

# **Principal Investigator's Report Advanced Technology QA Consortium**

**COG Meeting – Dallas, TX  
October 28, 2005**

**James A. Purdy, Ph.D.  
Department of Radiation Oncology  
UC Davis Medical Center  
Sacramento, CA, USA**

**Supported by NIH U24 grant CA81647,  
“Advanced Technology QA Center”**

# P.I.'s Report

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- Welcome
- Approval of minutes from Oct. 5, 2005 Teleconference
- Review of Action Items
- Update on ATC Supported Protocols
- Update on potential interactions with other cooperative groups (NABTT, UKCCSG)
- caBIG In Vivo Workspace
- Schedule of ATC conference calls and next meetings

# P.I.'s Report

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- Approval of minutes from Oct. 5, 2005 Teleconference
- Review of Action Items

## Review of Action Items

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1. Issue of does ATC software meet requirements of CFR 21, Part 11 pertaining to electronic records and electronic signatures. (Action required)
  - Dr. Deye distributed copy of CFR 21 Part 11 at ATC Meeting June 23, 2005. Dr. Purdy charged ATC IT Task Group (Dr. Bosch chair) to review and report back via ATC Teleconferences. Dr. Purdy asked ATC participants to provide names of any IT or compliance officers from their own groups that could shed light on this matter. IT TG to check on IHE effort in this regard.
  - Oct. 5 ATC Teleconference: No progress since last teleconference. Reminders sent to RTOG and QARC for some help on this subject.

## Review of Action Items

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2. Treatment Planning Verification (TPV) database at the ITC and the RTOG Outcomes database in Philadelphia: CMS in St. Louis has requested use of the TPV database; details are still being worked out, but both RTOG and ITC have indicated they are in support of this request. (Action required)
  - Oct. 5 ATC Teleconference: No progress
3. All subcontractors that have funds remaining from the 2004-05 year should submit carryover budget requests to Dr. Purdy. **(Action required)**
  - Oct. 5 ATC Teleconference: Dr. Purdy is working with Lois Smith to finalize ITC and UCD budgets. RPC to send in carryover request.

## Review of Action Items

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4. Dr. Purdy reviewed the ATC Steering Committee response with the group and will develop a response based on the feedback received. **(Action required)**
  - Oct. 5 ATC Teleconference: Dr. Purdy emailed draft to ATC members. Will finalize at ATC-COG meeting.

## Review of Action Items

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5. Dr. Palta as chair of the ATC IMRT TG to reconvene the task group and work with Drs. Jim Galvin and Ken Forrester to draft proposed credentialing requirements for the use of IMRT for intra-thoracic treatments, in which significant heterogeneities are encountered and tumor mobility is likely. **(Action required)**
  - Oct. 5 ATC Teleconference: Dr. Palta emailed updated NIH letter on IMRT guidelines. After some discussion, it was decided to change format and not use previous NIH letter format. Instead develop separate ATC guidelines that refer to NIH letter.

## Review of Action Items

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6. Drs. Bosch and Anthony Levering (ACRIN) to investigate what effort it would take to download the PET data (gray scale only with normalization) from RTOG 0522 Protocol to ITC. (Action required)
  - Oct. 5 ATC Teleconference: Dr. Bosch sent reminder to Dr. Saffer regarding data transfer trial using some phantom data.
7. Inconsistency in the definition of the target volumes in RTOG 0225: It was agreed that a task group would be formed (Dr. Michalski Chair, Dr. Lee, Dr. Garden, TBN M.D., Dr. Xia, Dr. Galvin, Dr. Purdy) to correct the written definitions. (Action required)
  - Oct. 5 ATC Teleconference: Dr. S. Narayan, UC Davis sent suggested corrections to Dr. Lee. Topic will be discussed at RTOG IGRT Committee.

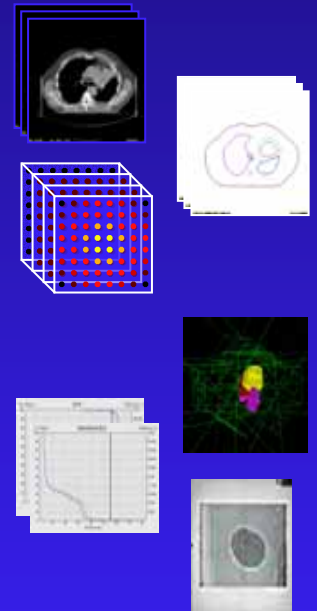
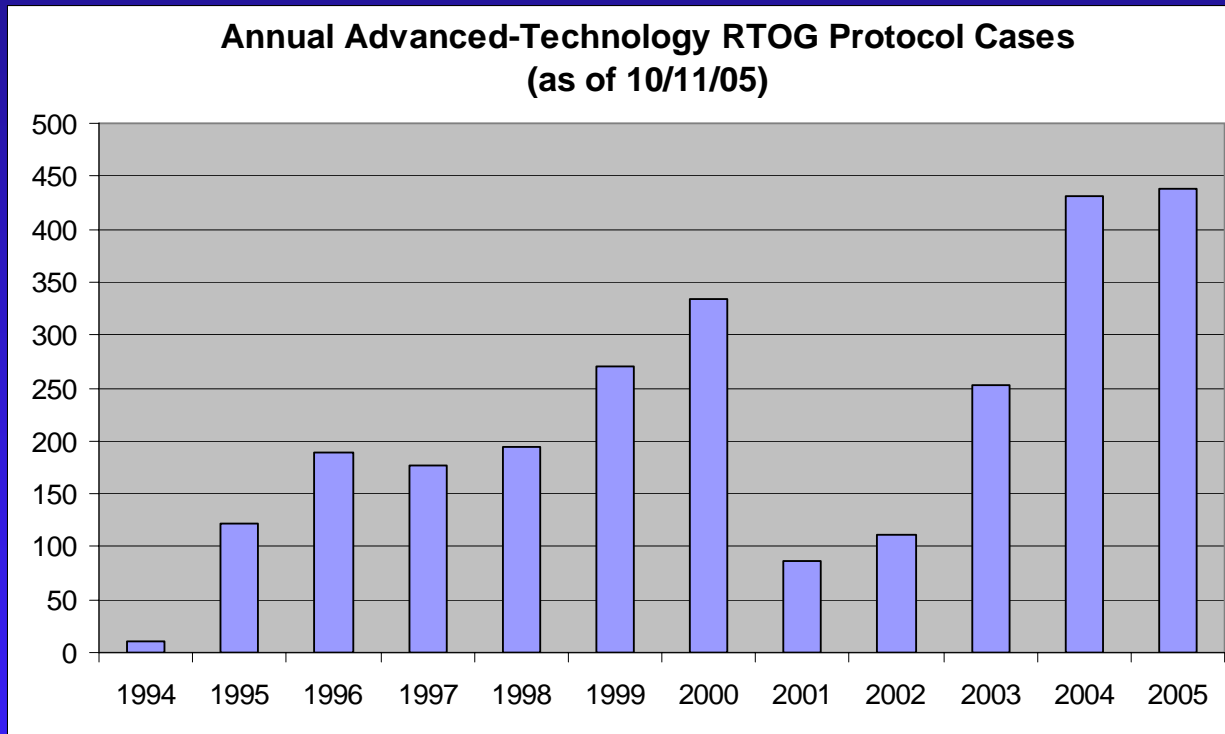


# Update on ATC Supported Protocols

Statistics below show the growth in the number of institutions with demonstrated ability to submit digital data using ATC Method 1, the cumulative number of protocol case data sets submitted, and average, weekly rate of data submission to the ITC's FTP server.

	Commercial, ATC-Compliant TPS		Institutions able to submit data	Cumulative protocol cases	Avg. Weekly FTP Uploads (4 wk avg.)
	RTOG Export	DICOM Export			
June 2004	7	4	121+	1939	1.45 GByte
Jan 2005	9	5	166	2180	1.99 GByte
June 2005	9	6	215	2441	2.94 GByte
Oct 2005	9	6	273	2618	3.57 GByte

# Oct. 11, 2005: 2618 Complete Digital Data Sets Submitted Over 11 Year Period using ATC Method 1\*



- **15 commercial RTP systems have implemented export capability (see <http://atc.wustl.edu>)**
- **273 institutions able to submit digital data**

\* as of 10/11/2005

## RTOG Digital Data Protocols (10/25/05)

Institutions  
 Credentialed

Cases Accrued

Protocol	Description	Institutions Credentialed	Cases Accrued
9406	Ph I/II 3DCRT Prostate Dose Escalation	54	1084
9311	Ph I/II 3DCRT Lung Dose Escalation	27	180
9803	Ph I/II 3DCRT GBM Dose Escalation	46	210
0022	Ph I/II 3DCRT/IMRT Oropharynx	35	69
0319	Ph I/II 3DCRT Partial Breast	31	58
0117	Ph I/II 3DCRT/chemo Lung	45	31
0126	Ph III 3DCRT/IMRT Prostate	124 (51 IMRT)	720 (133 IMRT)
0225	Ph I/II 3DCRT/IMRT Nasopharynx	36	65*
0232	Ph III Ext Beam/TIPPB Prostate	61	1571
0236	Ph II SBRT Lung	6	24
0321	Ph I/II HDR/Ext Beam Prostate	11	41
0413	Phase III Partial Breast Irradiation	171	328

ATC Supported Protocols - Microsoft Internet Explorer

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Address <http://atc.wustl.edu/protocols/rtog-devel/index.html> Go Links

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## PROTOCOLS IN DEVELOPMENT

<a href="#"><u>RTOG 0438</u></a> <i>(originally 0245)</i>	A PHASE I/II TRIAL OF HIGHLY CONFORMAL RADIATION THERAPY FOR PATIENTS WITH UNRESECTABLE PRIMARY HEPATOBIILIARY CANCER AND LIVER METASTASES
<a href="#"><u>RTOG 0415</u></a>	A PHASE III PROSTATE: RANDOMIZED CONVENTIONAL FRACTIONATION 3DCRT VS. HYPO-FRACTIONATION 3DCRT
<a href="#"><u>RTOG 0417</u></a>	A PHASE II STUDY OF AN ORAL EPIDERMAL GROWTH FACTOR RECEPTOR TYROSINE KINASE INHIBITOR (EGFR TKI) ZD 1839 (IRESSA(r)) IN COMBINATION WITH DEFINITIVE RADIOTHERAPY AND CISPLATIN CHEMOTHERAPY IN UNTREATED PATIENTS WITH LOCALLY ADVANCED CERVICAL CARCINOMA
<a href="#"><u>RTOG 0515</u></a>	A COMPARATIVE STUDY OF GROSS TUMOR VOLUME DEFINITION WITH OR WITHOUT PET FUSION FOR PATIENTS WITH NON-SMALL CELL LUNG CARCINOMA
<a href="#"><u>RTOG 0522</u></a>	A RANDOMIZED PHASE III TRIAL OF CONCURRENT ACCELERATED RADIATION AND CISPLATIN VERSUS CONCURRENT ACCELERATED RADIATION, CISPLATIN, AND CETUXIMAB (C225) [FOLLOWED BY SURGERY FOR SELECTED PATIENTS] FOR STAGE III AND IV HEAD AND NECK CARCINOMAS

Internet

Protocol 0417 - Microsoft Internet Explorer

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**RADIATION THERAPY ONCOLOGY GROUP  
RTOG 0417**

**A PHASE II STUDY OF AN ORAL EPIDERMAL GROWTH FACTOR RECEPTOR TYROSINE KINASE INHIBITOR (EGFR TKI) ZD 1839 (IRESSA(r)) IN COMBINATION WITH DEFINITIVE RADIOTHERAPY AND CISPLATIN CHEMOTHERAPY IN UNTREATED PATIENTS WITH LOCALLY ADVANCED CERVICAL CARCINOMA**

Optional Brachtherapy Imaging Study for RTOG 0417

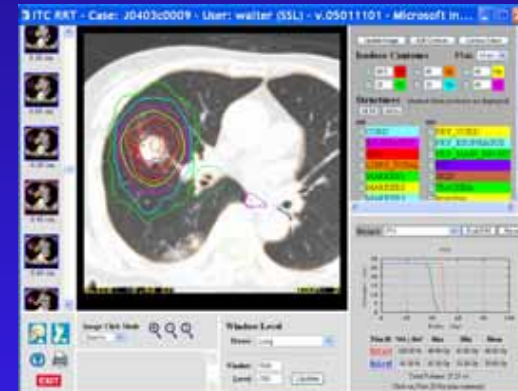
- [ATC Brachytherapy Imaging Guidelines](#) (draft, 11/19/2004)
- [Digital Data Submission Procedure](#)
- Facility Questionnaire (see [RPC](#) credentialing documents)
- [Digital Data Submission Information Form](#)
- [ATC Compliant Treatment Planning Systems](#)
- Structure Names
- [Protocol Text](#) (working draft, 8/11/2004)

[Back to developmental protocols](#)

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# Update on Interactions with JCOG

- **JCOG 0403: Phase II Study of Stereotactic Body Radiation Therapy In Patients with T1N0M0 NSCLC**
  - Institutions 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.
  - Dr. Ishikura forwards these data to the ITC for processing.
  - Data are reviewed by Dr. Ishikura or his delegate using the ITC Remote Review Tool.
  - Currently, 14 institutions are eligible to enroll patients and capable of digital data submission (42 patients registered as of 10/25/05).
  - 2nd JCOG protocol to be supported by ATC



# Update on Potential Interactions with other Cooperative Groups

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- **NABTT (Dr. John Fiveash, M.D., Department of Radiation Oncology, University of Alabama-Birmingham): will use ATC Method 1 and RPC**
- **EORTC (Bernard Davis, M.D., Univ. Hospital of Zurich contact person): will use ATC Method 1 to support EORTC 22042-26042**
- **UKCCSG Phase II Study of Prospective QA by Web-Based Review of Radiotherapy Fields in the Treatment of Standard Risk Medulloblastoma within the HIT-SIOP PNET4 Protocol (Dr. Susan Harden contact person) requested use of ATC Methods 1 and 2**

EORTC Protocol 22042-26042 - Microsoft Internet Explorer

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**EORTC 22042-26042**

**Adjuvant postoperative high-dose radiotherapy for atypical and malignant meningioma: a Phase-II and registration study**

Protocol Participation Information

- Credentialing
  - [Credentialing Requirements](#)
  - [Facility Questionnaire](#)
  - [Dry Run Guidelines](#)
- How to Participate
  - [Digital Data Submission Procedures](#)
  - [Digital Data Submission Information Form](#) (formerly T2 form)
  - [Submission Check list](#)
  - [ATC Compliant Treatment Planning Systems](#)
- QA Guidelines
- QA Scoring Criteria
- Structure Names
- Contouring Examples
- [Protocol Text](#) (study proposal, 26 Oct 2005)

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# ATC WEB SITE (<http://atc.wustl.edu>)

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News  
NCI IMRT Letter  
Digital Data Submission Info Form  
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### Advanced Technology Protocols supported by the ATC

- [RTOG Protocols](#)
- [NSABP Protocols](#)
- [JCOG Protocols](#)
- [NCIC Protocols](#)
- [COG Protocol Data Submission to QARC](#)
- [NABTT Protocols in Development](#) (requires password)
- [EORTC Protocols in Development](#) (requires password)
- [ATC-Compliant Treatment Planning Systems](#)

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## **New Business**

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- Dr. Robert D. Black, CEO/CTO, Sichel Technologies, Inc. 3800 Gateway Center Blvd., Suite 308 Morrisville, NC, 27560
  - Sichel is expecting to have the implantable dosimeter cleared by the FDA in the near future.
  - One of the most interesting aspects of the product is the vast amount of dose data that will be generated.
  - It would interesting to have a central repository for this data so that more extensive studies involving many institutions and patients could be facilitated.
  - Sichel has the ability to scrub the data so that it would be HIPPA compliant.
  - Is this something, conceptually at least, that might be a possible project for the ATC?

# **Future ATC Teleconferences and Meetings**

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- **Next Teleconference**
  - **Nov. 2, 2005**
- **Future Meetings**
  - **RTOG Semi-Annual meeting January 19, 2006**  
**Fontainebleau Hilton Resort, Miami Beach, FL**
  - **ATC Steering Committee 2006**