Principal Investigator's Report
Advanced Technology QA Consortium

RTOG Meeting – New Orleans, LA
January 15, 2009

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"Advanced Technology QA Center"

Acknowledgments

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.

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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

ATC Grant Objectives

The goals for the ATC as specified in the RFA are to be accomplished through the following ***developmental*, *coordination*, and *service* 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.

Agenda

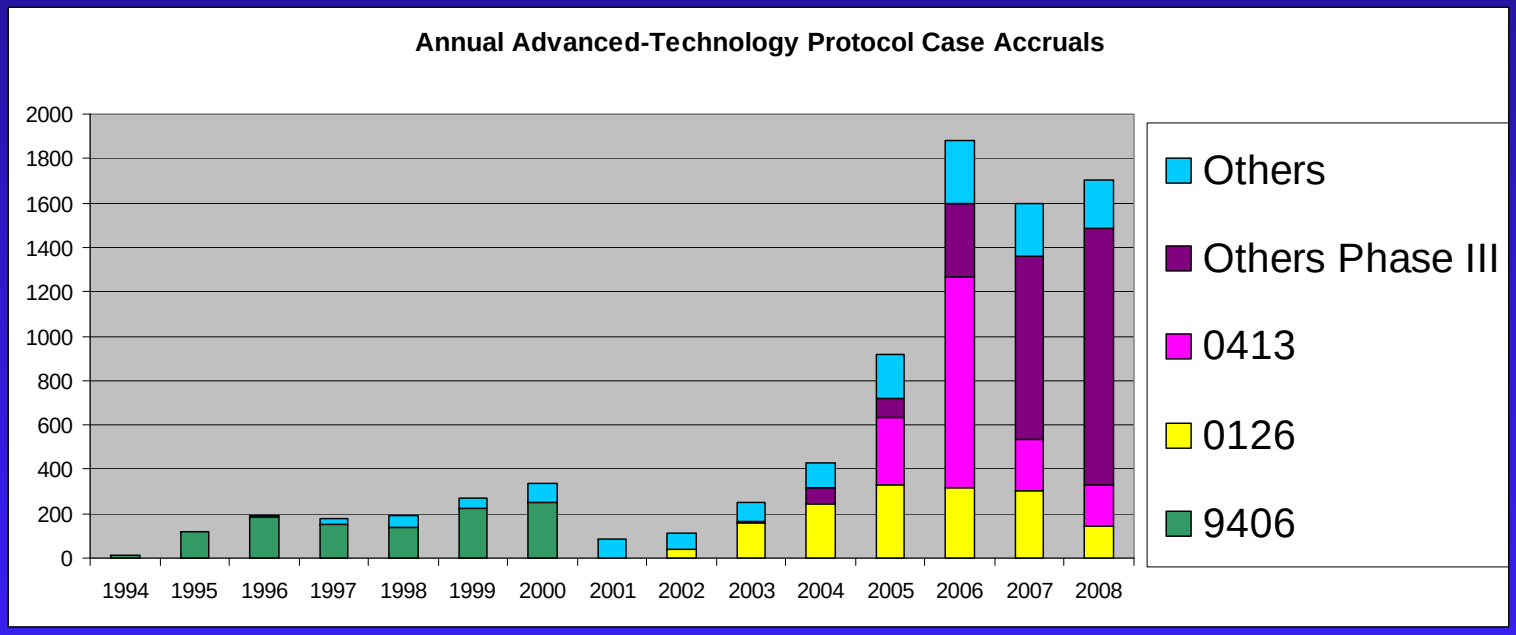
10:00 AM:	ATC Project Officer Report (Deye)
10:05 AM:	ATC P.I.'s Report (Purdy)
10:20 AM:	Review of Credentialing/QA Questions – Collaboration NCI-EqualEstro (Urie/Followill)
10:45 AM:	Review of EORTC QART Organization – Akos Gulyban
11:00 AM:	Review of IGRT Credentialing/QA Guidelines (Galvin)
11:20 AM:	Update on QRRO – ATC efforts (Bosch/QRRO Representative)
11:40 AM:	Update on NCIA-RTOG 0522/ACRIN 4500 Project ATC efforts (Jeraj/Fox)
12:00 AM:	Break - Lunch
1:00 PM:	Update on VIEW/RTOG 825 protocol – (FitzGerald/Apgar)
1:20 PM:	Update on Proton Credentialing (Ibbott/Urie/Gillin/Bosch)
1:35 PM:	Discussion; New Business
1:50 PM:	Adjourn

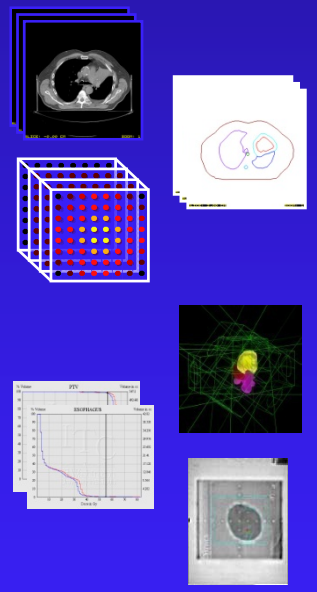
ATC P.I.'s Report

- caBIG Clinical Trials Management Systems and Imaging Face to Face Meeting, Mar 18-20, in Las Vegas
- ATC F2F meeting at RPC on April 14-15
- International Conference on Advances in Radiation Oncology (ICARO), Apr 27-29, in Vienna, Austria
- Propose to make use of WebEx meetings in the future.
  - Hold 1 F2F meeting at ITC each year
  - Hold 2 mini-meetings at RTOG Semi-Annual meeting
  - Hold 1 ATC Steering Committee (ATCSC) each year
  - Hold 1 WebEx/Teleconference with ATCSC each year
  - Hold ATC F2F at subcontractor QA Center on request and/or ATC PI request.
- ATC Progress Report (with proposed budgets) due to Dr. Purdy by April 1, 2009

Protocol Case Submissions

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





- 11 commercial TPS vendors (20 TPSs) have implemented ATC compliant export capability. **(Δ = 0/year)**
- 616 institutions able to submit digital RT data **(Δ = 81/year)**

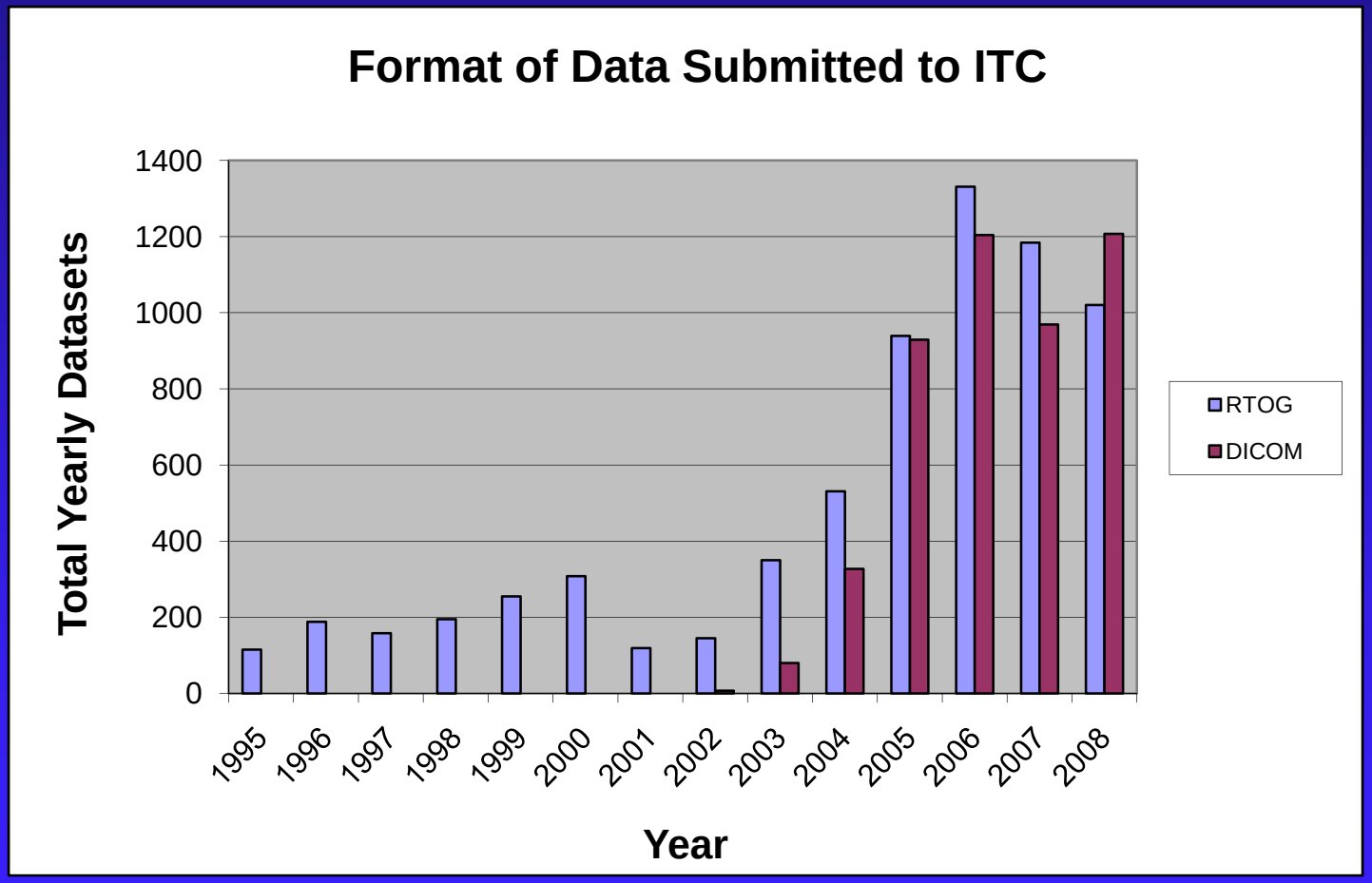
ATC Compliant Treatment Planning Systems Per Modality

- 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				✓		

QuASA²R – *Data Submission*

- **Over 50% of submissions now are DICOM**



Treatment Planning & Verification

↓

Data Submission

↓

Data Integrity QA

↓

Protocol Compliance Review

↓

Outcomes Analysis

Action Items - ATC Steering Committee Response

- Will depend on RTOG, RPC and QARC to continue to make ACRIN aware of ATC capabilities.
  - It should be noted that Dr. Ibbott is a member of the ACRIN QC committee and is in regular contact with Drs. Bruce Hillman and Mitch Schnall.
  - In the future, reports from Dr. Ibbott regarding these liaisons will be a standing agenda item for all ATC meetings
- Will encourage a high-level meeting with ACRIN leadership to discuss means of increasing collaboration and improving coordination of efforts of mutual benefit.
- ATC will try to enhance the cooperation between the ATC and caBIG, VIEW and ACRIN.
  - We are working closely with the caBIG In Vivo Imaging Workspace.
  - QARC is keeping us informed of the VIEW project
  - Brenda Young is working with us wearing both her RTOG and ACRIN hats to keep the ATC updated on relevant projects.
  - In the future, reports from these individuals regarding these liaisons will be a standing agenda item for all ATC meetings.

Action Items - ATC Steering Committee Response

- A teleconference/WebEx with the ATCSC and the ATC P.I and subcontractor P.I.s, Jim Deye, and B. Vikram and any other persons deemed appropriate by this group will be held in March/April 2009.
- A copy of the latest ATC progress report will be sent by ATC P.I. to the ATCSC two weeks prior to the ATCSC meeting.
- ATC will make a robust effort to allow the use of commercial TPSs to serve as remote QA review workstations. ITC is planning to explore use of a commercial TPS for remote QA review via Citrix server recently purchased.
- ATC will work with caBIG In Vivo Imaging Workspace (Dr. Joel Saltz's group) to interface QARC's MAX system and QuASA^{2}R system to the grid.
- Dr. Purdy has asked ITC, QARC, RTOG, and RPC to put together inventories of pertinent QA or treatment planning data that might be useful for research projects. First report of these inventories will be due at April 2009 ATC meeting at the RPC.

Action Items - ATC Steering Committee Response

- ATC will investigate possibilities to either adopt/modify an existing IGRT phantom or to initiate efforts to develop a new IGRT phantom for credentialing purposes.
  - ATC is committed to the development of a consensus IGRT credentialing and case QA process.
  - RTOG is to take the lead in this effort, with the understanding to work closely with the other ATC groups to insure we end up with uniform IGRT credentialing methodology/criteria.
- ATC is to reassess the types of tests that are done for credentialing.
  - Dr. Purdy has asked the ACQAC to review the current IMRT credentialing methodologies (QARC benchmark and RPC phantoms) used in the U.S. Preliminary report regarding this matter will be given by the ACQAC at the January 15th, 2009 ATC mini-meeting.
- ATC is considering developing a more formal relationship with the AAPM subcommittee on clinical trials QA regarding credentialing tests for clinical trials. Dr. Purdy will follow-up with Jean Moran and Art Olch regarding this recommendation and report back to the ATCSC.

ATC Developmental Objectives
QuASA²R Update

- **Past six months**
  - Updated DDIQA server, tape backup system
  - CERR in use for multi-series, multi-planar protocol case review (RTOG 0418)
  - Successful import of MR-based DICOM HDR TP data
  - CERR Remote Access Server implementation begun
  - Collaborative work on caGrid-enabled CERR prototype
- **Next six months**
  - CERR Remote Access Server in production for QA review
  - Data loading tools ready for Evercore archive
  - Implement caGrid CERR data server
  - WebTrev (multi-planar static image review / QA report generator) ready for testing
  - Purchase diagnostic imaging/RT review software (MIMvista)

ATC Standing Committee (Coordination Efforts)

- Appointed *ATC Council of Industry Participants* whose role will be to:
  - Interface with ATC Informatics Committee and 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
  - Mike Courtney - Philips
  - Damien Evans - TeraMedica
  - TBN-TomoTherapy
  - Armin Langenegger – Varian
  - Colin Sims - Accuray

ATC Coordination Objectives
Clinical Trial QA Harmonization

ATC • AdvancedTechnologyConsortium

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

Questions - Collaboration NCI-EqualEstro

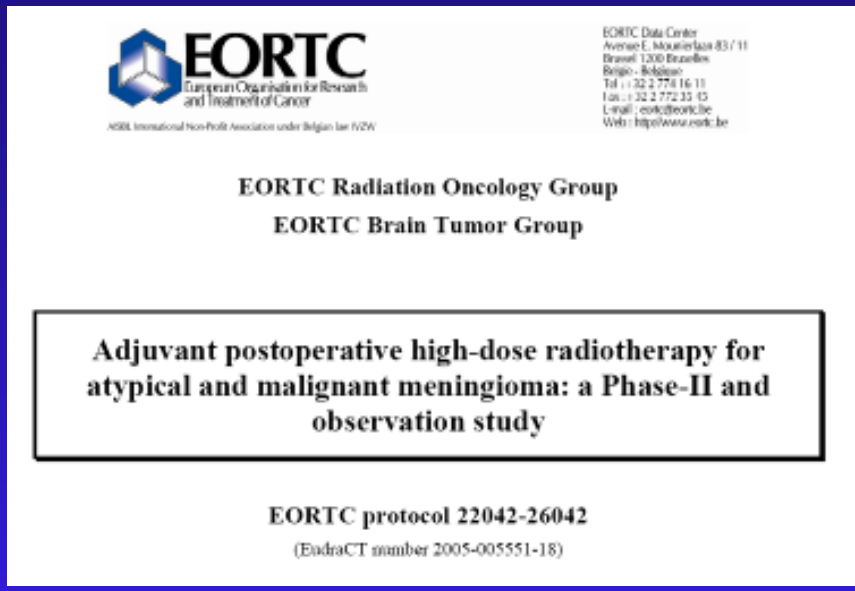
Date: December 9, 2008

Prepared by: Members of the ATC(ITC, RPC, QARC, RTOG)

1. Please provide more detailed information regarding EqualEstro TLD checks of institutions beam calibrations per the following questions:
   (a) How often do you perform checks?
   (b) If greater than every year, do you have published data that supports your audit frequency?
   (c) What is the charge per beam measured to the institution for this service?
   (d) What are your criteria for acceptability?
   (e) How many points of measurement are made with each beam check (please provide us with images or diagrams of your TLD phantom)?
   (f) What is the precision of your TLD measurements?
   (g) To which national standard is your system traceable?
   (h) What is the average time from TLD shipment from your facility until the report is mailed to the institution?
   (i) Please describe your quality assurance program for maintaining your TLD audit system.
   (j) What is your procedure for resolving any discrepancies revealed by the TLD audits?
   (k) What is the accuracy of this system for auditing proton beams?
2. What procedures have you implemented to credential institutions for participation in specific clinical trials?
3. Please provide more detailed information regarding your methodology for IMRT credentialing per the following questions:
   (a) Do you require an anthropomorphic phantom planning/delivery check or do you use something like QARC's IMRT Benchmark-like test?
   (b) What do you charge for this type of credentialing?
   (c) If you use an anthropomorphic phantom, do you have the capability of measuring 2-dimensional dose distributions? If so, what dosimeter do you use, and what is the precision of those measurements?
   (d) How many of these phantoms do you have in service?
   (e) What are your procedures for evaluating heterogeneity corrections under realistic clinical conditions? What are your acceptability criteria?
   (f) If you use a benchmark-like credentialing, how do you verify absolute dosimetry?
4. Same questions as #3 for SBRT.
5. Same questions as #3 for brachytherapy.
6. Same questions as #3 for proton beams.
7. What credentialing/QA methodologies do you use for protocols using IGRT (linac cone beam CT, tomotherapy, Cyber Knife, proton therapy)? Please specify techniques used for credentialing and individual case review.
8. For protocols that you support, do you require volumetric data (3D) (electronic digital data submission) or do you allow 2D (screen grabs) or hard copy of isodoses for participation?
   (a) Do you charge the institution for processing the submitted data?
   (b) What are your QA processes for assuring the integrity and accuracy of the submitted data?
9. Please provide detailed information regarding your current staffing. Specifically,
   (a) How many FTE physicists, dosimetrists, technical staff etc., do you have?
   (b) Does your staff include a radiation oncologist?
   (c) Please describe your access to radiation therapy resources.
10. Have you standardized protocol nomenclature (Target Volume(s) and OARs standard names)? If so, could you share some details?
11. Please provide detailed information regarding your clinical trials QA informatics infrastructure. Specifically:
    (a) What mechanisms for digital data exchange do you have available now in production mode. Please be specific, DICOM including DICOMRT, RTOG data exchange objects, quantitative PET(SUV), MR,...
    (b) Are the data objects stored in a queriable DICOM database?
    (c) Do you have software tools for remote review of these data objects? If so, could you share some details?
    (d) Do you have software tools for coordinated case QA review of RT image and pre/post diagnostic images?
    (e) Do you have case QA review tools for Adaptive RT protocols?
    (f) Has your clinical trials QA hardware/software gone through some sort of validation similar to that described in 21 CFR11?
12. Please provide detailed information regarding your case QA review process. Specifically,
    (a) Are CRA's responsible for gathering and organizing the data?
    (b) Does a physicist or dosimetrist review the beam data and dose distributions?
    (c) Does a radiation oncologist review the target/OAR volumes and the dosimetry?
    (d) Who does what in what order?
13. Do you provide pre-treatment and rapid treatment (within a few days of starting treatment) review? If so, what percentage of the protocols includes this requirement?

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

European Organisation for Research and Treatment of Cancer

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EORTC Radiation Oncology Group

EORTC Brain Tumor Group

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

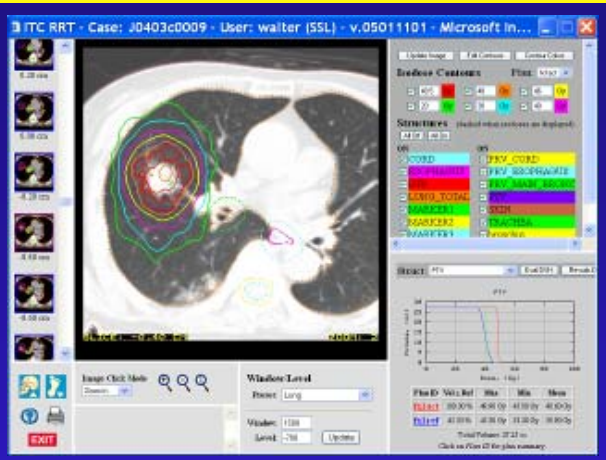
EORTC protocol 22042-26042

(EudraCT number 2005-005551-18)

- 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(ITC) Support of JCOG Clinical Trials

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

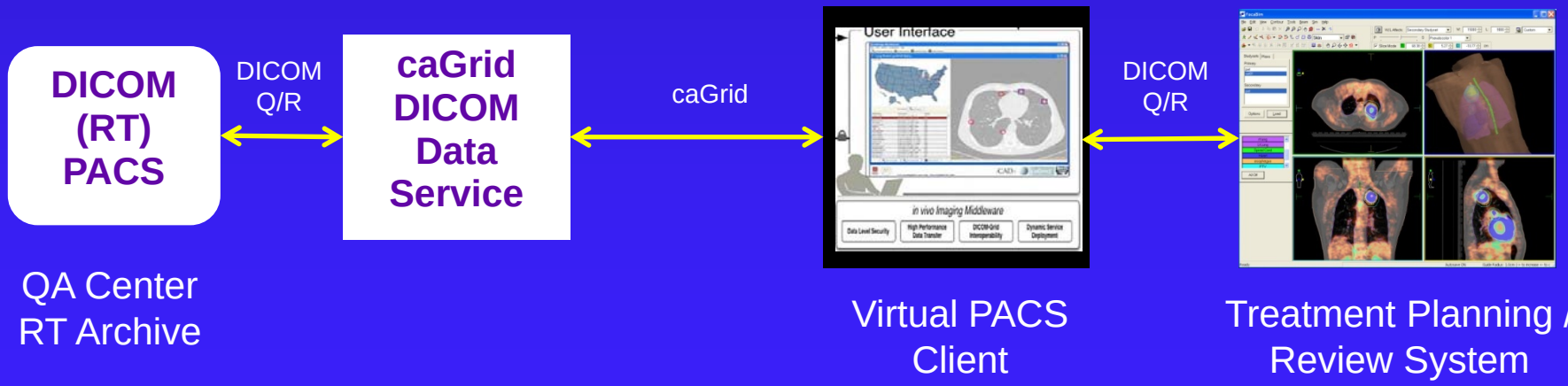


- Institutions participating in protocol JCOG 0403 submitted digital data representing CT images, structure sets, treatment plans, 3D dose distributions, and DVHs to Dr. Satoshi Ishikura, Director of the Radiotherapy Support Center, Tokyo, JAPAN. Dr. Ishikura forwards submitted data to ITC in St. Louis 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.
- JCOG 0702: 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).

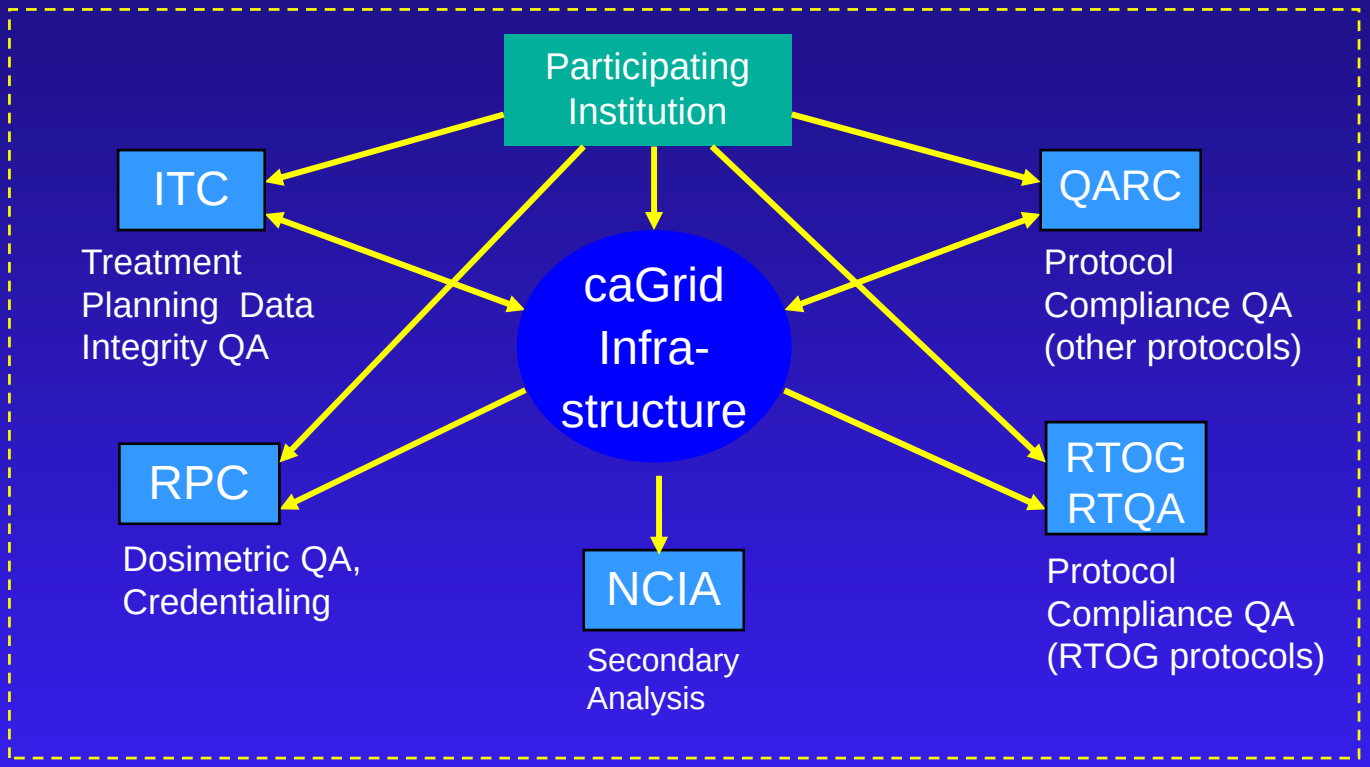
caBIG Imaging WG Tool Review Report

Applicability of Tool from an Image Based Clinical Trial Perspective

- Middleware/Virtual PACS
- In Vivo Imaging Middleware includes a DICOM data service for grid based access to DICOM PACS
  - Middleware services support query, retrieval, and submission of DICOM images and RT data for secure access to protocol case and credentialing data
  - Virtual PACS allows query and retrieval of data for distributed review using commercial treatment planning software



Use Cases for caGrid Infrastructure in Cooperative Group RT Clinical Trials



- **Replication of protocol case and credentialing data among QA centers**
- **Distributed review of images/RT data**
- **Submission of data from participating institutions**
- **Sharing of data for secondary analysis**

caBIG Imaging WG Tool Review Report

Applicability of Tool from an Image Based Clinical Trial Perspective

- Annotation Imaging Markup (AIM)
- Standard representation for adding information to images
- Defines syntax, semantics, and data format for annotations and markup
- Possible role in assessing image-based response to therapy in RT Clinical Trials