

RA Orientation: Participation in Advanced Technology Clinical Trials

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Advanced Technology Consortium

- Support for advanced technology clinical trials
- Digital data submission of elements necessary for review and analysis of advanced technology trials
- Coordinate Quality Assurance efforts between clinical trials quality assurance centers
- Develop uniform credentialing requirements across quality assurance centers.

The Advanced Technology Consortium for Clinical Trials QA

- **NCI Grant U24 CA 081647**
 - **Image-Guided Therapy Center (ITC – Washington University in St. Louis)**
 - **Radiological Physics Center (RPC – M.D. Anderson Cancer Center)**
 - **Radiation Therapy Oncology Group (RTOG)**
 - **Quality Assurance Review Center (QARC)**



Advanced Technology Consortium

- At this time RTOG participants need to deal with:
 - Image-Guided Therapy Center (ITC - Washington University in St. Louis)
 - Radiological Physics Center (RPC – MD Anderson Cancer Center in Houston)

Requirements for conducting multi-institutional clinical trials involving 3D imaged based planning

- Collect treatment planning data
 - Paper forms are inadequate for volumetric TP data.
 - Participants must be able to submit TP data digitally.
- Review 3D data to monitor protocol conformance
 - Volume definitions
 - Dosimetry: TV coverage, OAR avoidance
- Develop and test dose-response models
 - 3D dosimetry (including fractionation)
 - Clinical outcomes

13 RTOG Digital Data Protocols (June 22, 2006)

Protocol

Description

0117	Ph I/II 3DCRT/chemo Lung
0126	Ph III 3DCRT/IMRT Prostate
0232	Ph III Ext Beam/TIPPB Prostate

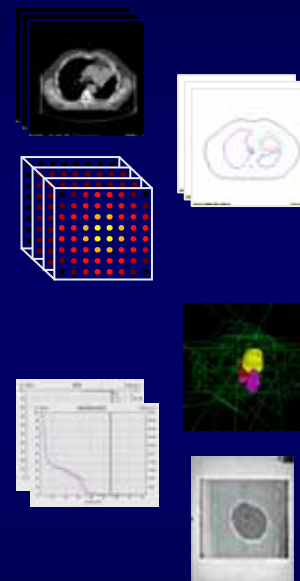
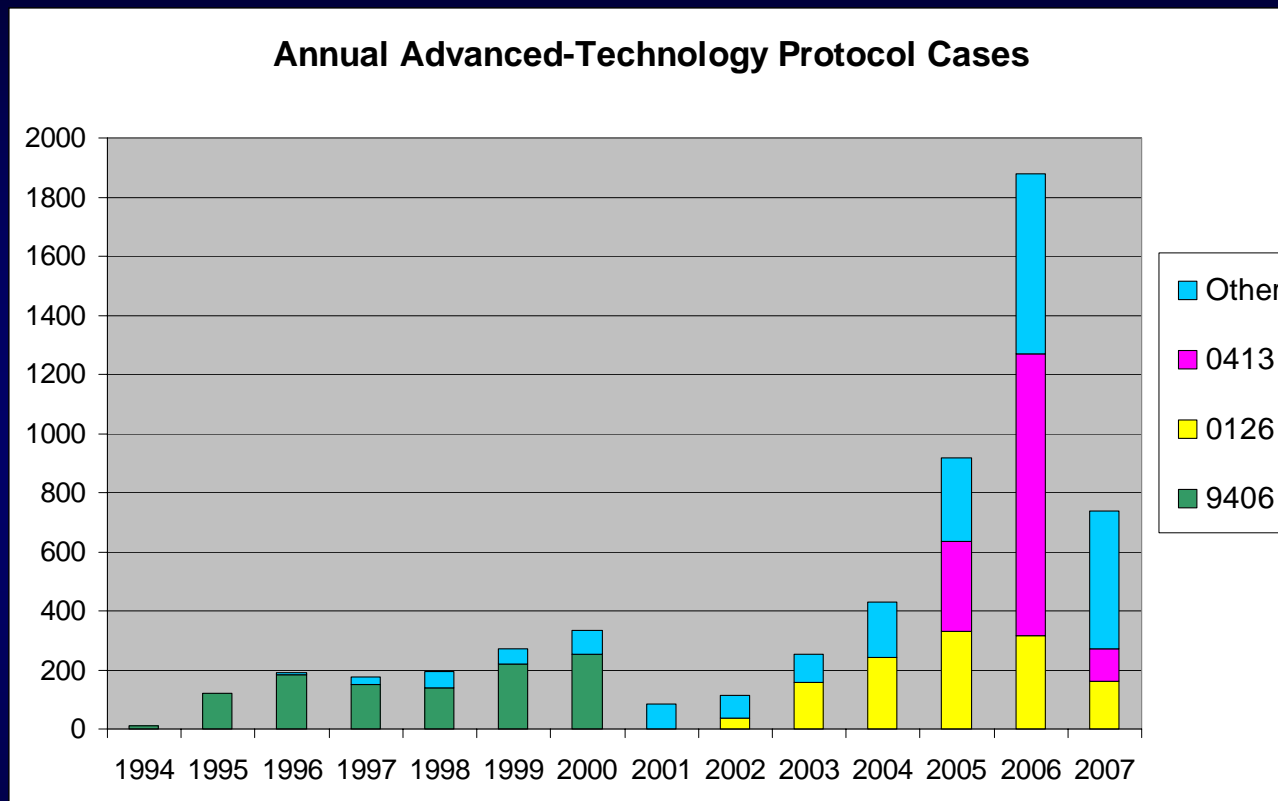
13 RTOG Digital Data Protocols (Oct , 2007)

Protocol	Description
0415	Phase III Rand Conventional Fx 3DCRT/IMRT vs Hypo Fx 3DCRT/IMRT in Prostate Ca
0418	Phase II IMRT + / - chemo for post-op endometrial or cervical Ca
0438	Phase I Unresect. Primary Bil Hepatobil. Ca & Liver Mets Extracranial Stereotactic RT
0515	Phase II NSCLC Volume definition+/- PET
0521	Phase III localized High Risk Prostate Cancer: Androgen Suppression with Radiation vs. Radiation with Chemotherapy and Prednisone
0522	Phase III Trial Comparing Radiation and Cisplatin with/without Cetuximab for Advanced Head and Neck Cancer
0529	Phase I/II Anal Cancer IMRT trial
0615	Phase I/II Nasopharynx trial
0617	Phase III Lung cancer trial

1 NSABP/RTOG ATC Supported Open Protocols (Oct, 2007)

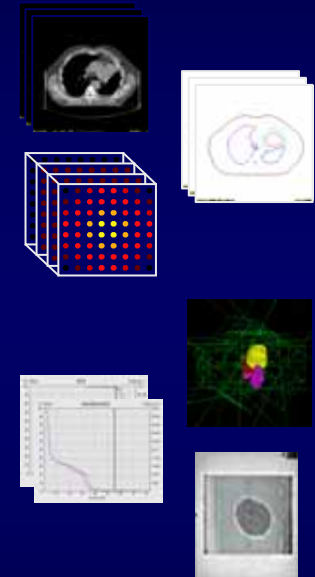
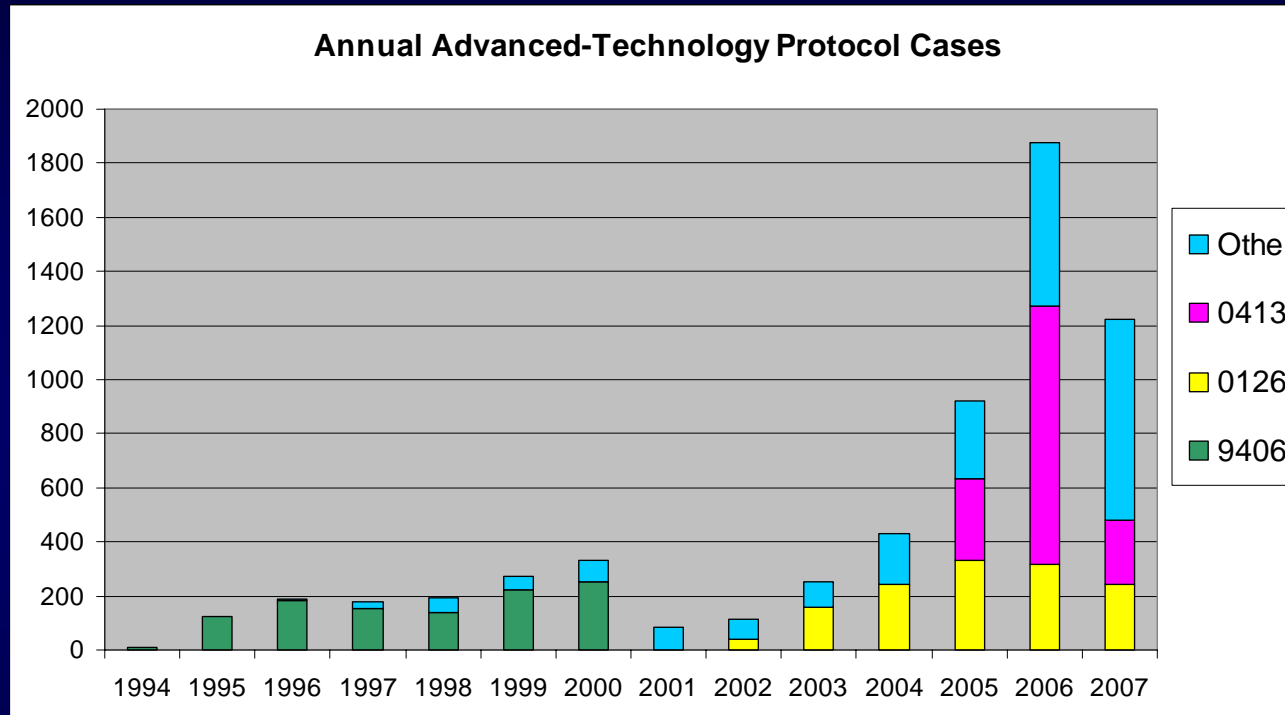
Protocol	Description	Institutions Credentialed	Cases Accrued	Accrual Goals
NSABP B39 RTOG 0413	Phase III Partial Breast Irradiation	Over 350	2800	4300

- June 12, 2007 ATC Mtg: 5706 Complete, Protocol-Case, Volumetric Digital Data Sets Submitted Over 13 Year Period using ATC Method 1



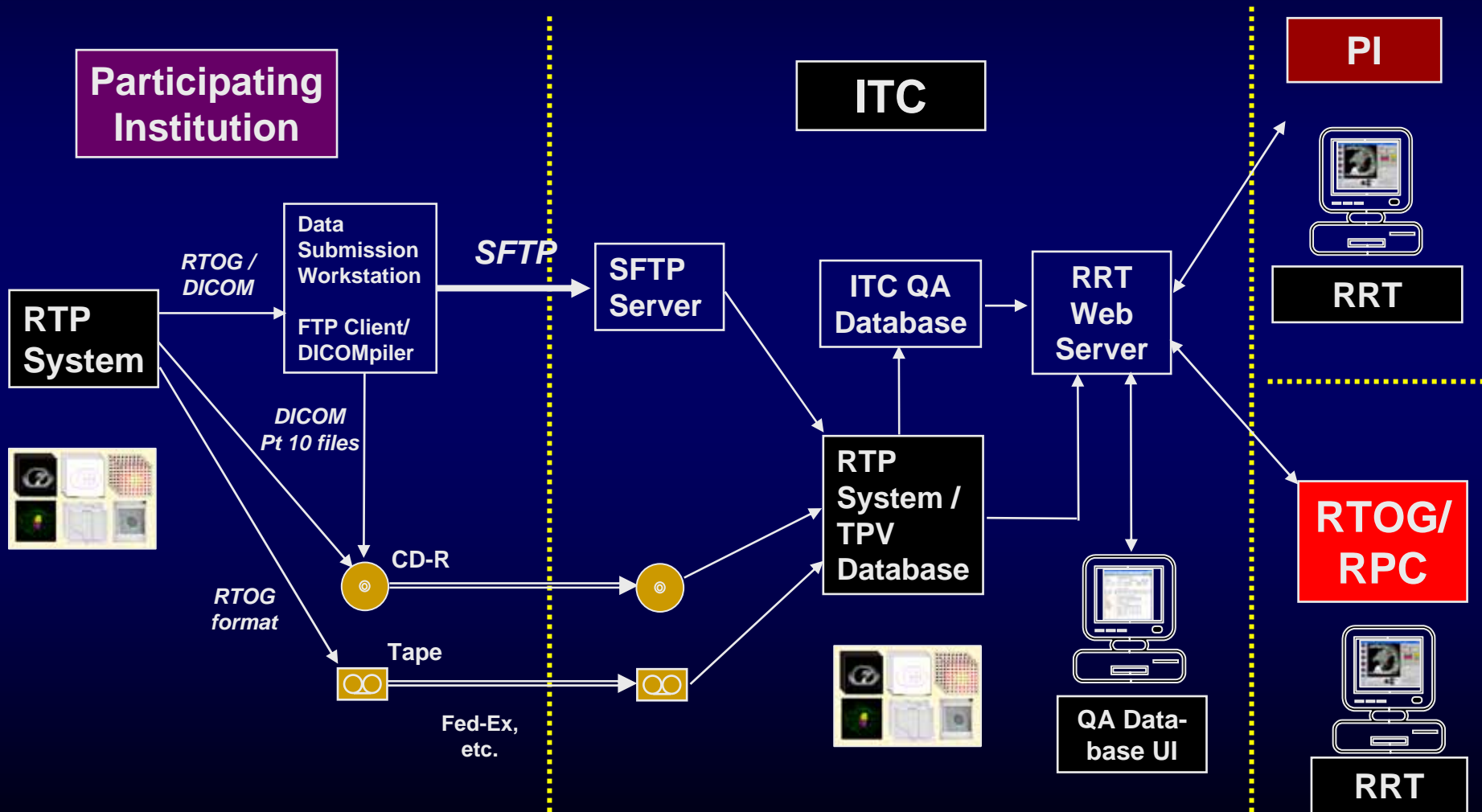
- **9 commercial TPS vendors (16 TPSs) have implemented ATC compliant export capability.**
- **523 institutions able to submit data**

- September 12, 2007 ATC Mtg: 6190 Complete, Protocol-Case, Volumetric Digital Data Sets Submitted Over 13 Year Period using ATC Method 1

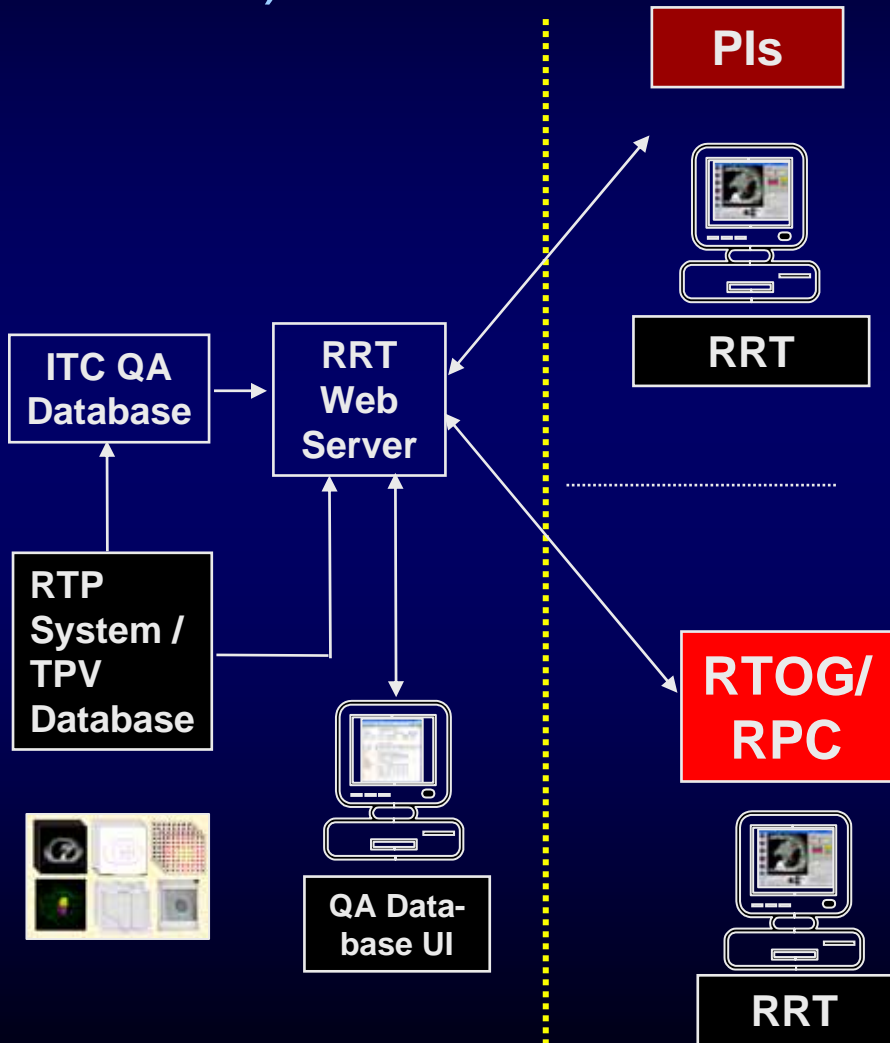


- 11 commercial TPS vendors (20 TPSs) have implemented ATC compliant export capability.**
- 536 institutions able to submit data**

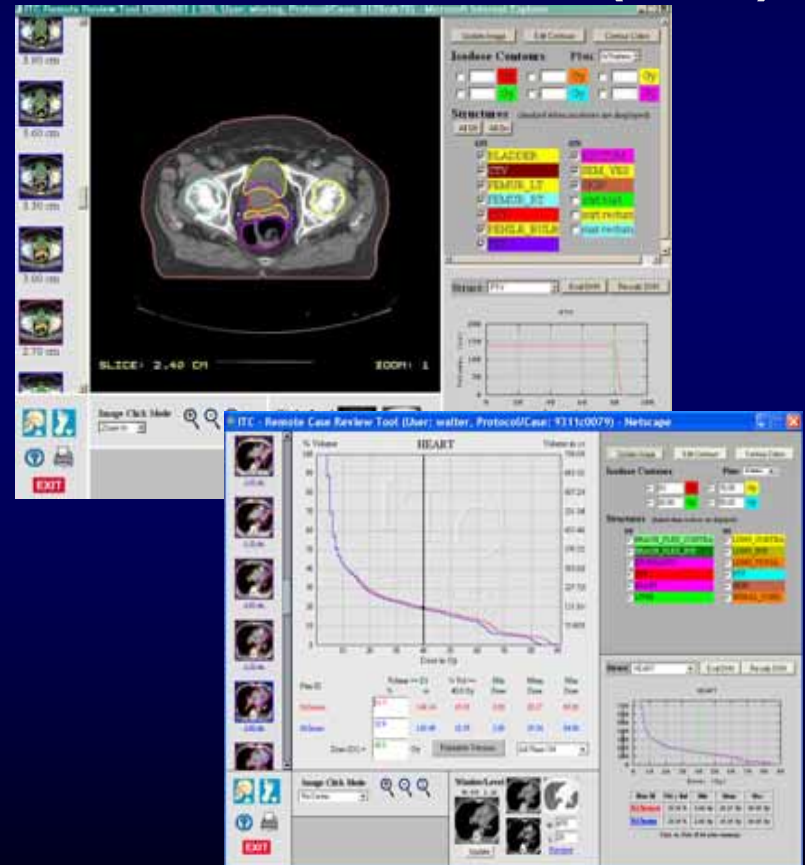
Digital Data Submission to ATC ("Method 1")



ATC Method 1: Remote QA Review (current ITC Method)



Remote Review Tool (RRT)



Commercial Treatment Planning Systems Capable of Submitting ATC- Compliant Digital Data

R = RTOG Data Exchange Format

D = DICOM RT Objects

ATC Compliant Treatment Planning Systems Per Modality

Treatment planning systems deemed to be *ATC Compliant* as of March 22, 2005 are listed in the table below. They are those with which ATC protocol participants have submitted *complete, reviewable* protocol data sets.

Vendor	Treatment Planning Systems			Treatment Modality				
	System	Version *	Exchange Format	3DCRT	IMRT	Seed Brachy	HDR Brachy	Protons
CMS	Focus/XiO	3.1	R	✓	✓	✓		
Elekta	RenderPlan 3D		R	✓				
	PrecisePlan	2.01	D	✓	✓			
Nomos	Corvus		R		++			
Nucletron	Helax TMS		R	✓	✓			
	TheraPlan Plus		R	✓				
	PLATO RTS	2.62	D	✓				
	PLATO BPS	14.2.6	D				✓	
Philips	Pinnacle ³		R	✓	✓			
	AcqPlan	4.9	R	✓				
Rosses Medical	Strata Suite CTPlan	4.0	R			✓		
RTek	PIPER	2.1.2	R			✓		
Varian	BrachyVision	6.5 (Build 7.1.67)	D				✓	
	Eclipse	7.1	D	✓	✓			
	VariSeed	7.1	D			✓		

Exchange formats for submission of ATC Protocol Data: **D** = DICOM RT Objects **R** = RTOG Data Exchange Format

ATC Website

<http://atc.wustl.edu>

ATC Advanced Technology Consortium
Providing support in quality assurance and data management for radiation therapy clinical trials

MEMBERS CREDENTIALING PROTOCOLS PUBLICATIONS RESOURCES HOME

RADIATION THERAPY ONCOLOGY GROUP

- [RTOG 0022](#) PHASE I/II STUDY OF CONFORMAL AND INTENSITY MODULATED IRRADIATION FOR OROPHARYNGEAL CANCER
- [RTOG 0117](#) PHASE I/II DOSE INTENSIFICATION STUDY USING THREE DIMENSIONAL CONFORMAL RADIATION THERAPY AND CONCURRENT CHEMOTHERAPY FOR PATIENTS WITH INOPERABLE, NON-SMALL CELL LUNG CANCER
- [RTOG 0126](#) A PHASE III RANDOMIZED STUDY OF HIGH DOSE 3D-CRT VERSUS STANDARD DOSE
- [RTOG 0225](#) A PHASE III RANDOMIZED STUDY OF HIGH DOSE 3D-CRT VERSUS STANDARD DOSE
- [RTOG 0232](#) A PHASE III RANDOMIZED STUDY OF HIGH DOSE 3D-CRT VERSUS STANDARD DOSE
- [RTOG 0236](#) A PHASE III RANDOMIZED STUDY OF HIGH DOSE 3D-CRT VERSUS STANDARD DOSE
- [RTOG 0319](#) A PHASE III RANDOMIZED STUDY OF HIGH DOSE 3D-CRT VERSUS STANDARD DOSE

[Protocols in Development](#)

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RADIATION THERAPY ONCOLOGY GROUP RTOG 0022

PHASE I/II STUDY OF CONFORMAL AND INTENSITY MODULATED IRRADIATION FOR OROPHARYNGEAL CANCER

[Protocol Participation Information](#)

- **Credentialing**
 - [Credentialing Requirements](#)
 - [Dry Run Guidelines](#)
 - [Facility Questionnaire](#)
- **How to Participate**
 - [Digital Data Submission Procedures](#)
 - [T2 Form](#)
 - [Submission Check list](#)
 - [ATC Compliant Treatment Planning Systems](#)
- [Instructions for Corvus Users](#)
- [QA Guidelines \(IMRT\)](#)
- [QA Scoring Criteria](#)
- [Structure Names](#)
- [Neck Node Atlas](#)
- [Protocol Text \(http://www.rtog.org/\)](#)

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- Facility Questionnaires
- Dry Run Test Guides
- Data submission forms
- Data submission checklists
- QA Guidelines (by protocol)
- Protocol text

Credentialing

- Facility Questionnaire
 - Modality specific
 - Trying to unify between QA centers
- Knowledge assessment form
 - Necessary for some of the protocols
- Phantom or Benchmark
 - Necessary for IMRT and SBRT protocols
 - Coordinated through the RPC or QARC
- Digital data submission test or dry run test case
 - Protocol Dependent
 - Mostly coordinated through the ITC
 - Some digital data being collected by QARC

Credentialing

- Many protocols are credentialed by the RPC
- Items may need to be sent both the RPC and the ITC.
- Examples of studies that utilize both digital data submission and RPC credentialing
 - B39/RTOG 0413 – Partial Breast irradiation study
 - RTOG IMRT studies
 - RTOG 0232 – Prostate Seed Permanent implant

DRY RUN TEST

- The Dry Run Test is intended to demonstrate:
 - Digital patient data exchange capability
- For most treatment planning systems an RPC phantom is sufficient to satisfy this requirement
- New Paradigm

Items that need to be sent with Digital Data

- Digital Data Submission Information Form
 - Filled out online on the ATC website
 - Login: atc-forms Password: submit
- Color isodoses
 - Color printouts – express mail
 - JPEG screen grabs – FTP or email
- Email to ITC notifying case was submitted

The Digital Data Submission Information (DDSI) Form

- Documents digital data submitted to ITC
 - Also provides information that can not be attained digitally
- Form may be acquired from ATC web site
- *Should not be sent until digital submission has been accomplished*
- Now only available as an online web form.

Online form requires
Login and password
Login: atc-forms
Password: submit

Form will not be accepted unless critical fields are filled in. These fields will be outlined in red if they are not filled in properly.

DDS Form - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address: https://cancer.wustl.edu/FORMS/DDS/ddsi.cgi

ATC Advanced Technology QA Consortium
Digital Data Submission
Information Form

Protocol Sponsor / Number
[Dropdown]
Case Number [Text]

SUBMISSION TYPE

Submission Category (select one)
 Initial Case / Rapid Review
 Protocol Case
 Bench Mark / Dry Run Submission
 Phantom Experiment

Submission Type (select one)
 Initial
 Final
 Correction

CONTACT INFORMATION

Institution Name [Text]
 Institution RTOG # (if applicable) [Text]
 Institution NSABP # (if applicable) [Text]

Patient Initials [Text]
 Institution RTF # (Look up RTF#) [Text]
 Institution NCI # [Text]

Personnel Involved with Protocol Patient

	Physician	Physicist	Dosimetrist	Research Associate
Name	[Text]	[Text]	[Text]	[Text]
Phone	[Text]	[Text]	[Text]	[Text]
Fax	[Text]	[Text]	[Text]	[Text]
Email	[Text]	[Text]	[Text]	[Text]

SUBMISSION DETAIL

Submission Method
 FTP
 Media

Dose Delivered Via
 3D Conformal RT
 IMRT
 SBRT
 TIPPB
 Multi-Catheter Brachytherapy
 Mammosite(r)

Dose Prescription (Protocol Specific) [Text]
 Data Directory Name (for FTP) [Text]

First Treatment Date (Date of Implant) [Dropdown] [Dropdown] [Dropdown] 2005

Done

Case Reviews

- Multi-faceted review process including PIs from protocol and their designates, Dosimetrists from RTOG and RPC, and ITC personnel.
- Three (3) Business Days are allowed for a Rapid Review Case (Case that requires approval prior to treatment start)

Case and Credentialing Review

- If data is received and able to be reviewed the institution will not hear back from the ITC
- Need to allow 3 business days for Rapid Reviews (Reviews requiring approval prior to treatment).
- Approximately 50% of the rapid reviews require resubmission.
- Notification regarding rapid reviews will come from a PI or study chair

How to submit digital data to the ITC

- Secure File Transfer Protocol - SFTP
 - Request SFTP account – email to ITC@wustl.edu
 - Include Institution name, address, and contact phone number
 - ITC now using SFTP (Secure FTP) – important to use FTP client software which allows SFTP transmission
- Media
 - Send media by express mail to ITC in St. Louis
 - Media accepted – CD or 4 mm DAT tape

How to submit digital data to the ITC

- Request SFTP Account by email to:
ITC@castor.wustl.edu
 - Include Institution name, address, and contact phone number (Physicist & RA), RTF #
 - ITC now using SFTP (Secure FTP) – important to use FTP client software which allows SFTP transmission
- Media
 - Send media by express mail to ITC in St. Louis
 - Media accepted – CD or 4 mm DAT tape

Instructions for Digital Data Submission

Advanced Technology Consortium - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Web Search Bookmarks Settings Mail My Yahoo! Answers Games Yahoo! Anti-Spy

mywebsearch Search Zwinky Smiley Central Screensavers Cursor Mania

Address http://atc.wustl.edu/ Go

Washington University School of Medicine ADVANCED TECHNOLOGY CONSORTIUM

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MEMBERS CREDENTIALING PROTOCOLS PUBLICATIONS RESOURCES HOME

About the ATC
Cooperative Groups
How to participate
Contact Us
News
Upcoming Events
NCI IMRT Letter **NEW**
Secure Upload to ITC
Data Items to Submit to ITC
Request for ATC data by investigators
ITC Tools
Digital Data Submission (DDS)

PLEASE READ - Important Information for Protocol Participants
Uploading Digital Data to ITC **UPDATED (12/19/06)**

http://us.lrd.yahoo.com/_ylc=X3oDMTEybnBhcTRzBF9TAzMS5NJU0NTEwNWRzZWMDdGJfc2VjBHNsawN0Y9zbG/-/SIG=10uec0tra/**http%3a//answers.

Internet

Procedures for digital data submission

Changes in Uploading Digital Data to ITC - Microsoft Internet Explorer

File Edit View Favorites Tools Help

mywebsearch Web Search Bookmarks Settings Mail My My Yahoo! Answers Games Yahoo! Anti-Spy

Search Zwinky Smiley Central Screensavers Cursor Mania Address http://atc.wustl.edu/home/news/SFTP. Go

About the ATC

- Cooperative Groups
- How to participate
- Contact Us
- News
- Upcoming Events
- NCI IMRT Letter **NEW**
- Secure Upload to ITC
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- Request for ATC data by investigators

ITC Tools

- Digital Data Submission (DDSI) Online Form
- ITC Remote Review Tool

Supported by the National Cancer Institute

Uploading Digital Data to ITC **UPDATED (12/19/06)**

Changes in ITC's network configuration have necessitated a transition from FTP to Secure FTP for all protocol participants uploading digital data to the ITC. Secure FTP (SFTP) uses the SSH network protocol and offers several advantages over FTP, including secure (encrypted) transport of usernames, passwords, and data, and compatibility with most firewall configurations.

Please note:

- **The old ITC FTP server (castor.wustl.edu) is no longer in service.** All network digital data submissions to ITC must use the new, Secure FTP server, **ITCsubmit.wustl.edu** (IP address 128.252.17.87).
- User names and passwords for SFTP are the same as those used for FTP.
- [Instructions for configuring SFTP clients](#) (WS FTP Pro, Filezilla, WinSCP3, and Linux sftp) **UPDATED (6/14/06).**
- Problems in connecting to the ITC SFTP server, may be caused by your institution's **firewall configuration**. An outbound connection from your computer to **TCP Port 22 on host ITCsubmit.wustl.edu** is required. (Although allowing such a connection is safe, it is sometimes disallowed by default.) Please consult you local firewall/network administrator.
- For many users, the SFTP upload procedure is essentially the same as for FTP, except that a new SFTP client may be needed. SFTP client software, both commercial and open-source, is broadly available. Windows clients include [WS FTP Professional](#) (commercial), [FileZilla](#) (free/open-source) and [WinSCP](#) (free/open-source). For Linux systems, both graphical (gftp) and command-line (sftp) programs are included with most distributions.

Done Internet

Where Do I Get More Info?

- ATC's Web Site
 - <http://atc.wustl.edu>

These slides
and handouts
can be found

here



Contact ITC with Questions

- Use <http://atc.wustl.edu> for information about what, when, and how to submit data to the ITC.
- Contact information:

Roxanna Haynes (314) 747-5415

Anna Eccher (314) 747-5421

Bill Straube (314) 362-9762

email questions to:

itc@wustl.edu

