1. The Advanced Technology Consortium (ATC) for Clinical Trials Quality Assurance (QA)

This brochure is intended to inform the AAPM Annual Meeting registrants of the latest developments by the ATC and the status of advanced technology clinical trials supported by the ATC. More information can be found at the ATC web site http://atc.wustl.edu.

The Advanced Technology Consortium (ATC) for Clinical Trials Quality Assurance (QA) is supported by a National Cancer Institute (NCI) U24 grant to Washington University. It functions as a virtual entity made up of the following clinical trials QA Centers: (1) Image-Guided Therapy QA Center (ITC – Washington Univ. in St. Louis and UC Davis); (2) Radiation Therapy Oncology Group (RTOG) Headquarters Dosimetry Group, (3) Radiological Physics Center (RPC, M.D. Anderson Cancer Center), and (4) Quality Assurance Review Center (QARC). It capitalizes on the existing infrastructure and strengths of national QA programs. The overall mission of the ATC is to facilitate and support NCI sponsored advanced technology clinical trials, particularly those requiring digital data submission. This effort includes radiation therapy QA, image and radiation therapy digital data management, and clinical research and developmental efforts. Efforts are made to utilize each group's strengths and avoid duplication of existing programs. We strongly believe that advanced medical informatics can create an environment in which clinical investigators can receive, share, and analyze volumetric, multimodality treatment planning and verification (TPV) digital data. Our ultimate goal is to improve the standards of care in the management of cancer by improving the quality of clinical trials medicine.

J.A. Purdy, Ph.D.
ATC Principal Investigator
July 21, 2007

2. ATC NIH U24 GRANT RENEWAL

The Advanced Technology QA Consortium grant (now consisting of ITC, RPC, QARC, and RTOG) administered through Washington University (P.I. J.A. Purdy, Ph.D.) was successful in its competitive renewal application. The funding period for the new grant is July 1, 2007 to June 30, 2012. The following ATC goals will be accomplished through coordination, service, and developmental 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 radiotherapy trial protocols.
4. Facilitate/manage digital data protocol submission.
5. Facilitate/manage the QA review of submitted data.
6. Further the development of methods for rapid analysis of volumetric treatment planning data.
7. Assist clinical trial cooperative groups in the development of clinical trial protocols including: (a) credentialing requirements; (b) target volume definitions; (c) quality assurance 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 Cooperative Group study chairs and, QA 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 the Cancer Bioinformatics Grid (cabIG) and DICOM RT.

3. Update of ATC(ITC)'s QuASAR System (previously referred to as ATC Method 1) reported on at XVth ICCR 2007 Meeting

QuASAR: Quality Assurance Submission, Analysis, & Review System for Advanced Technology Trials

W. Bosch, J. Matthews, W. Straube, J. Purdy
1 Washington University School of Medicine, St. Louis, MO
2 U.C. Davis Medical Center, Sacramento, CA

XVth International Conference on the Use of Computers in Radiation Therapy Toronto, Ontario, Canada, June 4, 2007

4. QuASAR System

- QuASAR developed by the ITC through the ATC
- National / International QA resource for RT cooperative protocol groups
- In active production at ITC and QARC
- Supports collection, QA review and analysis of volumetric images and dosimetry
- 22 active protocols (7 cooperative groups/sponsors)
  - 520 institutions
  - 18 commercial TPS (9 vendors)

5. QuASAR – Components and Data Flow

- 5023 complete, volumetric protocol-case data sets collected at ITC (July 2007) over 13+ years
- Dynamically evolving system with modular architecture
  - Data submission
  - Data integrity QA
  - Protocol compliance review

6. Yearly accrual statistics (as of July 2007)

<table>
<thead>
<tr>
<th>Year</th>
<th>Annual Advanced-Technology Protocol Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994</td>
<td>0</td>
</tr>
<tr>
<td>1995</td>
<td>0</td>
</tr>
<tr>
<td>1996</td>
<td>2</td>
</tr>
<tr>
<td>1997</td>
<td>10</td>
</tr>
<tr>
<td>1998</td>
<td>56</td>
</tr>
<tr>
<td>1999</td>
<td>192</td>
</tr>
<tr>
<td>2000</td>
<td>432</td>
</tr>
<tr>
<td>2001</td>
<td>650</td>
</tr>
<tr>
<td>2002</td>
<td>850</td>
</tr>
<tr>
<td>2003</td>
<td>1200</td>
</tr>
<tr>
<td>2004</td>
<td>1800</td>
</tr>
<tr>
<td>2005</td>
<td>2200</td>
</tr>
<tr>
<td>2006</td>
<td>2600</td>
</tr>
<tr>
<td>2007</td>
<td>3000</td>
</tr>
</tbody>
</table>

- Other
- 0413
- 0126
- 9406
ATC Supports JCOG 0403: Ph II Study of SBRT In Patients with T1N0M0 Non-Small Cell Lung Cancer

- 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, who then forwards these data to ITCs in St. Louis for processing.

- Data are reviewed by Dr. Ishikura or his delegate using the ITMC Remote Review Tool.

- Currently, 14 institutions are eligible to enroll patients and capable of digital data submission on JCOG 0403; 90 patients are registered to study.

SUMMARY AND CONCLUSIONS

- ATC is a “virtual entity” made up of the nation’s major clinical trials QA centers, including the ITC, RTGC, and QARC. It capitalizes on the individual strengths of these QA centers.

- The ATC(CTC) developed Quasar system provides the most advanced medical informatics infrastructure currently in use anywhere in the world to support radiation therapy clinical trials digital data quality assurance.

Quasar

- is based on practical experience in support of clinical trials QA.
- provides secure data submission, analysis, and review of radiation therapy and imaging data,
- has enabled the collection, review, and analysis of >5800 protocol case data sets, and
- will continue to evolve using appropriate information technology to meet the QA needs of RT clinical trials.

- 9 treatment planning system vendors (18 different planning systems) have released ACCEPT- compliant RTQDIOM compliant software.

- The ATC web site (http://atc.wustl.edu) links to each of the ATC member web sites and provides information and resources for participating institutions and reviewers regarding credentialing and QA processes for ATC supported protocols utilizing 3DCRT, IMRT, SBRT, HDR, and prostate brachytherapy.

- Volumetric 3D treatment planning digital data are collected, reviewed, analyzed, and stored in a database that can be linked to clinical outcomes; (over 5800 datasets thus far).

- Credentialing and QA processes for 3DCRT, IMRT, SBRT, HDR, and prostate brachytherapy multi-institutional clinical trials have been established to improve the consistency of treatment planning and delivery for these trials.

ACKNOWLEDGEMENTS

The Advanced Technology QA Consortium is a team effort, supported by NIH U24 Grant C2967 “Advanced Technology QA Center”. The individuals listed below have made significant contributions to this work:

NCI: James A. Daye, Ph.D. (Project Officer)

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., Sean O'Leary, M.S., Roxana J. Haynes, R.N., Anna Escher

QARC: Thomas J. FitzGerald, M.D., Marcia M. Urte, Ph.D., Kenneth Ulm, Ph.D.

RPC: Geoffrey S. Ibbott, Ph.D., David Woolfili, Ph.D., Jose Bencomo, Ph.D., Andrea Molinu, M.S., John P. Lowenstein, M.S., Irene Harris, B.S., CMD, Paula Alvarez, M.S., Joyce Roll, B.S., CMD, Nadia Hernandez, B.S., Huy Duong, B.S.

ATC: Walter J. Curran, M.D., Jim Galvin, Ph.D., Elizabeth Martin, CCRP, Lorraine Quaintes

For more information, please visit http://atc.wustl.edu