining/developing archival multimodality ITPV, credentialing, and QA databases for the advanced treatment modalities that can be linked with the cooperative group's clinical outcomes database.

ATC Progress Report
Specific Aims (Coordination Effort)

- **Specific Aim 3**: 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) quality assurance review procedures.

ATC Progress Report
Specific Aims (Educational Effort)

- **Specific Aim 4**: 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 Coordination Objectives

- Eliminate duplication / facilitate sharing of QA resources among cooperative groups, QA Centers.
- Help to insure that appropriate and uniform QA procedures and criteria for advanced technology trials are developed across all cooperative groups.
- Assist clinical trial cooperative groups in the development of clinical trials protocols including:
  a) credentialing requirements;
  b) target volume definitions;
  c) quality assurance procedures; and
  d) data submission instructions.

ATC Coordination Objectives

- Appoint ATC Credentialing/QA Committee whose mission will be to promote uniformity in credentialing/QA across cooperative groups (one of the specified goals of the ATC).
  - Marcia Urie (Chair), Dave Followill (Co-chair), Bill Straube, and Jim Galvin.
- Will be one of the key groups to show ATC is meeting its goals.
- I believe there remains a strong perception that the ATC has not been as successful in this important task as we should have been.

ATC Developmental Objectives

- ATC *QuASA²R (Quality Assurance Submission, Archive, Analysis, and Review)* system
- Develop / Implement / Maintain …
  - Electronic exchange of digital planning data
  - Web-based tools to facilitate protocol digital data reviews
  - Archival treatment planning, verification, imaging, and QA databases
  - Methods for data analysis
  - Compatibility with electronic health record standards and software including the Cancer Biomedical Informatics Grid (caBIG), DICOM RT.

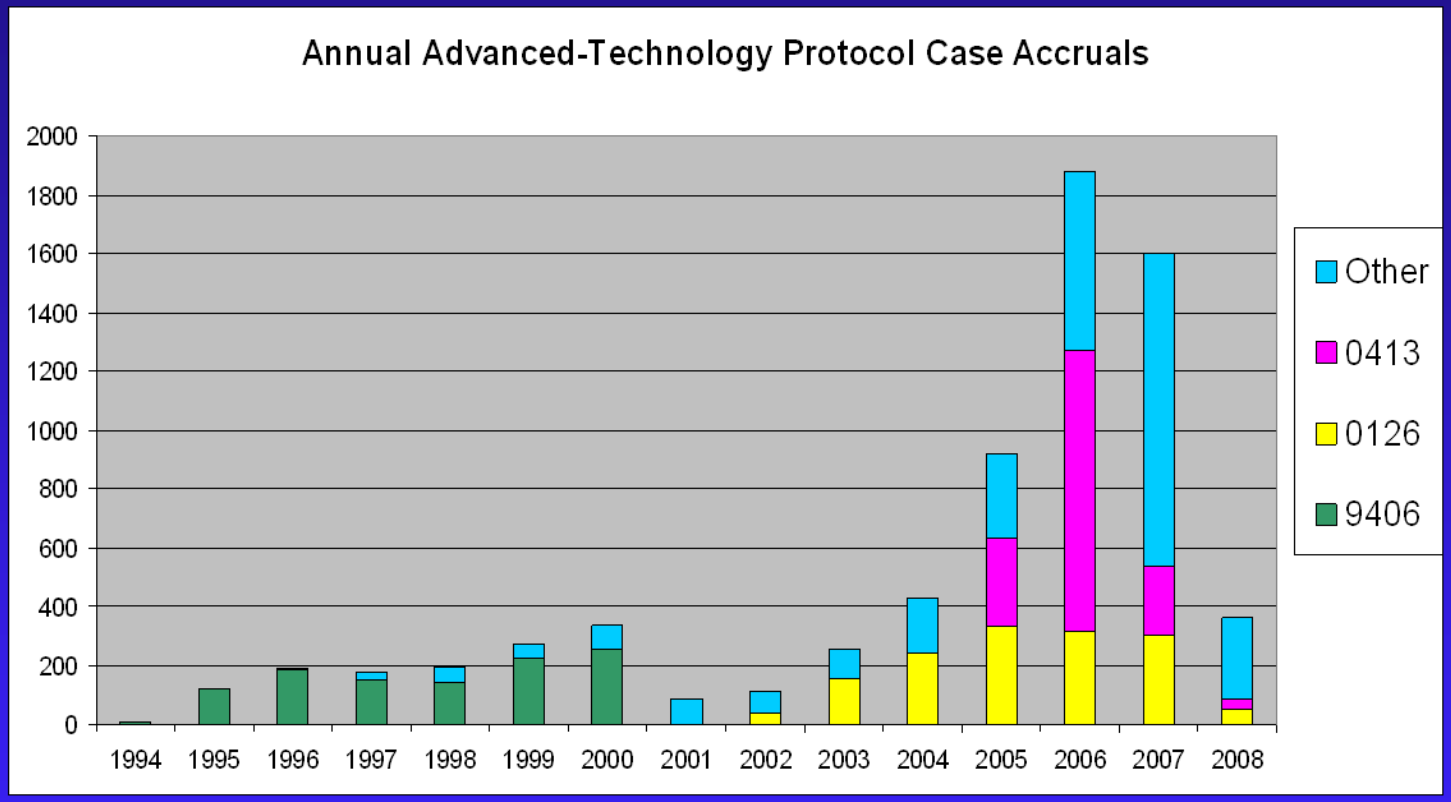
ATC Service Activities (QuASA²R)

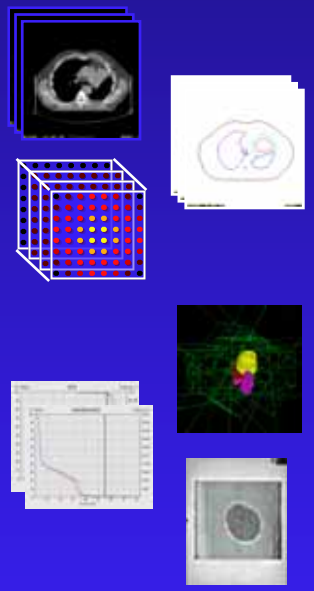
- RTOG
- NSABP
- NABTT
- GOG
- JCOG
- EORTC
- AstraZeneca

ATC Developmental Objectives

- Must take in to consideration other groups needs and developmental efforts.
  - QARC: MAX
  - ACR: TRIAD
  - caBIG

- As of 1st Quarter, 2008: nearly 7000 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

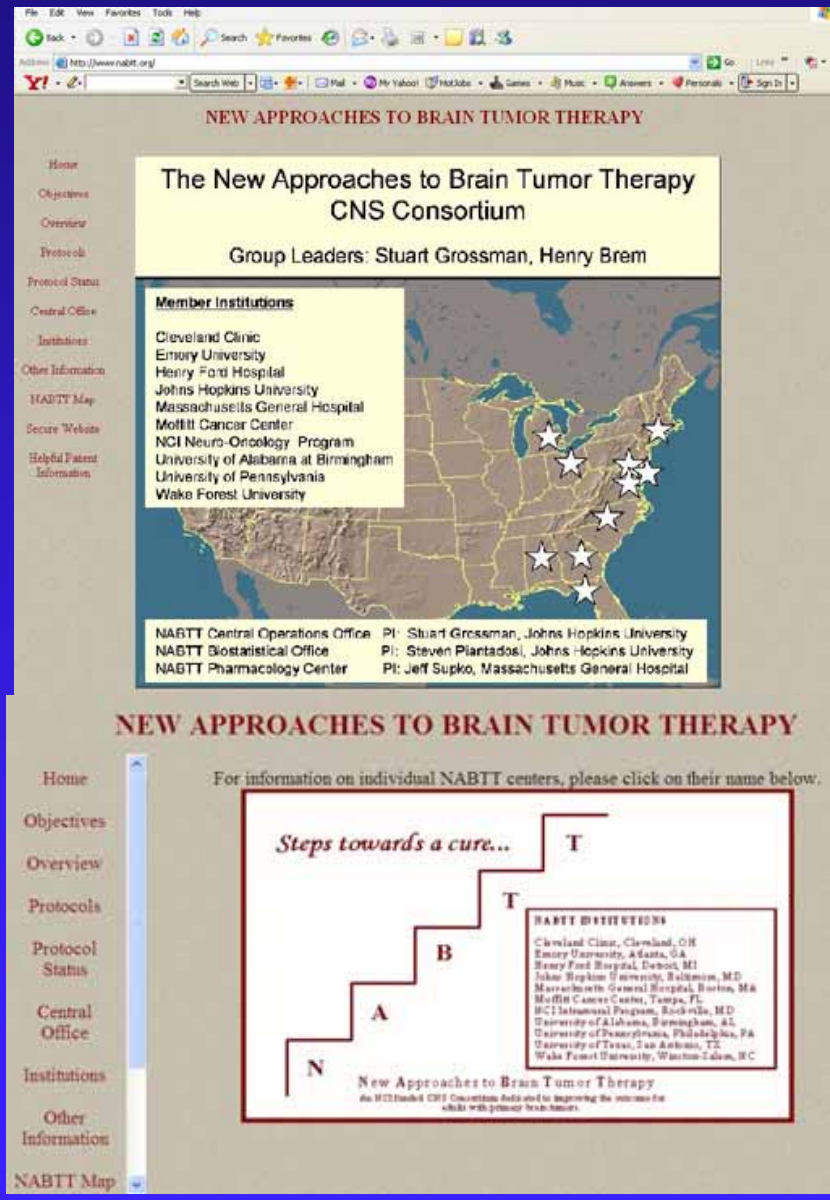
ATC Compliant Treatment Planning Systems Per Modality

- 11 commercial TPS vendors (20 TPSs) have implemented ATC compliant export capability.

Treatment Planning Systems			Exchange Format	Treatment Modality					
Vendor	System	Version[1]		3DCRT	IMRT	SBRT[2]	Seed Brachy	HDR Brachy	Protons
Accuray	MultiPlan	1.5.2	D			✓			
CMS	Focus/XiO	3.1	R	✓	✓	✓	✓		✓
	XiO	4.3.1	D	✓	✓				
Elekta	RenderPlan 3D		R	✓					
	PrecisePlan	2.01	D	✓	✓	✓			
Nomos	Corvus		R		✓[3]				
Nucletron	Helax TMS		R	✓	✓				
	TheraPlan Plus		R	✓					
	Oncentra MasterPlan	1.5	D	✓	✓				
	PLATO RTS	2.62	D	✓					
	PLATO BPS	14.2.6	D					✓	
Philips	Pinnacle[3]		R	✓	✓	✓			
	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[4]	D		✓				
Varian	BrachyVision	6.5 (Build 7.1.67)	D					✓	
	Eclipse	7.1	D	✓	✓	✓			✓
	VariSeed	7.1	D				✓		

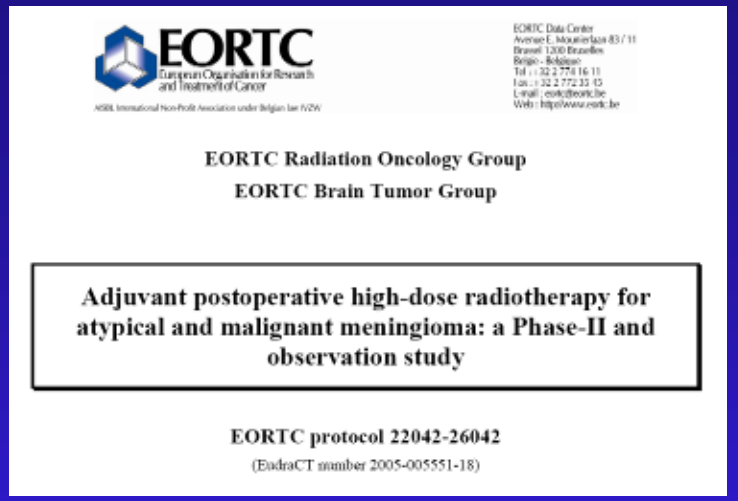
ATC(ITC) Support of NABTT Clinical Trials

- NABTT (ATC(ITC) is working with Dr. John Fiveash, M.D., Department of Radiation Oncology, Univ. of Alabama Birmingham)
  - There are 9-10 NABTT institutions participating in these studies.
  - Protocols are Phase I/II with maximum of 90-100 cases.
  - Plan is to review approx. 30-50% of protocol cases (all IMRT and first case for 3DCRT)
  - 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 for EORTC Trials

- **EORTC Protocol 22042**
  - ITC performs data integrity QA for Protocol 22042 “Adjuvant postoperative high-dose RT for atypical and malignant meningioma: a Phase-II and registration study”
  - Sample size: 64, ~10 institutions
  - Data submission testing and institutional credentialing are underway



EORTC

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

(EudraCT number 2005-005551-18)

EORTC

AGREEMENT FOR THE PERFORMANCE OF THE QUALITY ASSURANCE REVIEW FOR AN INTERGROUP CLINICAL TRIAL

22042-26042

INVOLVING

Advanced Technology Consortium (ATC) & Image-Guided Therapy QA center (ITC)

Registered Office: Washington University, 4511 Forest Park Ave., Suite 200, St. Louis, MO 63108

AND

European Organisation for Research and Treatment of Cancer
International non-profit association

Registered Office: Av. E. Mounier 83/11
B-1200 Brussels

Version 1.0

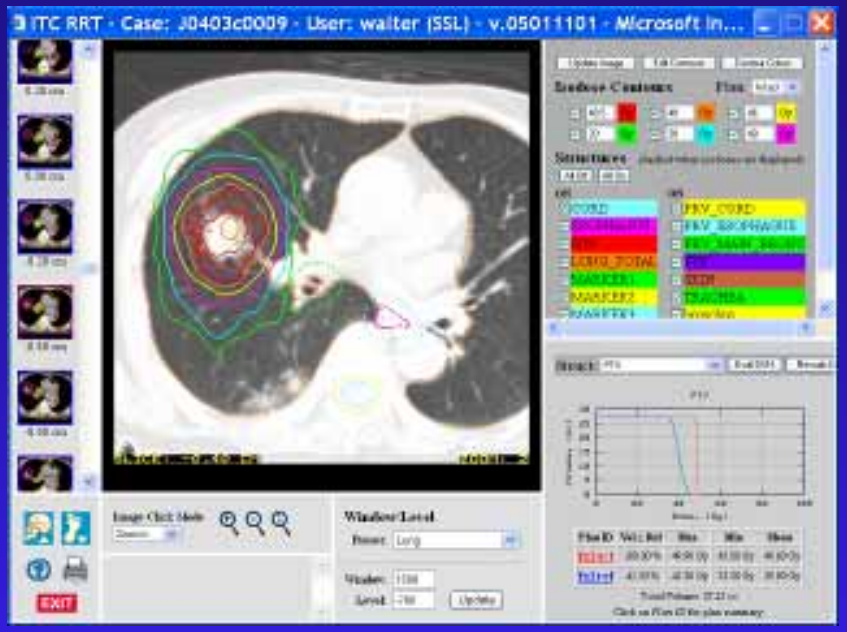
ATC(ITC) Support for EORTC Trials

- Thank you very much for your strong interest to collaborate with the EORTC ROG.
- The ROG QA team has now gathered information about various software platforms that can be used for QA.
- I also talked to Marcel van Herk again and he is also interested in collaborating with EORTC and ATC, although he is very busy.
- EORTC will discuss various scenario's of performing QA in the future in the coming months. An expanded cooperation with ATC is one of the most promising options, but it will take probably some time to establish this.
- Therefore, the EORTC for example has to think about whether it would be useful to have an additional software platform within the EORTC to support all the QA.
- We will keep you informed about developments. Hopefully we can meet during the AAPM meeting, although at this time a trip to the AAPM meeting is not yet planned for one of the ROG QA team members.

Coen Hurkmans, Ph.D., Clinical Physicist
Department of Radiotherapy
Catharina Hospital , 5602 ZA Eindhoven, The Netherlands

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 the ITC Remote Review Tool.
- Currently, 14 institutions are eligible to enroll patients and capable of digital data submission on JCOG 0403; 136 patients are registered to study.

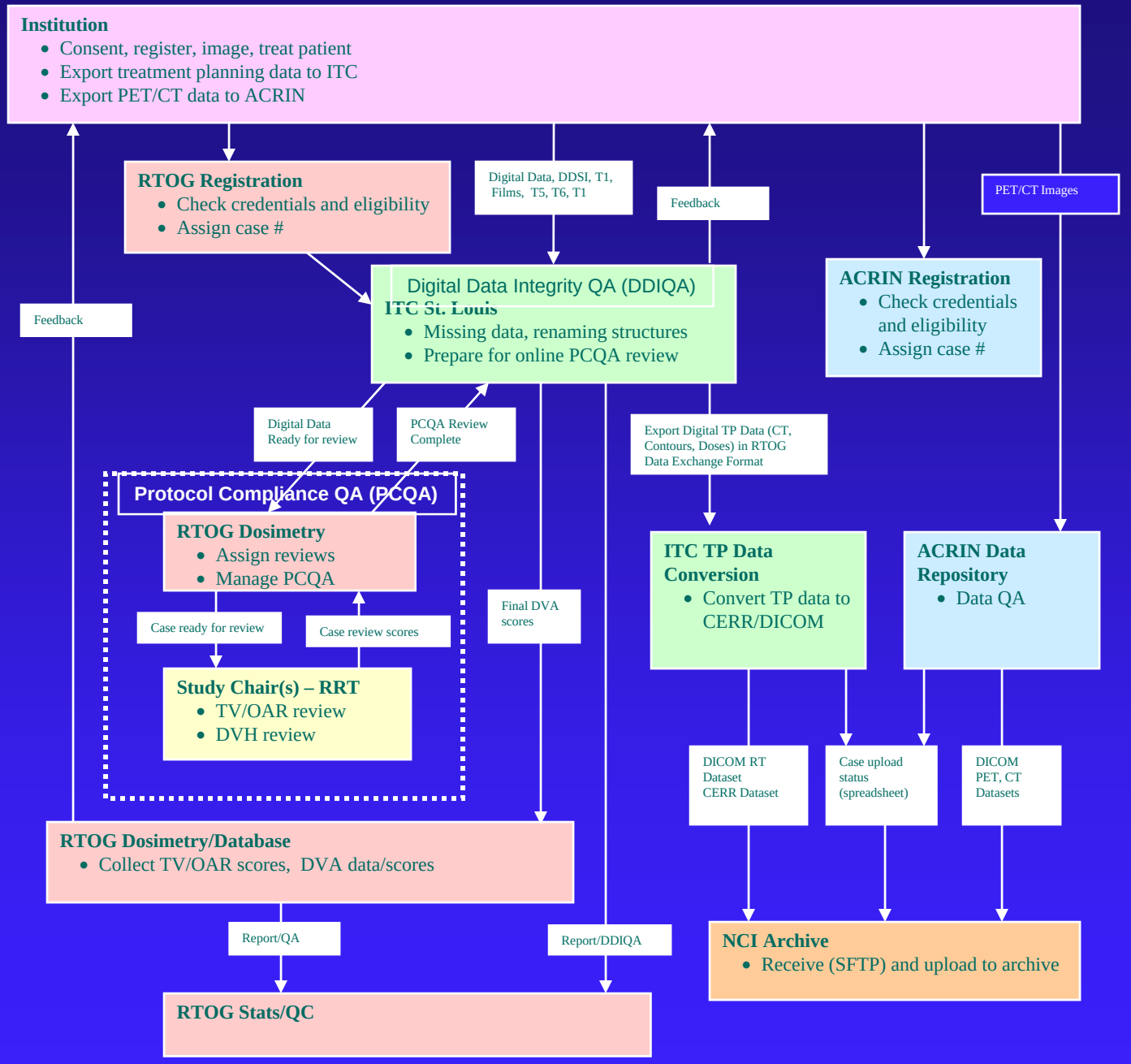
ATC(ITC) Support for Industry Trials

- ATC(ITC) Support for AstraZeneca Trials
  - RT QA for AstraZeneca ZD6474 (Tyrosine Kinase Inhibitor) Trial
  - Three institutions credentialed
- In discussion with Eli Lily

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

RTOG 0522
Quality Assurance Workflow



ATC Posters/Presentations at 2008 Meetings

- AAPM, July 27-31, Houston, TX
- ASTRO, Sep 21-25, Boston, MA

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 #(s): _____

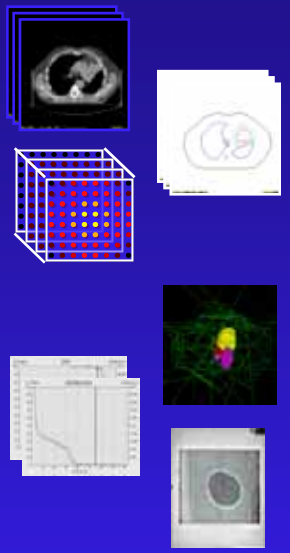
All requests must be accompanied by a research plan for the proposed data use. The research plan must include: names of investigators; objectives; background; type of data requested; and data analysis description.

Specify what data is being requested:

Cooperative Group Approval: 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

Challenges/Opportunities: ATC Supported Trials

- Continue to update QuASA^{2}R without disrupting support of ongoing clinical trials;
- Developing a more formal mechanism for evaluating how well ATC is meeting its ***developmental*, *coordination*, and *service*** objectives**;**
- 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
- NCI (Dr. Deye) to appoint independent Evaluation Committee (EC)