Principal Investigator's Report
Advanced Technology QA Consortium

Houston, TX
April 14, 2009

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Supported by NIH U24 grant CA81647,
"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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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**:

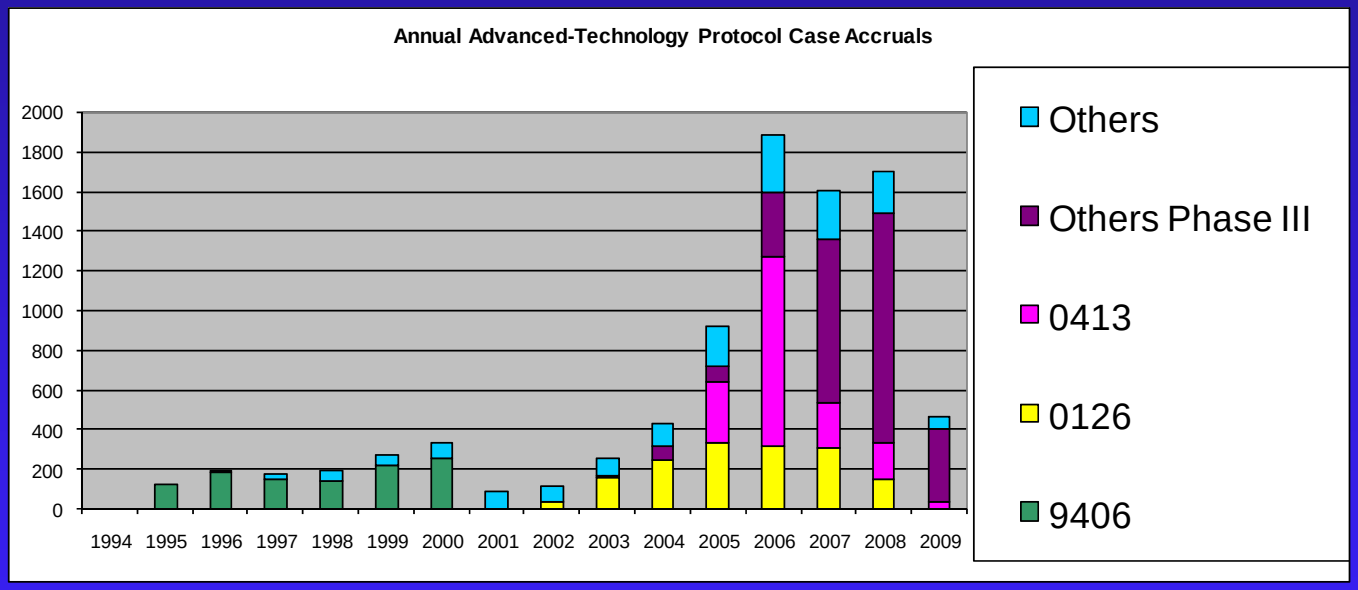
1. Eliminate duplication of infrastructure developmental efforts and facilitate sharing of QA resources among cooperative groups.
2. Help to insure that appropriate and uniform QA procedures and criteria for advanced technology trials are developed across all cooperative groups.
3. Facilitate/help manage 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.

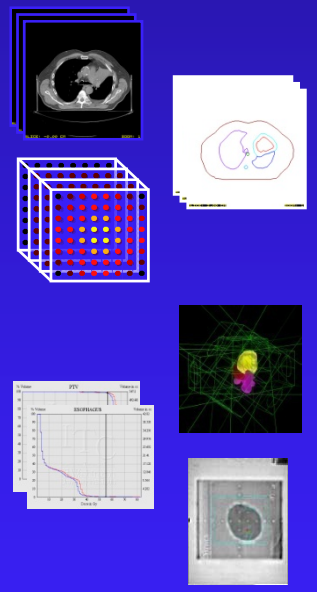
ATC P.I.'s Report

- ATC Progress Report (with proposed budgets) due to Dr. Purdy by April 1, 2009
- Schedule ATC Steering Committee TCon in April/May
- QRRO-ATC Efforts
- EMBRACE Project
- P.I. Transition Plan
- Protocol Case Accruals
- caBIG-ATC Efforts
- ACIP Report
- Harmonization of Clinical Trials Credentialing/QA

Protocol Case Submissions

- **As of April 3, 2009: 8736 Complete, Protocol-Case, Volumetric Digital Data Sets Submitted Over 15+ Year Period using the ATC QuASA²R System**





- 626 institutions able to submit digital RT data

Radiation Oncology Project
A Proposal by ATC
to CaBIG Imaging/CTMS Workspaces

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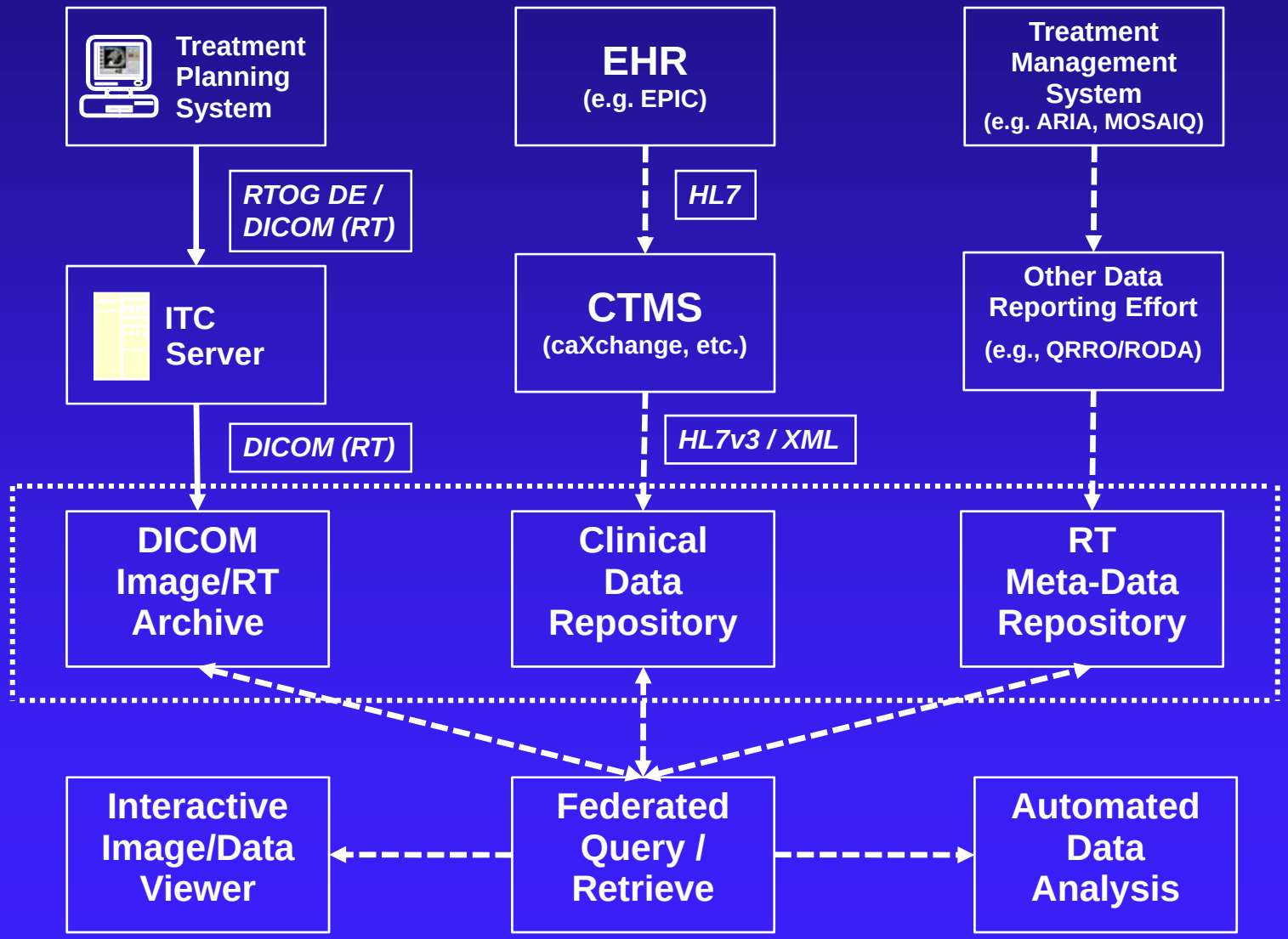
caBIG® Clinical Trials Management Systems and Imaging Workspace Combined Face-to-Face Meeting and Conference
March 18-20, 2009, Las Vegas, NV

caBIG
ATC Imaging/*CTMS* QRRO



- Demo-graphics
- Diagnostics
- RT Course
- Lab Values / QoL
- Tumor Prognostic
- ODA Assessments

ATC Council of Industry Participants (ACIP)

- In 2008, Dr. Purdy appointed *ATC Council of Industry Participants* whose role is 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
  - Armin Langenegger – Varian
  - Colin Sims - Accuray
  - TBN-TomoTherapy

ATC Council of Industry Participants (ACIP)

- While a select group of vendors have been included in the ACIP, it is possible that other vendors who wish to participate or are otherwise critical to the achievement of ATC objectives have not.
- It is recommended that the ATC develop a mechanism to be as inclusive as possible and practical as it moves forward with this program.
- Recognizing that some of this is already available, this might include enhanced web pages and email digests dedicated to providing updates and progress reports to all interested vendors.

ATC Council of Industry Participants (ACIP)

- Concern that the set of tools currently being used and new ones being proposed may be more diverse than necessary.
- Such diversity could potentially render the scope of products and thus the resultant system difficult to manage.
- Consideration for some simplification of the plans with respect to the number of different tools (for example, MiMVista, Focal, CERR all can review diagnostic images and perform/ review fusion results) is therefore suggested.

ATC Council of Industry Participants (ACIP)

- Another concern was that while the QuASA^{2}R system aptly addresses technological issues, **education and training** of users was not as well described.
- Nor were **personnel /resource requirements in support** of the development plan.
- While some of this may be covered by virtue of use of commercial systems where training of end-users and provision of support personnel and required resources is generally included, it is not clear how the ATC plans to manage end-user training of components within their realm of control.
- This will be particularly important as the system evolves and scales.

ATC Council of Industry Participants (ACIP)

- In addition, while the report was inclusive of entities such as caBIG and IHE-RO, it is suggested that a bit more clarity be provided as to how these entities relate to and affect the ATC.

ATC Council of Industry Participants (ACIP)

Summary Statement

- The ATC QuASA^{2}R system as described in their “Review of the Advanced Technology Consortium Quality Assurance Submission Archive, Analysis and Review (QuASA2R) System” appears conceptually sound.
- While a number of questions and suggestions are provided regarding the overall processes, scheme, and architecture, the ATC should be lauded for their efforts in designing, developing and supporting such systems.
- The continued use of open standards, along with broad industry participation is further encouraged.
- The ACIP looks forward to participating with the ATC in their quest to support advanced technology clinical trials.

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?