

ATC Steering Committee (Architecture Issues)

1. Open Architecture Open Source

- Should ATC be developing their software with the intention of allowing it to be open and shared?
- Discussion included issues of making the software available to outside groups, development of the software with inclusion of relevant standards, and, but more controversial, publishing standards for accessing the data gathered by trials.

ATC Steering Committee (Architecture Issues)

2. Work to help customers make their data open; Making sure that access is done in a properly scientific manner

- The issues associated with opening data to others is one that is not completely an ATC question, as the “owners” of the data are ATC’s customers, not ATC.
- What is the appropriate group for discussion of the issues of ownership, particularly with regard to NCI-sponsored trials.
- Should ATC be working to develop hardware/software systems that encourage sharing (?require?) in line with NCI interests in making this data more available?
- If so, how can we improve the likelihood that such data would be used in a reasonable manner, rather than for drawing biased conclusions?
- How are such data made available to the public in a meaningful way?

ATC Steering Committee (Architecture Issues)

3. **Work to get Method 2 in place; Leverage the work of NCIC in improving Method 2**
 - The development of a robust 'method 2' remains a priority, but is not yet a reality.
 - How can ATC leverage the work of other groups, such as NCIC, to improve the robustness and perhaps speed the development?

ATC Steering Committee (Architecture Issues)

4. How do we link disparate databases?

- One of the issues in trying to make more effective use of the data is the need to mine across study groups and perhaps even QA organizations.
- Should ATC be working with its customers to structure access to the data in a way to enable this?
- This would likely include developing a common access method, consistent security and perhaps creating a methodology for assigning a consistent patient identifier.
- This last item is necessary if different QA databases contain common patients; for example, physics QA information along with outcomes

ATC Steering Committee

(opportunities for expansion
refinement of its informatics infrastructure)

- ATC is a vital component of NCI's clinical radiation oncology infrastructure, providing unique and essential services for managing data (especially images with related dosimetry with treatment plans for 3D methods), ensuring quality, and qualifying sites.
- Since the last ATC steering committee meeting there has been an expansion of services and developmental efforts.
- There have been significant increases in the number of cases received, sites credentialed, number of protocols supported, and interfaces to multicenter clinical trials group.
- International activities in Canada and Japan are new and important.
- The PI relocated and accommodations were made to ensure continuity in ATC's leadership.

ATC Steering Committee

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- The PI, Jim Purdy PhD, has moved to the University of California at Davis, but remains engaged in the ATC direction and oversight. He presented the accomplishments and short term plans for the ATC in a clear and convincing manner at the meeting.
- The ATC has matured and serves as a guide to success for multicenter clinical trials which involve complex new technology.
- There are highly functional components of ATC that provide phantoms, rigorous measurements and standardized performance criteria for site credentialing, review of treatment plans, archiving of datasets, and management tools which are increasingly automated and effective.

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- The ATC has no peer and serves a critical and immediate need effectively, ensuring consistency and interpretability of multicenter clinical trials that involve state-of-the-art radiotherapy methods.
- The ATC is sufficiently mature to report results of quality analysis and monitoring, success in completing large multicenter trials, influence on industry to adapt commercially available instrumentation to their standards, and accumulation of data sets.
- This work enables RRP (and NCI) to realize the promise of clinical trials data archiving, so secondary analyses can be done by investigators who were not involved in the original protocol design and implementation.

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- The ATC is already well known to the radiotherapy community, but not to the clinical cancer community at large. This is a pity, since the ATC experience has many features that make it unique and highly significant:
- ATC successfully completed complex multicenter clinical trials involving new and emerging technology for cancer treatment. Services for credentialing, quality control and review, and archiving of datasets were established and provided.
- ATC innovated services and developed tools which had no precedent, but were needed to ensure trial data quality and interpretability.
- A virtually complete record of trial data is available in electronic form on-line, so secondary analyses are feasible. Secondary analysis of completed trials is underway.

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- The ATC should be reported to the clinical cancer community and medical research enterprise as a landmark in the evolution of clinical trials. An appropriate venue would be the JAMA Contempo annual issue which reports significant innovations that have impact outside a narrow field of interest.
- The ATC has completed many of the key items in its strategic plan outlined in response to the prior steering committee meeting.
- As a result of this meeting and the discussion by all of the participants, there are several new and reiterated items that deserve attention for the future.

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- These items, discussed at the meeting, include:
 - ATC must eventually adopt a completely open architecture and open source strategy for its long term viability. At present, some proprietary software modules are used. In the long term, this is a serious potential vulnerability that could be corrected by making a gradual conversion of all software to an open system architecture. This may be inevitable for many practical reasons, but the principle of “open” technology for ATC is important for long term viability and success.
 - The ATC has existing on-line archives and has developed processes to update, extend and improve the archives’ utility.
 - A major reason for assembling the archives is to perform secondary analyses, but even more fundamentally, to address important questions that were not posed at the time each trial was designed.
 - ATC needs an inventory of important questions that can be answered by interrogating this archive.
 - Furthermore, ATC needs to complete demonstration projects that show the archive is successful in addressing these questions.

ATC Steering Committee

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- These items, discussed at the meeting, include (2):
 - ATC serves many constituencies, including the radiation oncology community, NCI radiation research program, cooperative groups, cancer centers, industry, and especially cancer patients and their families. The needs of each constituency are important, but the mechanism for assessing these needs is informal. A needs assessment should be done so resources and future plans can be aligned with priority requirements.
 - DICOM has evolved with IHE and related initiatives to take an “enterprise view” rather than a site or image-centric view of information. Many aspects of IHE – the Integrated Healthcare Enterprise – deal with modeling and addressing workflow, so the technical assets can be most effectively used. ATC should endeavor to study and apply IHE technology to the workflow of clinical trials that involve radiation therapy. This is a particularly attractive area for ATC to pursue, given the great success they have demonstrated with DICOM-RT development.

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- These items, discussed at the meeting, include (3):
 - Given the commitment made to caBIG, caCORE and related cancer informatics technology by NCI, ATC should study and plan the use of these elements in their current and future tools development projects. An outline of how integration with caBIG and caCORE and related informatics technologies will be accomplished should be prepared and considered in long term planning for the future of the ATC.