Advanced Technology Consortium for Clinical Trials QA Meeting
Held at the RTOG Semi-Annual Meeting in Miami, Florida

January 19, 2006

Dr. Purdy welcomed the attendees and called the meeting to order at approximately 8:00 a.m. EST. Attendees are listed in **Appendix 1**.

AGENDA ITEMS	COMMENTS
1. Project Officer Report (Deye)	Dr. Deye also welcomed the attendees. He reviewed briefly the importance of ATC's efforts in caBIG's In Vivo Workspace and ATC interactions with ACRIN in support of the RTOG 0522 protocol. He also asked all ATC subcontractors to forward him any suggested new participants for the ATC Steering Committee. He will be working with Dr. Purdy over the next few weeks to finalize the agenda, meeting dates, and location.
2. P.I.'s Report (Purdy) • Approval of minutes from January 4, 2006 Teleconference • Change in admin personnel at WU • Review of Action Items List • Update on potential interactions with other cooperative groups • ATC Website Review • Treatment Planning Database Studies • Plans for participation in 2006 Scientific Meetings • Schedule of ATC conference calls and next meetings • ATC accrual number comparison • ATC challenges	• Minutes were approved as written. • Change in WU Dept. of Radiation Oncology research administration support to ATC grant – Lois Smith's position eliminated. – ATC admin support will be provided by Ms. Kathy Feurer (contact info below) Washington University School of Medicine Department of Radiation Oncology (Cancer Biology, Clinical and Physics Divisions) Research Administrator 4511 Forest Park St. Louis, MO 63108 URL: Feurer@radonc.wustl.edu Phone: (314) 362-9773; FAX: (314) 362-9790 • Action items were reviewed. – CFR 21, Part 11 software requirements at ITC is reported on in item 13. – Proposal for requesting access to he Treatment Planning Verification (TPV) database at the ITC and the RTOG Outcomes database in Philadelphia will be presented. (See **Appendix 2**) – All subcontractors with funds remaining from the 2004-05 year should submit carryover budget requests to Dr. Purdy. Subcontractor progress reports with budgets are due by April 1, 2006. Please submit to Ms. Kathy Feurer with electronic copy of scientific progress report to Dr. Purdy. – Dr. Bosch will present update to work with (ACRIN) in support of RTOG 0522 Protocol in item13. • A review of the status of interactions with cooperative groups other than RTOG was presented.

	– NSABP: support for B39 going well, except that ITC support personnel are being overwhelmed with current workflow/process. Proposed changes in workflow/process will be presented later in this meeting by B. Straube and R. Haynes. – JCOG: Support for JCOG 0403 going well. Details will be presented by Dr. Ishikura later in the meeting. Plans for approved 2nd protocol will also be reviewed. – COG: this will be reviewed in the QARC presentation – EORTC (Bernard Davis, M.D., Univ. Hospital of Zurich contact person): Interest again expressed at ASTRO. Potential protocol has been identified. However, no real progress has been made. – NABTT (Dr. John Fiveash, M.D., Department of Radiation Oncology, University of Alabama-Birmingham): Group will use modified ATC Method 1. Dr. Purdy spoke with Dr. Fiveash last week and he indicated they were moving forward. – TROG (Trans-Tasman Radiation Oncology Group, Annette Haworth, Senior Radiotherapy Physicist, Dept of Radiation Oncology, Sir Charles Gairdner Hospital, Nedlands, Perth., W Australia. 6009): Group is working to develop software similar to that developed at the ITC to support TROG clinical trials. • ATC Website issues – Service and Developmental Priority Lists will be updated at this meeting and posted within the next week. – Timeline for ATC Method 1 at QARC will be deleted as it is now in use. – Timeline for ATC Method 2 at ITC (at NCIC) will be updated after this meeting. – Please provide Dr. Purdy a copy of any publication (PDF) that lists the NIH U24 grant CA81647 – Henceforth, responsible individual for individual items on each protocol developmental page will be explicitly listed. • Proposal for "Guidelines for Requests for ATC Data by Investigator" was presented. See **Appendix 2**. This will be forwarded to the IGRT Committee and to Dr. Curran for consideration. • Plans for participation in 2006 Scientific Meeting – AAMD Annual Meeting, June 4-8, 2006, in Vancouver, BC, Canada: B. Straube and B. Martin are working with AAMD leadership to have an ATC "hands-on" workshop. – AAPM Annual Meeting, July 30-Aug. 3, 2006, in Orlando, Florida: Dr. Purdy will prepare an ATC Brochure. There will not be an ATC Booth, but will utilize MDACC/RPC booth for distribution of brochure. Dr. Purdy encouraged RCET, RPC, ITC, QARC, and RTOG to submit individual abstracts. – ASTRO Annual Meeting, Nov. 5-9, 2006, in Philadelphia, PA: Dr. Purdy will prepare an ATC Brochure. There will not be an

	ATC Booth, but will utilize NCI booth for distribution of brochure. Dr. Purdy encouraged RCET, RPC, ITC, QARC, and RTOG to submit individual abstracts. • Meeting/Teleconference schedule – Next ATC Teleconference is scheduled for March 1, 2006. – ATC Meeting at COG/PBTC Semi-Annual meeting March 24, 2006 (Chicago) – ATC Steering Committee Meeting tentatively scheduled for April 3-4, 2006 • ATC accrual number comparisons from last RTOG semi-annual meeting. – Previous June 23 2005 ATC Mtg: 2441 complete digital data sets submitted over 11 Year period using ATC Method 1. There are 15 commercial RTP systems that have implemented ATC compliant export capability (see http://atc.wustl.edu); 215 institutions able to submit digital data – This ATC Mtg: 3026 complete digital data sets submitted over 12 Year period using ATC Method 1. There are 15 commercial RTP systems that have implemented ATC compliant export capability (see http://atc.wustl.edu); 331 institutions now able to submit digital data • Dr. Purdy pointed out that there are many challenges/opportunities facing the group including: – Workload at ITC – Increased use of ATC Method 1 at QARC – PET (quantitative) data import and image fusion QA – ATC compliant stereotactic radiosurgery or radiotherapy RTP systems – 4-D CT (several 100 MB) – Image-Guided RT (EPID, MV and kVp Cone beam CT, Helical Tomotherapy megavoltage CT) – Adaptive Radiation Therapy (Daily Confirmation/Adjustment using On-Board Imaging) – Successful implementation of ATC Method 2a at ITC and 2b at NCIC – Move of ATC effort toward integration with industry informatics efforts – ATC software being caBIG compliant – RTOG Grant Renewal/ATC Grant Renewal 2007
2. Update on caBIG In Vivo Imaging Workspace (Purdy/Bosch)	The first face-to-face meeting of the caBIG In Vivo Imaging (IVI) Workspace was held in Philadelphia on Dec. 15-16. Dr. Bosch attended on behalf of Dr. Purdy. Other ATC members, including RTOG and QARC, sent representatives to the meeting. A major focus of the meeting was to lay the foundation for the designation of initial special-interest groups (SIGs) for the IVI workspace. The following SIGs have now been formed: 1. **Vocabulary and Common Data Elements (VCDE) SIG (Leads: Dr. Daniel Rubin, Stanford University; and Dr. Curt Langlotz, University of Pennsylvania)**: The scope

	of the VCDE SIG encompasses the creation, adoption, and use of terminologies, ontologies, and common data elements (CDEs) for medical imaging. The mission of the VCDE SIG is (1) to promote, support, develop, and evaluate standards-based vocabularies, ontologies, and CDEs for radiology and allied imaging fields, and (2) to complement and augment the activities that are underway in other SIGs within the IVI Workspace, in the VCDE Workspace, as well as throughout the entire caBIG effort. This mission includes participating in the design of the testbed and providing the VCDE- and ontology-related elements required by the testbed. In particular, the VCDI SIG, in collaboration with other SIGS, will help develop the standards for creating, storing, and retrieving image metadata and image annotations, will harmonize VCDEs developed in the VCDE SIG with those being created by the VCDE workspace, and will develop VCDE-specific tools and resources that can be deployed on the grid to help realize the strategic vision of the caBIG effort. Specific goals of the VCDE SIG encompass the following major areas of work: (1) to develop vocabularies, ontologies, and CDEs for medical imaging to meet the needs of the IVIWS; (2) to harmonize these VCDEs across the caBIG workspaces as well as to augment existing VCDE resources; (3) to create tools and schemas to make radiological information explicit and computable, collected either directly from practitioners in structured form or extracted from unstructured free text; and (4) to associate the structured information with radiological images through standards and tools to enable intelligent image retrieval and analysis. Bi-weekly teleconference held Tuesdays (starting 1/31/06) 11:00am - 12:00pm EST. 2. **Standards & Interoperability (SIO) SIG (Leads: Dr. David Channin, Northwestern University; and Dr. Paul Nagy, University of Maryland)**: Focused on the promotion and use of appropriate technical standards and frameworks to insure the compatibility of caBIG Imaging activities within caBIG and with clinical imaging and information systems that are often the source of image and non-image data vital to cancer research. To achieve this goal, the SIOSIG has identified a number of priorities. The SIOSIG would like to sponsor a delegation from the Imaging Workspace to the DICOM and HL7 (and possibly other) standards development organizations so as to proactively represent the interests of the research imaging community. The SIOSIG is preparing a white paper comparing the clinical and clinical trial imaging workflows as one step in identifying gaps in standards with respect to clinical trial imaging. With respect to standardizing clinical trial imaging acquisition, the SIOSIG is going to convoke a group to work with existing entities such as UPICT in

	specifying protocols. SIOSIG will work to then promulgate these standard mechanisms. Similar use of standards will need to be developed for annotation and markup of images for both clinical and clinical trial purposes. SIOSIG will assist other SIGs in identifying standard reference data sets. Lastly, SIOSIG will work closely with the Software and Architecture SIGs to develop open source standards based tools and facilitate their demonstration in public venues. Bi-weekly teleconference held on Thursdays (starting 2/9/06) 4:00pm - 5:00pm EST. 3. **Software SIG (Lead: Dr. Fred Prior, Washington University; and Dr. Brad Erickson, Mayo Clinic Cancer Center)**: The goal of the Software SIG is to create and adapt open source software tools to promote and enhance the use of imaging in cancer research. The primary foci of the SIG are tools for image acquisition, management and analysis for use in clinical trials. The SIG will identify existing tools, and define requirements for new, open source tools that need to be developed. Based on the results of an initial workshop at the Imaging Workspace face-to-face meeting in December, 2005, the Software SIG will begin work on the following items: (1) viewing and annotation software that can make use of the caBIG grid infrastructure to retrieve images and information from a distributed database; (2) image acquisition and redistribution software to acquire de-identified data from multiple sites and redistribute this data to multiple reader/analysis sites using the caBIG grid infrastructure; and (3) database resources and software for change analysis including methodologies for software and algorithm validation. Bi-weekly teleconference held on Fridays (starting 2/3/06) 3:00pm - 4:00pm EST. 4. **Testbed Project SIG (Lead: Dr. Joel Saltz, Ohio State University)**: The Testbed SIG is responsible for design, development and implementation of an in-vivo imaging testbed along with key architectural components needed to enable the testbed effort. The testbed will span multiple Cancer Centers and will be a grid based platform that will support storage, access, processing and visualization of images and correlative clinical and molecular data. The testbed will be used to carry out: 1) translational research directed by Cancer Center and Cooperative Group principle investigators and 2) systematic evaluation of computer aided diagnosis (CAD) and other image quantification algorithms. In addition, investigators will be able to use the testbed to carry out exploratory studies involving substantial collections of deidentified image and correlative data. The testbed working group will also collaborate with other SIGs to develop key testbed architectural components such as DICOM and IHE compliant grid services and workflow components able to execute in environments

	provided by proprietary imaging workstations. The initial products of the testbed group will be to develop: 1) demonstration projects at the caBIG 2006 Annual meeting, RSNA 2006 and Supercomputing 2006, 2) working persistent testbed (in effect a type of image research RHIO) by RSNA 2006 and 3) development of key architectural components. Bi-weekly teleconference held on Wednesdays (starting 2/8/06) 3:00pm - 4:00pm EST. Currently, Dr. Purdy has directed that the ATC funded effort in the In Vivo Workspace be focused on the Standards & Interoperability SIG and to the Testbed Project SIG.
3. QARC report including update of ATC Method 1regarding its use for Selected COG Protocols (FitzGerald/Urie/Ulin)	Dr. Ulin provided a brief update regarding the use of ATC Method 1 QARC. • Remote Review Tool is running on a Linux server at QARC and functioning as a local web application. The system is now fully functional, including data acquisition via ftp to QARC (with secure user accounts). • Current Protocols Supporting Digital RT Submission using ATC Method 1 – COG ACNS0121: Phase II Trial of Conformal Radiotherapy for Children with Localized Ependymoma – COG ACNS0126 (closed 9/6/2005): Phase II Study of Temozolomide For Children With High Grade Glioma – COG ACNS0331: Newly Diagnosed Standard Risk Medulloblastoma • Protocols to be added – CALGB 80101: Phase III Intergroup Trial of Adjuvant Chemoradiation after Resection of Gastric or Gastroesophageal Adenocarcinoma – Also considering COG ARST0531: Intermediate Risk Rhabdomyosarcoma • Current accruals with ATC Method 1 – ACNS0121 5 cases – ACNS0126 5 cases – ACNS0331 11 cases – 8002(test) 3 test cases – Total of 24 cases from 13 institutions • How to increase rate of accrual? – The fax reminders of data to be submitted now encourage <u>all</u> institutions participating in these selected studies to submit RT data digitally. – Amendments are being prepared for ACNS0121 and ACNS0331, and statements encouraging submission of digital RT data will be included in the protocol guidelines. – QARC may also include a standard comment encouraging digital RT submission in on-treatment letters for cases on the designated studies.
4. Status of implementing ATC Method 2a at ITC (Bosch-	An update of the status of ATC Method 2a implementation at ITC was presented by Drs. Bosch and Frouhar. The timeline, shown

ITC, Frouhar-RCET)

below, for testing the current iteration of testing of the RCET software was reviewed.

6/23/05	ITC presents detailed report of test results for version 2.3 at ATC meeting
7/5/05	POLARIS server returned to UPDATE MODE for installation of version 2.4
8/24/05	Meeting (Bosch, Frouhar, Palta) at IHE-RO to finalize plans for version 2.4
9/7/05	Decision to expedite completion of version 2.4 (postpone support for PET) confirmed at ATC teleconference
10/7/05	Continuing problems in grayscale rendering of Rapid Image Viewer prompt the use of JPEG 2000 compression under MS .Net Framework 2.0
10/12/05	ITC installs MS Windows 2003 server on POLARIS to support .Net Framework 2.0. RCET notified that server is ready for installation of SQL Server, RCET software
10/26/05	RCET begins installation of SQL Server, version 2.4 software
1/12/06	ITC receives formal notification that version 2.4 software is ready for testing
1/13/06	RCET/ITC teleconference to review bug fixes in version 2.4

Dr. Bosch indicated that the ITC had encountered difficulty in installing version 2.4 of the WebSys client program on a PC. He reviewed the test procedure for this system, indicating that, once the client software could be installed, Mr. O'Leary would be performing a pre-test evaluation of the software before ITC would start the four-week test cycle.

Dr. Frouhar presented WebSys 2.4 Release notes, which describe changes and bug fixes incorporated in this version of the software.

It was agreed that the ITC would collaborate with Colin Field and Lam Pho of the NCIC CTG in performing tests of version 2.4 of the RCET software.

Following the ATC meeting, on 2/2/06, ITC submitted to RCET and NCIC an "RCET Software version 2.4 Pre-test Report" document **(Appendix 3)** detailing problems encountered in the installation of the WebSys v 2.4 client, as well as run-time errors in this software encountered while attempting to retrieve data from the server.

Dr. Frouhar presented a resolution of these issues at a joint RCET/ITC/NCIC teleconference on 2/10/06 and summarized them in a "WebSys 2.4 Pre Test Issues resolution" document **(Appendix**

	4). As of 2/15/06, the ITC is awaiting installation of updated WebSys client software on the POLARIS server.
5. NCIC report on use of ATC Method 3 and plans for implementing Method 2b (Field/Frouhar)	Colin Field reported on NCIC's use of ATC Method 3 and their plans for implementing ATC Method 2b • MA.20 Accrual to January 18, 2006 – Total Accrual Required: 1787 – To date: 1515 total: (NCIC/Canadian – 1312); (CTSU – 79); TROG (AUST) – 124) – ~30 patients per month; 272 accruals remaining; ~9 months left – 28 participating centers; 8 credentialed for electronic submission • Progress (21-Jun-2005 to 17-Jan-2006) – 3+ Dry Runs in progress – Meetings: (1) weekly ROQAC MA.20; (2) semi-annually NCIC CTG; (3) occasional conference calls with RCET & ATC – Installation of NCIC CTG Developmental Server completely independent from Production Server – Establish Standard Operating Procedures (SOPs) – 21CFR Part 11 testing and compliance • Reviewed ROQAC goals • Have begun development of Pilot Project to evaluate ATC Method 2B; will use NCIC CTG APBI protocol • Proposed collaborative grant application between NCIC CTG & ATC/RCET to assist with development and clinical support of NCIC CTG Data Warehouse. • Pointed out that it is still not clear as to how software changes made to RCET software in Kingston, Gainsville, and St Louis are merged .
6. Update on ATC compliant Treatment Planning Systems and IHE Effort (Bosch)	• The list of ATC Compliant Treatment Planning Systems is attached as **Appendix 5**. • ITC (Dr. Matthews) has continued to work with vendors toward ATC compliance – BrainLab BrainScan v. 5.31?? (RTOG): Vendor complete (without "patient localization"), but not generally available. Reviewable data received by ITC from clinical users – TomoTherapy Hi-Art (DICOM): Vendor complete, but not yet generally distributed. Reviewable data received by ITC from clinical users – Note, BrainLAB (1/12/06) and TomoTherapy (3/29/05) have declined posting of their products on ATC website, due to the limited distribution of export-capable systems. – Philips Pinnacle3 v. 7.9f/2.5b (DICOM): Vendor complete (external beam only) – CMS XiO (DICOM): Vendor complete. DRR (RT Image) submission added on 1/5/06 – AccuRay CyRIS Multiplan v. 1.1 (DICOM): Vendor complete, to be released soon

	– 3D Line Ergo (DICOM): Vendor complete, but distribution status unknown. Reviewable phantom data received from clinical user. • IHE-RO Update – First "Use Case" supports "normal flow" of clinical data from CT scan through dose display for 3D conformal, external beam RT. o Primary goal is to reduce ambiguity and improve basic interoperability in the use of DICOM RT objects. o Includes DICOM objects used for ATC protocol submissions – Not included in the first year (2006) Use Case are o HIS/RIS connectivity o Workflow management o IMRT o Brachytherapy – IHE-RO: Timeline o Technical Framework document final drafts of "Transactions" reviewed at 12/21/05 teleconference. Final form to be ready for Jan 2006 Technical Committee meeting Jan 25-27, 2006 o Connectathon (Aug 2006) will be held to prove systems can interoperate with 3+ others. Successful systems may participate in public demo. o Public Demonstration (ASTRO) scheduled for Nov 2006 to demonstrate interoperability
7. ITC report on issues in credentialing and QA Review of AT Protocols (Straube/Haynes)	Mr. B. Straube and Ms. R. Haynes reviewed the current workload issues at ITC. This has become a critical issue for ITC and thus all ATC supported clinical trials. A draft document addressing these concerns was reviewed and is attached as **Appendix 6.**
8. RPC report on issues in credentialing and QA Review of AT Protocols (Ibbott/Followill)	Dr. Ibbott provided the following report: • Eclipse (with BrachyVision) has been installed. Training is scheduled for the period Jan-April. Anticipate use in 6 months • Emphasized the need to receive plans electronically and brought up the question, could an ATC Method 1 server be setup at RPC as was done at QARC. ITC will consider this issue and will report back to the group. • Reviewed several issues regarding NSABP B39/RTOG 0413, RTOG 0232, and 0412. • RPC is now receiving QARC IMRT benchmarks (2 thus far) and is evaluating them in same fashion as QARC. • RPC is beginning to prepare for proton clinical trials – Completed evaluation of MD-55 film and EBT film – Conducting evaluation: of TLD, Presage 3D dosimeter, and Normoxic gel dosimeter • Phantom credentialing test results are listed below: Phantom H&N Liver Prostate Thorax

	Irradiations	176	2+	22	11
	Pass	128	2+	16	6
	Fail	48	0	3	0
	Under analysis or at institution	-	0	3	5
9. RTOG report on issues in credentialing and QA Review of ATC Protocols/Developing Protocols (Martin/Galvin)	Betty Martin reviewed the status of all RTOG protocols supported by the ATC. Details on accruals are presented in the PowerPoint file posted on the ATC Steering Committee webpage. She reviewed the process by which an institution is notified by RTOG when they have passed all the credentialing requirements. RTOG provides the resources for the monthly ATC teleconferences (chaired by Dr. Purdy) that are held on the first Wednesday of each month to keep all ATC participants up to date on ongoing activities. In addition, RTOG provides the resources for the bi-monthly Friday teleconferences (chaired by Ms. Martin) for RTOG/ITC/RPC specific issues.				
10. Update regarding Varian Eclipse brachytherapy software and other software needs at RPC (Ibbott/Followill)	This topic was previously discussed in Dr. Ibbott's RPC report. See item 8.				
11. RCET Plans for implementing WebSys Interface to Varian Eclipse (Dempsey)	Dr. Jim Dempsey provided a live demonstration of the new version of WebSys. This software will under go testing as described previously by ITC and NCIC.				
12. Review of ATC Guidelines for use of IMRT for intra-thoracic treatments, in which significant heterogeneities are encountered and tumor mobility is likely (Ken Forester)	Dr. Forester reviewed the draft document he emailed to the ATC IMRT Task Group in December. He asked all participants to forward suggested changes/additions to him. Dr. Palta will distribute a revised copy prior to the March 1 ATC teleconference.				
13. Status of ATC PET support for advanced technology protocols (Bosch) • RTOG 0515 • RTOG 0522 (ITC-ACRIN PET Core Lab process)	Dr. Bosch reviewed the current status of PET image review procedure for RTOG 0515: (a) Institution submits PET DICOM Images and TP data to ITC using FTP or media; (b) ITC places (anonymized) PET data on ATC secure web server for download by MIR Nuclear Mededicine (LaForest); (c) PET studies read (qualitatively) using eFilm or Syngo (Siegel); (d) PET/CT image registration checked at ITC using FOCAL (Bosch, Forster); (e) TV contours evaluated using FOCAL with/without PET (Bradley). Outstanding issues include PET/CT registration QA using FOCAL screen captures, Data submission forms, and ATC Web page review. For RTOG 0522, the procedure is as follows: (a) PET data				

	submitted to ACRIN Core Lab; (b) ACRIN checks PET images and forwards image data (and SUV scale factors) to ITC; (c) ITC receives CT images, RT Structure sets, 3D Dose (DICOM, RTOG formats); (d) PET images registered with CT images, structures, dose reviewed at ITC using CMS/FOCAL. Outstanding issues include Transfer of SUV scaling information from ACRIN to ITC and ATC Web page review.
14. HERMES system and how it is used in Clinical Drug Trials (Jeff Grenier/Richard Lewis)	Richard Lewis (Director of Clinical Services, Hermes Medical Solutions) presented to the group an overview of the HERMES workstation capability: (a) Fully functional workstation for clinical trials; (b) Validated data import for all modalities; (c) Configurable storage for varied settings; (d) Image registration and VOI analysis; (e) Validated audit trail; (f) Remote viewing solutions. Details are available at www.hermesmedical.com.
15. Status of JCOG 0403 Protocol: Phase II study of SBRT in patients with T1N0M0 NSCLC and second SBRT protocol (Ishikura)	Dr. Ishikura provided an update of JCOG 0403. This is a phase II study of stereotactic body radiation therapy (SBRT) in patients with T1N0M0 non-small cell lung cancer. Its purpose is to evaluate the safety and efficacy of SBRT for T1N0M0 NSCLC. The primary endpoint is 3-year overall survival with a sample size of 165 (65 operable; 100 inoperable). Accrual will be completed in 2008. Patient accrual as of 1/12/06 is as follows: (Number of enrolled pts = 57, approximately 3-6/mt; number of submitted cases = 53; number of reviewed cases = 53). He also reviewed the second study (JCOG 060X) that ATC as agreed to support. This is a phase I dose escalation study of SBRT in patients with T2N0M0 non-small cell lung cancer. Its purpose is to define the recommended dose of SBRT for T2N0M0 NSCLC. The primary endpoint will be Grade $\geq$2 pneumonitis; sample size not yet available (inoperative or "unfit" for surgery). Accrual should take 2-3 years.
16. ATC support of potential protocols to compare protons to IMRT (Michalski/Purdy)	The ITC has successfully received images, contours, and 3D dose distribution for proton beam treatment plans from MDACC (Eclipse) and MGH (CMS). ITC has provide RRT accounts to the two institutions and asked for feedback regarding the need for any new QA review tools for support of proton clinical trials. This information was reported at the special Proton Clinical Trials Meeting held later in the day.
17. Views on 3D data storage and outcomes analysis (Deasy)	Dr. Joe Deasy presented "Data and outcomes archiving: issues and opportunities." He reviewed the following: • Current 3D de-archiving capabilities: the view of an outside de-archiver • Current 3D & outcomes RTOG de-archiving capabilities: the view of an outcomes modeler • Future opportunities: the databank paradigm Dr. Deasy reviewed his successful NIH R01 proposal that made use of the ATC TPV and RTOG Outcomes databases. He stated that

	his overall experience with ATC/RTOG was excellent. He urged the ATC to push for public availability of this data for others, so it could be combined/tested with future datasets and models. He also pointed out the need for accurate dose re-calculations (will be difficult for RTOG format archives, but should be practical for DICOM files). In conclusion, he strongly supported the ATC vision of TPV/Outcomes database(s). ATC/RTOG now has over 3000 datasets. This databank model will allow single-institution or collaborative trial investigators to (a) archive high quality outcomes and treatment planning data; (b) test and compare treatment results against growing database; (c) improve models of tumor and normal tissue response to radiation; (d) learn much more effectively from the past; and (e) make RT meta-analyses much more precise. He pointed out other cooperative groups should utilize growing QA and informatics capabilities of ATC. Dr. Deasy stated the importance of creating user-accessible databases of these NCI funded results which is very much in line with Dr. Purdy's proposal for data access (see **Appendix 2**). Other opportunities included (a) facilitating greater user access and manipulation of data via CERR/Matlab and facilitating greater dosimetric accuracy via Monte Carlo recalculations of DICOM submissions. Note this was proposed in original ATC grant proposal, but was not funded.
18. ITC Status Report (Bosch/Purdy) • ITC/WUCON Network Re-configuration • Credentialing Events database UI – progress review • ITC Data Security Policy / 21CFR11 Compliance – SOPs in process • MINERVA/PEREGRIN	Dr. Bosch reviewed several issues pertaining to the ITC-WU as follows: • Reviewed ITC / WUCON Network Re-configuration issues – Re-configuration is necessitated by changes in Internet connectivity at ITC.. ITC is to be integrated into WU Radiation Oncology secure network, which is part of WU Clinical Operations Network, (WUCON). – Network security policy at WU (and submitting institutions) requires secure upload of patient data. – It should be noted that the following ITC internet functions must remain functional 1. Email (itc@castor.wustl.edu) 2. Public WWW Servers (ATC, ITC) 3. Digital Data Upload to ITC 4. Secure Data Review (Remote Review Tool) 5. Secure online forms (DDSI, Facility Quest., etc.) 6. Digital Data Download (HTTPS) 7. CMS/FOCAL Broadband Data Review 8. WebSys / Rapid Image Viewer – ITC plans to migrate from FTP to SFTP for data submission (Note SFTP is *not* the same as FTPS). SFTP uses SSH server with restricted accounts: (a) Non-interactive login with restricted command set; (b) Limited file access (user locked into chroot "jail"). Broadly available clients include Windows (Filezilla, WinSCP, WSFTP (recent versions)) and for Linux: (sftp, gftp) – Internet access to the Remote Review Tool will be through the WU Radiation Oncology Citrix server. This will require download of free Citrix Presentation Server Client

	(available for Windows, Mac OS X, Linux, etc.) RRT will run on web browser on Citrix server at WU. Behavior (and responsiveness) of the tool under Citrix is essentially the same as with a local browser. However, printing images and DVHs will require access to reviewer's local printer (currently in testing). – ITC is exploring CMS/FOCAL access via Citrix. Review Features will include (a) Multi-modality image fusion (PET/CT, MR/CT, etc.) and (b) 3D Plan review. Data Import will include DICOM RT / RTOG Data Exchange treatment planning data imported via ITC software and DICOM images files (CT, MR, PET) imported directly into FOCAL. The ITC Citrix Server gives ITC users access to FOCAL tools. However, internet access to selected users via WU Rad Onc Citrix Server is still a work in progress. • The ITC QA Events Database was presented. Allows tracking of dates and status of QA process steps performed at ITC and has been in use since Jan 2005. • The ITC Credentialing Events Database was presented. This database allows tracking the sequence of credentialing steps per protocol, e.g., (Start, Digital data submitted, DDSI submitted, Color isodoses submitted, All data received, Digital data review ITC, Sent to RPC for review, ITC process complete, Finished), thus providing report generation capability showing status (success/failure), date, and comments. • The status of the ITC Data Security Policy was reviewed. The timeline for documenting ITC data security is as follows: – 4/30/2006 – Completed draft documents for (a) Standard Operating Procedures and (b) Software Validation – 6/30/2006 – Risk Assessment draft document complete – 10/31/2006 – Audit draft document complete – 12/31/2006 – Data Security Plan in place • Update on MINERVA/PEREGRIN effort was postponed until next meeting.
19. Strategic planning for ATC Grant Renewal (Purdy)	Dr. Purdy led the discussion regarding plans for the grant renewal due in early 2007. The current grant supports three main efforts: (a) Coordination: (1) eliminate duplication of developmental effort and facilitate sharing of QA resources among cooperative groups; and (2) develop appropriate and uniform QA procedures and criteria for advanced technology trials across all cooperative groups. (b) Service: (1) assist clinical trial cooperative groups in protocol development including credentialing requirements, data collection, and QA procedures; and (2) manage and facilitate Credentialing of institutions, protocol digital data submission, QA review of submitted data, and analysis of treatment planning data. (c) Developmental: (1) electronic data exchange of digital planning data between protocol participating institutions and ATC QA Centers; (2) web-based software tools to facilitate protocol digital data submissions and QA reviews by Study

	Chairs, RTOG Dosimetry Group, RPC, and QARC; and (3) archival treatment planning & QA databases that can be linked with the cooperative group's clinical outcomes database Dr. Purdy believes that the first two efforts (coordination and service) must receive a higher priority in the new grant, as many more RTOG protocols that are being developed are going to require digital data submission, plus many more cooperative groups will be requiring digital data submission for their protocols. Under the assumption, that there will not be increased funding for this grant, this will mean less money for software/ development. He proposed that we work more closely with industry and other efforts (e.g., IHE) to achieve our goals. More likely we will need to focus on interfaces with commercial software/databases. The one area that was proposed in the last submission that was not funded was the Monte Carlo recalculations. A new area could be outcome analysis as discussed by Dr. Deasy. Dr. Purdy pointed out that he will be setting up some future conference calls with subcontractor P.I.'s to discuss grant renewal.
20. Review of ATC Priority List and Open Discussion (Purdy and all participants)	The ATC Service and Developmental priority lists were reviewed and the following new priority rank order were established: **Service Priorities** 1. Provide daily operational support to institutions participating in cooperative group protocols (RTOG, NSABP, JCOG) utilizing advanced technology and requiring digital data submission using ATC Method 1. See ATC website for protocol details. This service effort includes the following: (a) evaluate, approve, and notification regarding institution's credentialing tests for each specific protocol; (b) facilitate and perform QA reviews of submitted data including integrity of digital data submissions; target volumes, organs at risk, and dose distribution protocol compliance; and (c) maintain QA and treatment planning databases. 2. Provide operational support for the use of ATC Method 1 technology at QARC and increase use of this technology by other cooperative groups, i.e., COG, SWOG, and CALGB. 3. Provide expertise in the areas of protocol design, credentialing, monitoring, and analysis for new clinical trials that utilize advanced technologies and require digital data submission (e.g., NSABP B-39/RTOG 0413). The effort includes the following: (a) develop credentialing tests and criteria (including periodic review/modification of existing requirements/criteria); (b) design/manufacture phantoms for credentialing; (c) develop QA procedures, documents, criteria, and ATC web page/links; develop new protocol module for TPV and QA databases 4. Facilitate outcome analysis and data mining for ATC supported closed protocols. 5. Provide support to NCIC in their use of ATC Method 3 technology for MA.20 protocol.

	6. Foster implementation of ATC compliant DICOM export capability. This includes the following: (a) working with radiation treatment planning systems (TPS) vendors; specifically, ATC will target TPSs manufactured by BrainLab, Radionics, Elekta Gamma Knife, TomoTherapy Hi-ART, Cyber-Knife systems, and Prowess; (b) ATC representation in NEMA/DICOM Working Group 7; and (c) ATC representation in the IHE initiative. **Developmental Priorities** 1. Increase number of publications referencing ATC NIH U24 grants CA 86147. 2. Develop/implement QA process for protocols requiring multi-modality imaging (PET, MRI, Image fusion). 3. Develop ATC consensus on credentialing requirements for the use of IMRT for intra-thoracic treatments, in which significant heterogeneities are encountered and tumor mobility is likely. 4. Develop/implement brachytherapy QA software to facilitate RPC support of clinical trials. (See current time line for this work). 5. Develop, test, and implement ATC Method 2b technology at NCIC. (See current time line for this work). 6. Develop, test, and implement ATC Method 2a technology at ITC. (See current time line for this work).

Drs. Purdy and Deye thanked all for their participation, with particular thanks to Ms. Betty Martin and RTOG for their efforts in arranging the meeting facilities. The meeting adjourned at approximately 4:00 pm.

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