

Advanced Technology Consortium for Clinical Trials QA Meeting Held at the RTOG Semi-Annual Meeting in Toronto, Ontario, Canada

June 22, 2006

Dr. Purdy welcomed the attendees and called the meeting to order at approximately 8:00 a.m. EDT. Attendees are listed in **Attachment 1**, which was passed out at the meeting.

AGENDA ITEMS	COMMENTS
1. Project Officer Report (Deye)	<p>Dr. Deye also welcomed the attendees.</p> <ul style="list-style-type: none"> • He introduced Dr. Bhadrasain Vikram who has joined the NCI RRP as Branch Chief of the Clinical Radiation Oncology Branch (CROB), the position previously held by Drs. Cumberlin and Wallner. Dr. Vikram will be attending this and future ATC meetings. • He introduced Dr. Alison Martin, NCI CTEP, who has taken the position previously held by Dr. Scott Saxman • He reviewed briefly the status of the new RFA.
2. P.I.'s Report (Purdy)	<ul style="list-style-type: none"> • Minutes of June 7 ATC Teleconference were approved as written. • Brief Update on changes at ITC –WU presented. <ul style="list-style-type: none"> – WUCON Network Re-configuration (discussed during ITC report) – Workload at ITC being addressed; hired new CRA Ms. Anna Eccher, QA Data Coordinator. – Research admin support change (Ms. Kathy Feurer replaced Ms. Lois Smith) going well. WU still awaiting Yr08 Award Statement from NIH. – ITC 21 CFR 11 effort is on-going • Workload statistics: <ul style="list-style-type: none"> – As of June 22, 2006, there have been <u>3913</u> complete, protocol-case digital data sets submitted to the ITC over a 12-year period using ATC Method 1. This compares to 3026 complete cases reported at the Jan. 19 ATC meeting (an increase of 887 cases for this 6-month period). – 418 institutions able to submit data as compared to 331 institutions 6-months ago (increase of 87 institutions). – Protocols supported by ATC (see Attachment 2).

- 4 closed RTOG protocols and 14 open RTOG protocols.
 - 1 open NSABP/RTOG protocol.
 - 1 open JCOG protocol.
 - 3 open COG protocols (QARC).
 - 1 open CALGB protocol (QARC).
 - 1 open ACOSOG protocol (QARC).
 - 1 open NCIC protocol (ATC Method 3) (NCIC/RCET).
- A review of the status of interactions with other Coop. groups was presented.
 - EORTC: Dr. Bernard Davis will step down as QA Physics coordinator of the EORTC Radiotherapy Group. This will take effect at the next group's meeting in the autumn. His successor is Dr Edwin Aird, Chief Physicist at the Mount Vernon Hospital in the UK. Collaboration with the ATC will continue as planned regarding the QA of the atypical meningioma study (No. 22042-26042) chaired by Dr Damien Weber of Geneva University Hospital. He and physicist Giovanna Di Pasquale will be looking after the QA for the EORTC, together with Philip Poortmans and Edwin Aird, responsible for clinical and physics QA of the EORTC RTGroup. Data integrity QA will be performed by the ITC as in RTOG, NSABP, and JCOG studies.
 - NABTT (Dr. John Fiveash, M.D., Department of Radiation Oncology, University of Alabama-Birmingham): No activity to report.
 - TROG (Trans-Tasman Radiation Oncology Group, Annette Haworth, Senior Radiotherapy Physicist, Dept of Radiation Oncology, Sir Charles Gairdner Hospital, Nedlands, Perth., W Australia. 6009): No activity to report.
 - ATC compliant treatment planning systems:
 - As of June 22, 2006, there are 15 TPS that are deemed to be *ATC Compliant* and are listed on the ATC website (http://atc.wustl.edu/credentialing/atc_compliant_tps.html). Those TPSs are those with which ATC protocol participants have submitted *complete, reviewable* protocol data sets to the ITC.
 - ITC (Dr. Matthews) has continued to work with vendors and users toward ATC compliance over this last 6-month period.
 - CMS XIO 4.3.1 was released in early June; this version has DICOM export, which was Vendor Complete as last tested. No data from a clinical site has been received by ITC using XIO 4.3.1 DICOM export.
 - Simuplan TPS (Simuplan, S.L.), a MAC based TPS for Mammosite, submitted DICOM test data 11 May 2006 (CT, RS, RP, and RD). Only the CT was readable

	<p>by the Merge library. Simuplan asked for more specifics, but Dr. Matthews has not yet been able to follow-up because of his focus on WUCON reconfiguration efforts.</p> <ul style="list-style-type: none"> • ITC has received TomoTherapy Hi-Art digital data from UC Davis using Tomo Research Workstation and is reviewing for ATC compliance. • Proton beam data sets have been submitted to the ITC by MDACC (Varian Eclipse) and MGH (CMS Xio). ITC has asked each institution to review data using the Remote Review Tool and provide feedback back as to adequacy for review of clinical trials using proton beams. <ul style="list-style-type: none"> • CDRP-ATC <ul style="list-style-type: none"> – Mr. Bill Straube maintains the CDRP-ATC table (listing CDRP credentialing status for ATC supported protocols (see Attachment 3)). <ul style="list-style-type: none"> • Singing River is now credentialed for 0413 3DCRT and working on 0126 using IMRT. • UPMC/Mckeesport is credentialed for 0413 using 3DCRT. • Several of the mentoring institutions were “grandfathered” into many of the new RTOG protocols that opened recently using IMRT • 2006 Scientific Meeting <ul style="list-style-type: none"> – ATC Workshop (Special Interest Session) was held at AAMD Annual Meeting on June 6, 2006, in Vancouver, BC, Canada. <ul style="list-style-type: none"> • Held as breakout session while main program held in another room. • First session involved Eclipse (8:30 - 9:30); second session involved Pinnacle (10:00-11:00); third session involved Rahd and Nucletron (11:00-12:30) • Bill Straube presented an overview of ATC and digital data submission to the groups prior to each session and then vendors demonstrated TPS digital data submission UI's. • All Vendors brought equipment to demonstrate their submission. • All vendors plan on putting together information for the ATC website. • ATC should plan to do another workshop at the next AAMD Annual meeting to be held in New Orleans. – AAPM Annual Meeting, July 30-Aug. 3, 2006, in Orlando, Florida: <ul style="list-style-type: none"> • ACTION: Dr. Purdy will prepare an ATC Brochure. There will not be an ATC Booth, but will utilize MDACC/RPC booth for distribution of brochure. • Abstracts accepted (if there are others please email to Dr. Purdy title and ATC groups involved).
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	<ul style="list-style-type: none"> ○ Testing of ATC Method 2 for Supporting QA of Cooperative Group Advanced Technology Clinical Trials Requiring Digital Data Submission (ITC/RCET/NCIC) ○ Implementation of ATC Method 1 for Clinical Trials Data Review at the Quality Assurance Review Center (ITC/QARC) ○ Digital Data Integrity QA for Multi-Institutional Clinical Trials (ITC) ○ ITC Assists Developers of ATC Compliant DICOM Export for Clinical Trials (ITC) ○ Implementation of MINERVA/PEREGRINE as a Possible ATC Review Tool (ITC-UCD, Idaho National Laboratory, Idaho Falls, ID, Montana State University, Bozeman, MT) ○ Evaluation of heterogeneity corrections algorithms through the irradiation of a lung phantom (RPC) ○ Heterogeneity dose calculation accuracy in IMRT using an anthropomorphic thorax phantom (RPC) ○ The State of Radiotherapy Physics Through The Eyes of a Quality Auditor (RPC) <p>– ASTRO Annual Meeting, Nov. 5-9, 2006, in Philadelphia, PA:</p> <ul style="list-style-type: none"> • ACTION: Dr. Purdy will prepare an ATC Brochure. There will not be an ATC Booth, but will utilize NCI booth for distribution of brochure. • Abstracts accepted. <ul style="list-style-type: none"> ○ A Review of the Activities of the ITC in Support of RTOG Advanced Technology Clinical Trials (ITC/RTOG for poster discussion session) ○ ACTION: Other RTOG protocol specific abstracts supported by ATC (titles to be supplied by B. Martin) <ul style="list-style-type: none"> • ATC-caBIG In Vivo Imaging Workspace <ul style="list-style-type: none"> – ATC is one of the funded participants in the caBIG In Vivo Imaging Workspace. ATC members are participating in the following Special Interest Groups (SIGs) Teleconferences: <ul style="list-style-type: none"> • Testbed SIG • Standards and Interoperability SIG • Software SIG – ATC members (ITC, QARC) will participate in the upcoming In Vivo Imaging Workspace face to face meeting to be held in Rockville, MD on July 20-21, 2006. • ATC Task Group: Guidelines for use of IMRT for intra-thoracic treatments <ul style="list-style-type: none"> – Dr. Deye circulated the near final version of this report to ATC members and
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participants. Dr. Mike Gillin (Chair, RTOG Medical Physics Committee) provided a critique and report will be discussed at the Medical Physics Committee meeting on Friday. It is hoped that all concerns can be addressed and the report finalized at that time.

- ATC WEB SITE (<http://atc.wustl.edu>) update
 - Table of credentialing requirements for RTOG studies has been added (<http://atc.wustl.edu/credentialing/index.html>)
 - Priority Lists, Development Timeline and Status of ATC Method 2 at ITC maintained under Steering Committee
 - Publication Page updated (please inform Dr. Purdy of any publications having ATC grant acknowledged).
 - In coming year, plan to use ATC website to facilitate an increased educational mission for ATC regarding the use of advanced technologies.
- Dr. Purdy reported he is working to motivate industry to become more aware of ATC and caBIG efforts and to encourage a move of ATC software developmental efforts toward integration with industry and caBIG informatics efforts. To that end, he has invited representatives from Elekta/IMPAC, Varian, TeraMedica, and Cedara to attend. Presentations from the first three listed were presented in the afternoon session.
- Dr. Purdy pointed out that there are many challenges/opportunities facing the group including:
 - Developing a more formal mechanism as to how it is decided as to which clinical trials are to be supported by ATC funding.
 - ATC compliant stereotactic radiosurgery or radiotherapy RTP systems
 - PET (quantitative) data import and image fusion QA
 - 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)
 - Increased use of ATC Method 1 at QARC
 - Successful implementation of ATC Method 2a at ITC and 2b at NCIC
 - Move of ATC effort toward integration with industry informatics efforts
 - caBIG compliant software
 - RTOG Grant Renewal/ATC Grant Renewal 2007

	<ul style="list-style-type: none"> • Meeting/Teleconference schedule <ul style="list-style-type: none"> – Next ATC Teleconference is scheduled for July 5, 2006. – caBIG In Vivo Workspace Meeting July 20-21 in Rockville, MD – AAPM Annual Meeting, July 30-Aug. 3, 2006, Orlando, Florida – ATC Meeting at Fall COG Semi-annual meeting Oct. 5-6, Los Angeles, CA – ASTRO Annual Meeting, Nov. 5-9, 2006, Philadelphia, PA • ATC Steering Committee Response <ul style="list-style-type: none"> – Dr. Deye has forwarded the summarized response of the ATC Steering Committee to Dr. Purdy. ACTION: Dr. Purdy will prepare a response and circulate to the ATC subcontractors.
2. RTOG report on their ATC subcontract supported/related efforts (Martin/Galvin)	<ul style="list-style-type: none"> • 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. • She also provided details on developing protocols potentially wanting to utilize ATC resources. Dr. Purdy pointed out this was pertinent to the point he made regarding the need to develop a more formal mechanism as to how it is decided as to which clinical trials are to be supported by ATC funding. This will need to be an agenda item for the RTOG IGRT Steering committee. • ACTION: RTOG will be taking on some of the function provided by ITC in future protocols (and in some current ones), i.e., managing the actual protocol specific QA review, including entering the QA scores for compliance. ITC will continue to provide data integrity QA. • There was some discussion regarding CTSU and ATC supported protocols. In the past there had been some meeting attended by both ATC participants and CTSU. The group felt we should periodically meet (or teleconference) to keep CTSU better informed regarding credentialing requirements. ACTION: Betty Martin agreed to contact Martha Hering to set up a conference call later this summer. • 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. • RTOG provides the resources for the bi-monthly Friday teleconferences (chaired by Ms.

	Martin) for RTOG/ITC/IPC specific issues.
3. ITC report on their ATC supported efforts (Bosch/Straube/Purdy)	<p>Dr. Bosch reviewed several issues pertaining to the ITC-WU as follows:</p> <ul style="list-style-type: none"> • Reviewed ITC / WUCON Network Re-configuration issues <ul style="list-style-type: none"> – Necessitated by changes in Internet connectivity at ITC. – ITC is now part of WU Radiation Oncology secure network, part of WU Clinical Operations Network (WUCON). – Opportunity to implement secure upload (SFTP) of patient data. – Detailed information is provided on ATC Web Site – Anticipated Issues <ul style="list-style-type: none"> • Replacement for FTP clients on TPS platforms <ul style="list-style-type: none"> ◦ Integrated FTP submission mechanism in TPS (XiO) ◦ Command-line client on TPS platform (Pinnacle) • Users <ul style="list-style-type: none"> ◦ Acquire and configure SFTP clients ◦ Make workflow changes in data submission • Manufacturers <ul style="list-style-type: none"> ◦ Provide alternative SFTP client software ◦ Help with alternative workflow and submission procedures – Note, former internet connectivity to be disconnected in July. • Lessons learned in reconfiguration effort <ul style="list-style-type: none"> – Broadcasts sent by RTOG and NSABP reached institutions, but not necessarily the people responsible for maintaining data submission (physicists, IT personnel). – Untested assumptions regarding the consistency of features in software led to difficulty in re-engineering network connections. – Network performance and reliability have improved substantially since May 27. Minor issues remain and are being addressed. – ITC is receiving good support from WU and RO department networking personnel, but is now substantially more dependent on them to diagnose problems. – This network transition has been costly regarding ITC effort in the short term. • CMS/FOCAL is being developed for (a) Multi-modality image fusion (PET/CT, MR/CT, etc.) and (b) 3D plan review. Reviewer access will be through ITC Citrix Server which gives ITC users access to FOCAL tools. Work is in progress to provide access for selected users via WUCON VPN. • Update on 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.

	<ul style="list-style-type: none"> • Update on 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 at 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: <ul style="list-style-type: none"> – 5/30/2006 – SOP draft documents (Standard Operating Procedures and Software Validation) – 7/30/2006 – Risk Assessment draft document complete – 10/31/2006 – Audit draft document complete – 12/31/2006 – Data Security Plan in place 																				
<p>4. RPC report on their ATC subcontract supported/related efforts (Ibbott/Followill)</p>	<p>Dr. Ibbott provided a report on RPC ATC related activities:</p> <ul style="list-style-type: none"> • Eclipse (with BrachyVision) has been installed. Training of 3 staff has been completed. They are in the process of commissioning system. Emphasized the need to receive films and plans electronically in order to use the system for dose recalculations. • Reviewed phantoms’ design and credentialing test results are listed below <table border="1" data-bbox="764 792 1482 1023"> <thead> <tr> <th><u>Phantom</u></th> <th><u>H&N</u></th> <th><u>Prostate</u></th> <th><u>Thorax</u></th> <th><u>Liver</u></th> </tr> </thead> <tbody> <tr> <td>Irradiations</td> <td>217</td> <td>58</td> <td>28</td> <td>4</td> </tr> <tr> <td>Pass</td> <td>146</td> <td>41</td> <td>14</td> <td>3</td> </tr> <tr> <td>Fail</td> <td>57</td> <td>13</td> <td>5</td> <td>-</td> </tr> </tbody> </table> <ul style="list-style-type: none"> • Presented results of lung phantom irradiation regarding dose calculation algorithm heterogeneity correction (will present results at AAPM Annual Meeting). • Reviewed RPC’s role in NSABP B39/RTOG 0413 regarding credentialing and QA review pointing out that RPC reviews all the brachytherapy cases. • Reviewed credentialing effort for all RTOG ATC supported protocols including use of QARC IMRT benchmark. • With regard to proton clinical trials, RPC has: <ul style="list-style-type: none"> – Completed evaluation of MD-55 film and EBT film – Conducting evaluation: of TLD, Presage 3D dosimeter, and Normoxic gel dosimeter 	<u>Phantom</u>	<u>H&N</u>	<u>Prostate</u>	<u>Thorax</u>	<u>Liver</u>	Irradiations	217	58	28	4	Pass	146	41	14	3	Fail	57	13	5	-
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<p>5. QARC report on their ATC subcontract supported/related efforts (FitzGerald/Urie/Ulin)</p>	<p>Dr. FitzGerald provided a report on QARC ATC related activities:</p> <ul style="list-style-type: none"> • 65 QARC IMRT benchmarks have been approved (13 since Jan. 1, 2006). 9 more are currently on hold. Reasons for hold are as follows: <ul style="list-style-type: none"> – 5 PTV dose uniformity unacceptable – 1 OAR dose too high – 1 dose distribution and DVHs not sent – 2 insufficient dose verification data • There have been a total of 168 IMRT benchmarks approve or on hold counting analysis by QARC and RPC. <ul style="list-style-type: none"> – Type of IMRT includes 9 MIMiC serial tomotherapy, 5 helical Tomotherapy, 46 DMLC (sliding window), 83 SMLC (step & shoot), 16 DMLC & SMLC, and 9 not recorded. – 14 different treatment planning systems – Relative dosimeters used for dose verification included 95 EDR2 film, 23 XV film – 32 diode array, 2 ion chamber array, 6 portal imager, and 9 other • Update of use of ATC Method 1 at QARC <ul style="list-style-type: none"> – The system is now fully functional, with studies linked to the patient’s record in the QARC database. – Supports data acquisition via CD or FTP to QARC (with secure user accounts). – QARC responsible for FTP account management – Procedure for processing FTP account requests has been formalized. – Currently there are 17 FTP accounts. • Current protocols supporting digital RT submission using ATC Method 1 <ul style="list-style-type: none"> – COG ACNS0121: Phase II Trial of Conformal Radiotherapy for Children with Localized Ependymoma (8 accruals) – COG ACNS0126 (closed 9/6/2005): Phase II Study of Temozolomide For Children With High Grade Glioma (5 accruals) – COG ACNS0331: Newly Diagnosed Standard Risk Medulloblastoma (15 accruals) – CALGB 80101: Phase III Intergroup Trial of Adjuvant Chemoradiation after Resection of Gastric or Gastroesophageal Adenocarcinoma – ACOSOG Z4032: Phase III Study of Sublobar Resection Plus Brachytherapy in High Risk Patients With Non-Small Cell Lung Cancer – In all, there has been a total of 38 cases submitted from 18 institutions • QARC caBIG initiatives <ul style="list-style-type: none"> – QARC is participating in the Clinical Trials Management Systems Workspace. They
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	<p>will send representatives to the face-to-face meeting on July 10-11 in Chicago. Specifically they are participating in the following SIG's:</p> <ul style="list-style-type: none"> • Clinical Trials Database • CRF (Case Report Form) standardization • System Interoperability and Harmonization • Credentialing <p>– QARC is participating in the in vivo Imaging Workspace. They will send representatives to the face-to-face meeting on July 20-21 in Bethesda. Specifically they are participating in the following SIG's:</p> <ul style="list-style-type: none"> • Testbed • Software Development (Note QARC submitted a letter of intent for the eXtensible Imaging (XIP) Platform RFP. QARC's plan is to participate with an industry partner. <ul style="list-style-type: none"> • Proposed revision of QARC 3D BENCHMARK (Current one is out-of-date as it was designed when 3D systems just becoming commercially available). Proposed new QARC 3D Benchmark's aim is to verify expertise in using 3D planning system. There was considerable discussion on this issue. There are currently different 3DCRT benchmarks being used by ATC subcontractors. Dr. Purdy would like all subcontractors to work together to come up with a common 3DCRT benchmark. ACTION: This will be an agenda item for the next ATC Teleconference.
<p>6. RCET report on their ATC grant/subcontract supported/related efforts (Palta/Frouhar)</p>	<p>Dr. Palta provided a report on RCET ATC related activities:</p> <ul style="list-style-type: none"> • Reviewed the RCET Scope of Work • Reviewed what the RCET System components are (NetSys and WebSys) (referred to as ATC Method 2b in this grant. • Reviewed Product Requirement Specification Document developed in collaboration with the NCIC in terms of (a) data content, (b) data transfer, (c) storage, and (d) data review. <p>Dr. Frouhar presented a brief demonstration of the software using his laptop. This demo was cut short and resumed during the lunch hour for the visiting industry representatives.</p>
<p>7. Status of implementing ATC Method 2a at ITC (Bosch-ITC, Frouhar-RCET)</p>	<p>Dr. Bosch provided an update of the status of ATC Method 2a implementation at ITC.</p> <ul style="list-style-type: none"> • The ATC Method 2 Test Cycle process was reviewed <ul style="list-style-type: none"> – RCET installs updated software on ITC server (POLARIS) – Pre-test evaluation performed by ITC – POLARIS disconnected from Internet (TEST MODE) – ITC tests software

	<ul style="list-style-type: none"> - Evaluation of database changes (included (a) UI function checks, (b) upload, download comparison of test data, and (c) evaluation of administrative tools, web-based image viewer - ITC reports findings to RCET (and other ATC members) - POLARIS reconnected to Internet (UPDATE MODE) - RCET updates software to correct problem(s) and then ITC restart test cycle process. • The timeline listed below for testing version 2.4 of the RCET software was reviewed.
3/15/06	RCET installs updated WebSys client (v. 2.4.2) on POLARIS
4/3/06	Release notes for version 2.4.2 and announcement that system is updated and ready for testing received by ITC
4/13/06	ITC issues pre-test report for version 2.4.2 indicating failure to retrieve successfully uploaded data (viewable via Rapid Image Viewer)
5/3/06	RCET evaluates ITC pre-test report (4/13/06) and issues statement indicating resolution of MIME-types problem in downloading data from server
5/4/06	ITC begins pre-test evaluation of version 2.4.2.1.
5/8/06	RCET indicates release of version 2.4.2.2 with bug fixes based on internal QA and NCIC response. ITC halts pre-test evaluation of version 2.4.2.1.
3/15/06	RCET installs updated WebSys client (v. 2.4.2) on POLARIS
4/3/06	Release notes for version 2.4.2 and announcement that system is updated and ready for testing received by ITC
4/13/06	ITC issues pre-test report for version 2.4.2 indicating failure to retrieve successfully uploaded data (viewable via Rapid Image Viewer)
5/3/06	RCET evaluates ITC pre-test report (4/13/06) and issues statement indicating resolution of MIME-types problem in downloading data from server
5/4/06	ITC begins pre-test evaluation of version 2.4.2.1.
5/8/06	RCET indicates release of version 2.4.2.2 with bug fixes based on internal QA and NCIC response. ITC halts pre-test evaluation of version 2.4.2.1.
5/26/06	ITC receives notification that updated version 2.4.2.2 with bug fixes based on internal QA and NCIC response has been installed on POLARIS server.

	6/5/06	ITC issues pre-test report for version 2.4.2.2 indicating failure to retrieve successfully uploaded RTOG Data Exchange format data (indicated in Electronic Folder).
	6/7/06	RCET announces resolution of problems in pre-test report (6/5/06) for version 2.4.2.2.
	6/13/06	ITC issues pre-test report for version 2.4.2.3 indicating that problems noted in version 2.4.2.2 (failure to retrieve uploaded RTOG Data Exchange format data) remain.
	<ul style="list-style-type: none"> • In summary, since January 2006 ITC has performed preliminary testing on six versions (configurations) of RCET client/server software: <ul style="list-style-type: none"> – 2/2/06 v. 2.4 fails to retrieve DICOM data – 3/8/06 v. 2.4.1 crashes, fails to retrieve DICOM data – 4/13/06 v. 2.4.2 fails to retrieve DICOM data – 5/4/06 v. 2.4.2.1 (testing halted when 2.4.2.2 released) – 6/5/06 v. 2.4.2.2 fails to retrieve RTOG format data – 6/13/06 v. 2.4.2.3 fails to retrieve RTOG format data • Several issues (WebSys client install, DICOM download, Rapid Image Viewer grayscale) have been addressed and resolved. • Formal testing (upload/download/comparison of ITC test suite datasets) has not yet been started with v. 2.4 as we remain stuck on the pretest-fix-pretest-fix... point in the formal process. • Dr. Frouhar proposed to come to ITC and work directly with ITC over the next two weeks. Dr. Bosch pointed out that this would not work because of the continued effort needed to complete the ITC-WUCON reconfiguration and also the AAPM posters. ACTION: It was agreed that Drs. Deye, Purdy and Palta would have a conference call to review the situation and decide on what further efforts should be placed on this effort. 	
8. NCIC report on use of ATC Method 3 and experience implementing Method 2b (Field)	<p>Colin Field reported on NCIC's use of ATC Method 3 and their efforts regarding ATC Method 2b</p> <ul style="list-style-type: none"> • ATC Method 3 and MA.20 accrual as of June 21, 2006 <ul style="list-style-type: none"> – To date: 1650 total: (NCIC/Canadian – 1413); (CTSU – 88); TROG (AUST) – 149) – 10 participating centers credentialed for electronic submission; 3 more in progress. – 43 electronic submissions to date • Progress during period (17-Jan-2006 to 21 June-2006) 	

	<ul style="list-style-type: none"> – Meetings: (a) weekly ROQAC MA.20; (b) semi-annually NCIC CTG; (c) occasional conference calls with RCET & ATC – Credentialed centers (2 more, 3 in-progress, 1 or 2 in-hibernation) – 4 more registered users – 16 submitted cases – ‘Firewall’ problems at a couple of centers – Feedback is that Electronic Submission Manual is ‘too dense’ • Summary ATC Method 3 and MA.20 <ul style="list-style-type: none"> – Electronic submission is ticking along slowly – Accrual is almost complete • Colin presented information regarding proposed randomized trial of accelerated partial breast protocol (RAPID) and possible use of ATC technology (Method 3 or Method 2b). <ul style="list-style-type: none"> – • ATC Method 2b: Progress during period (17-Jan-2006 to 21 June-2006) <ul style="list-style-type: none"> – Meetings <ul style="list-style-type: none"> • Gainesville meeting, March 31-April 1 • NCIC CTG Spring Meeting, April 28-30 • Weekly NCIC CTG & RCET teleconferences • Pilot Project team teleconferences • ICTR 2006 conference (Interest expressed from Germany, Italy, UK, Australia) – ATC Method 2b Software Testing <ul style="list-style-type: none"> • WebSys 2.4.+ <ul style="list-style-type: none"> ◦ Eclipse interoperability problems identified (Phantom export / import, Copying of structures from one data set to another, 3D volume and export of original CT slices) • NetSys 4.0 <ul style="list-style-type: none"> ◦ Bugs identified ◦ New version to be tested • Rapid Review Applet <ul style="list-style-type: none"> ◦ Limitations with viewing structures, beams, doses • Robust Installers <ul style="list-style-type: none"> ◦ remove previous versions, caches, applets, etc • Summary ATC Method 2b <ul style="list-style-type: none"> – Needs more testing of WebSys, NetSys, and RR Applet with different TPSs and different planning techniques
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	<ul style="list-style-type: none"> – Pilot Project team is ready to go – RAPID protocol needs NCIC CTG support now
9. Status of NSABP B39/RTOG 0413 support by ATC (Straube/Ibbott/Martin)	<p>Bill Straube provided a brief update on NSABP B39/RTOG 0413</p> <ul style="list-style-type: none"> • Over 1500 cases have been registered • 172 cases were registered last month (some consideration is being given to extending accrual because of more lower risk patients than anticipated) • Mammosite accrual is still lagging far behind • 97 of 195 Rapid Review cases have required resubmission due to protocol review. • In summary, credentialing and web-based QA process is going very well. RPC, RTOG, ITC, and NSABP are working very much as a team, clearly documenting the value of the ATC approach.
10. Status of ATC PET QA capability for ATC supported protocols 0515, 0522 (Bosch)	<p>Dr. Bosch reviewed the current status of the ATC PET image review procedures</p> <ul style="list-style-type: none"> • RTOG 0515 <ul style="list-style-type: none"> – Credentialing Requirements (listed on ATC web site) <ul style="list-style-type: none"> • Be credentialed for RTOG S-0132/ACRIN 6665 or RTOG 0235/ACRIN 6668 • Demonstrate ability to submit 3DCRT Digital Data to the ITC <ul style="list-style-type: none"> ◦ Credentialed for another ATC supported 3DCRT study ◦ Submit Facility Questionnaire with digital data (CT, Structures, Plan, Dose) ◦ Demonstrate digital submission of PET or PET/CT images to ITC • Collect Data for Developing QA Procedures (Screen captures of fused PET/CT images in T/S/C planes) – PET Image Review for RTOG 0515 <ul style="list-style-type: none"> • Institution submits PET DICOM Images and TP data to ITC using FTP or media. • ITC places (anonymized) PET data on ATC secure web server for download by Nuc Med radiologist • PET studies read (qualitatively) using eFilm or Syngo (Siegel) • PET/CT image registration checked at ITC using FOCAL (Bosch, Forster) • TV contours evaluated using FOCAL with/without PET (Bradley) • RTOG 0522 <ul style="list-style-type: none"> – Quantitative PET (PET/CT) images submitted to ACRIN, forwarded to NCI Archive – CT, Structures, Doses, Plans submitted to ITC (DICOM or RTOG Data Exchange), forwarded to NCI Archive (DICOM) <ul style="list-style-type: none"> • ITC has forwarded one DICOM dataset to NCI Archive for testing. (Remaining

	<p>five cases are in RTOG format.)</p> <ul style="list-style-type: none"> • RTOG-to-DICOM conversion will be needed for data sets submitted in RTOG Data Exchange format. • Current transfer of data to NCI Archive is via SFTP. • ITC plans to use specially-configured MIRC Field Center software for future transfers of DICOM (RT) data to NCI.
11. Industry informatics efforts and how they may be integrated into ATC (TeraMedica, IMPAC, Varian)	<ul style="list-style-type: none"> • Jacob Philip and Joel Goldwein, MD provided a presentation on IMPAC MOSAIQ and the ATC: Oncology PACS, Clinical Trials and caBIG. • Tim OConnor presented an overview of the TeraMedica Evercore™ Clinical Information Manger software system pertinent to the ATC. • Armin Langenegger presented an overview of the Varian Aria Oncology Information System and the Eclipse software tools pertinent to the ATC. • The emphasis of the industry presentations was to find out what tools (plan review, DICOM import/export, databases, data mining, etc) may be available from companies that would make sense for ATC to interface with rather than re-invent the wheel. Dr. Purdy will continue to work to find a “win-win” situation for industry and NCI sponsored cooperative groups supported by the ATC.
12. Issues in 4DRT QA (Low)	<p>Dr. Low presented a review of issues pertaining to 4DRT (breathing motion). A PDF of his presentation is available on the ATC website under the ATC Steering Committee. His conclusions were:</p> <ul style="list-style-type: none"> • QA needs to consider the unreliability of phase-based gating • QA needs to allow for irregular frequency and amplitude of breathing • Amplitude-based gating = ability to extrapolate from existing image data • 4D treatment process has not yet been finalized
13. Strategic planning for ATC Grant Renewal (Purdy)	<p>Dr. Purdy led the discussion regarding plans for the grant renewal. The current grant supports three main efforts: (a) coordination, (b) service, and (c) developmental. All three will need to be addressed. He pointed out that ATC can not assume that there will be continued funding at the current levels. We need to focus on new opportunities and the needs of the cooperative groups and build on our past successes. Many more RTOG protocols are being developed that require digital data submission, plus many more cooperative groups will be requiring digital data submission for their protocols. We need to wait for the new RFA, but Dr. Purdy encouraged each subcontractor to go ahead and put</p>

	their thoughts on paper regarding their role and proposed scope of work within the ATC and send it to him.
14. Review of ATC Priority List and Open Discussion (Purdy and all participants)	<p>The ATC Service and Developmental priority lists were reviewed and the following new priority rank order were established:</p> <p>Service Priorities</p> <ol style="list-style-type: none"> 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.

	<p>Developmental Priorities</p> <ol style="list-style-type: none">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. Further develop ATC Method 1 to include (a) review of transverse and coronal slices (isodoses and volumes); (b) review of verification images, i.e. Electronic View Box.4. Work with RTOG to move protocol QA database and scoring to RTOG HQ.5. Develop/implement brachytherapy QA software to facilitate RPC support of clinical trials. (See current time line for this work).6. Develop, test, and implement ATC Method 2b technology at NCIC. (See current time line for this work).7. Develop, test, and implement ATC Method 2a technology at ITC. (See current time line for this work).
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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 4:45 pm.

Respectfully submitted June 30, 2006
James A. Purdy, Ph.D.
ATC Principal Investigator