## **ITC Status Report**

June 22, 2006

### Walter R. Bosch, D.Sc.





## **ITC Status Report**

- ITC / WUCON Network Re-configuration
- Credentialing Events Database
- ITC Data Security Policy / 21CFR11 Compliance
- ATC Compliant Treatment Planning Systems
- IHE-RO Effort

## ITC / WUCON Network Re-configuration

- 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.

ATC • AdvancedTechnologyConsortium Providing support in quality assurance and data management for radiation therapy clinical trials

## **ITC WUCON Transition Timeline**

#### DATE MILESTONE

- Jan Network transition plan developed
- Feb SFTP server testing with institutional volunteers
  - "Reality check" on submission procedures, firewall policies, technical support issues.
  - Ten clinical physicists (representing a variety of institutions and TPS) were invited to submit data using prototype SFTP server.
  - Seven submitted data and reported on their experience.
  - No significant problems reported.
- Mar Submission procedures updated
- Apr Broadcasts to RTOG, NSABP institutions and on ATC web site
- May 23 New ITC mail server / ATC web server installed
- May 27-29 New SFTP server / RRT server installed; ITC desktops and internal servers migrated to WUCON
- July Existing internet connectivity to be disconnected

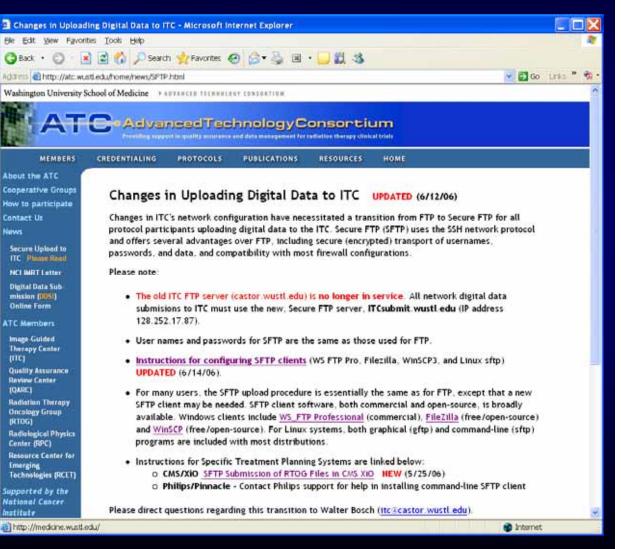
# **Anticipated Issues**

- Replacement for FTP clients on TPS platforms
  - Integrated FTP submission mechanism in TPS (XiO)
  - Command-line client on TPS platform (Pinnacle)
- Users
  - Acquire and configure SFTP clients
  - Make workflow changes in data submission
- Manufacturers
  - Provide alternative SFTP client software
  - Help with alternative workflow and submission procedures

#### ATC AdvancedTechnologyConsortium Providing support in quality assurance and data management for radiation therapy clinical trials

## Information Provided on ATC Web Site

- SFTP server name (ITCsubmit.wustl.edu) and IP address.
- Links to open-source SFTP client software
- Configuration guide for SFTP clients
- Instructions for users of specific treatment planning systems.



## Secure Web Server

- Currently shares hardware with SFTP server
- Distinct hostnames will allow future move to separate hardware, if necessary:
  - ITCsubmit.wustl.edu SFTP
  - ITCreview.wustl.edu HTTPS (RRT, etc.)
- New secure certificate for ITCreview.wustl.edu
- Supports
  - Remote Review Tool
  - Online Forms (DDSI, Facility Questionnaires, JCOG Data Submission Form)
  - Secure Download of Digital Data

## **Remote Review Tool**

- New URL: <u>https://itcreview.wustl.edu/Review/RRT/rrt.html</u> (Use link on Resources page of ATC web site.)
- The ITC Remote Review Tool has been implemented with a new architecture:
  - Secure web server in network DMZ (public IP address, limited network ports)
  - Data server (NFS) in private network
- Minor issues in current configuration
  - Data cache on web server (~30s delay for copying data on first access only)
  - Importing user-edited contours for general use requires manual intervention.

### Please wait while data files are copied to the RRT server.

Copying will take approximately 28 seconds.

# Access to CMS/FOCAL Via VPN

- CMS/FOCAL is being developed for
  - Multi-modality image fusion (PET/CT, MR/CT, etc.)
  - 3D Plan review
- Data Import
  - DICOM RT / RTOG Data Exchange treatment planning data imported via ITC software
  - DICOM images files (CT, MR, PET) imported directly into FOCAL
- Reviewer Access
  - ITC Citrix Server gives ITC users access to FOCAL tools.
  - Work is in progress to provide access for selected users via WUCON VPN.

# **Remaining Network Issues**

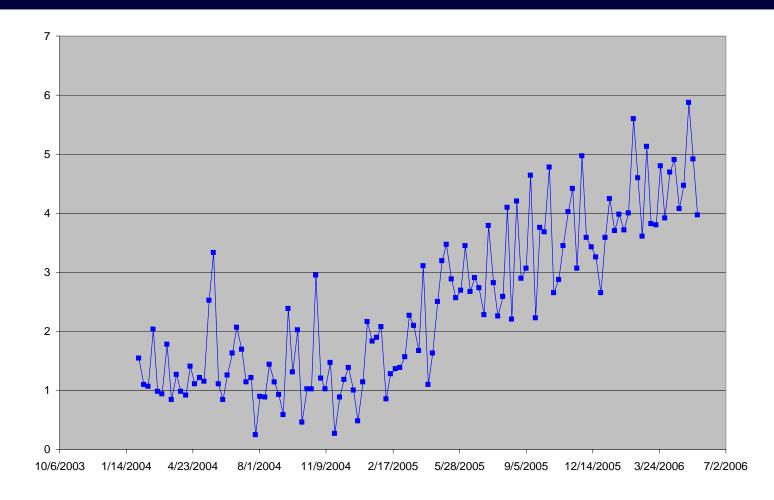
- ITC Access to ATC Review Workstations
  - Outgoing network connections from ITC now originate from different IP addresses.
  - Access to workstations at RTOG, QARC has been restored.
  - Problems remain in connecting to workstation at RPC.

## Lessons Learned

- 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 substantially more dependent on them to diagnose problems.
- This network transition has been costly in ITC effort in the short term.

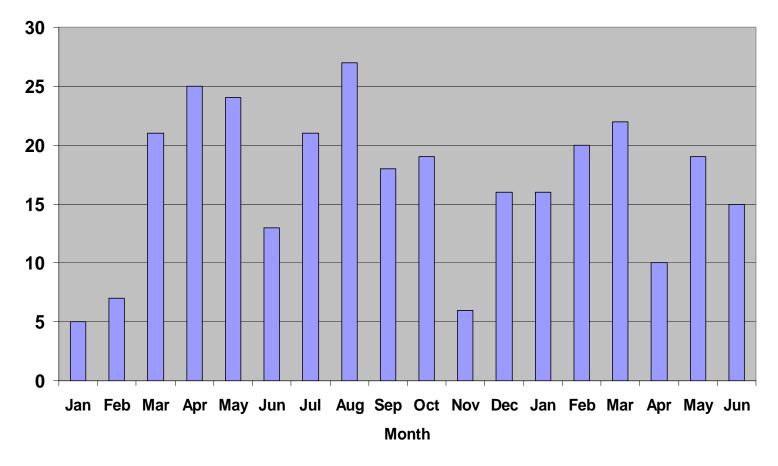
#### ATC • AdvancedTechnologyConsortium Providing support in quality assurance and data management for radiation therapy clinical trials

### ITC Data Submission Rate (Gbyte/week)











## ITC QA Events Database

- Track dates and status of QA process steps performed at ITC
- In use since Jan 2005.

📧 ITC QA Event	5						
	als QA	Version 04122701					
Sponsor	RTOG  Data_Inventory_Complete 5/20/2 Sent_for_OARTV_Review 6/9/20						
Protocol	0126 OARTV_Review_Complete	og gent					
Case	Sent_for_DVA_Review       220       VA_Review_Complete						
Institution	TORSB						
Event Reviewer Requested by Comment	Data_Inventory_Complete rjh rjh						
Modified by Modified date	haynes 1/7/2005 1:25:16 PM						

## Credentialing Events Report

Example: QA Events Report for RTOG 0413

ase	Institution	Registration	Data Rev'd	DVA Sent	DVA Done	PI Sent	PI Done	DVA Pending	PI Pending	DVA days	PI day
2	WMBH	3/23/2005	3/29/2005	3/29/2005	3/29/2005	3/29/2005	3/29/2005	-1		0	C
3	UCOLHS	4/7/2005	4/11/2005	4/11/2005	4/11/2005	4/11/2005	4/11/2005	-	-	0	C
5	WMBHTr	4/18/2005	4/19/2005	4/19/2005	4/20/2005	4/20/2005	4/20/2005	÷	-	1	0
7	WMBH	4/25/2005	4/29/2005	4/29/2005	4/29/2005	4/29/2005	4/29/2005	÷	-	0	(
9	AOS	4/27/2005	5/5/2005	5/5/2005	5/6/2005	5/6/2005	5/6/2005	÷	-	1	(
13	WMBH	5/3/2005	5/12/2005	5/16/2005	5/16/2005	5/16/2005	5/16/2005	2	20	0	
16	WMBH	5/6/2005	5/12/2005	5/16/2005	5/25/2005		5/25/2005	2		9	12
18	AOS	5/10/2005	5/17/2005	5/17/2005	5/18/2005	5/17/2005	5/18/2005	2	28	4	29
20	CONHNH	5/12/2005	5/17/2005	5/17/2005	5/19/2005	5/19/2005	5/19/2005	2	<u>⊈</u> ;	2	1
21	WMBH	5/13/2005	5/20/2005	5/23/2005	5/23/2005	5/23/2005	5/23/2005	2	<u>4</u> 5	0	1
22	WMBH	5/16/2005	6/2/2005	5/25/2005	5/25/2005	6/2/2005	6/2/2005	2	¥3	0	1
25	WMBH	5/17/2005	5/20/2005	5/23/2005	5/23/2005	5/23/2005	5/23/2005	2	<u>2</u> 4	0	
29	DMCSPC	5/17/2005	5/27/2005	6/1/2005	6/1/2005	5/31/2005	6/1/2005	2	<u>1</u> 4	0	E
30	WMBH	5/18/2005	5/20/2005	6/16/2005	8/24/2005	6/16/2005	8/24/2005	2	<u>1</u> 24	69	6
33	MKDOGD	5/25/2005	5/25/2005	5/25/2005	5/27/2005	5/26/2005	5/27/2005	2	56	2	8
34	WMBH	5/26/2005	6/10/2005	6/10/2005	6/13/2005	6/10/2005	6/13/2005	2	75	3	8
35	STNFRD	5/31/2005	6/3/2005	6/6/2005	6/6/2005	6/6/2005	6/6/2005	2	25	0	2
38	WMBH	6/3/2005	6/10/2005	6/10/2005	8/24/2005	8/24/2005	8/24/2005		78	75	
39	ERLANG	6/3/2005									
40	HOACNY	6/3/2005	6/7/2005	6/7/2005	6/8/2005	6/8/2005	6/8/2005		78	1	1
42	CCSTAG	6/6/2005	6/10/2005	6/10/2005	6/10/2005	6/10/2005	6/10/2005	-	55	0	1
43	UAB	6/7/2005	6/8/2005	6/8/2005	6/8/2005	6/8/2005	6/8/2005	-	55	0	9
44	BRYNPA	6/8/2005	6/14/2005	6/15/2005	6/15/2005	6/15/2005	6/15/2005	-	5	0	1
45	WBI	6/8/2005									
46	ROSPRK	6/9/2005									

# ITC Credentialing Events Database

- Sequence of credentialing steps per protocol (e.g., for NSABP B-39/ RTOG 0413)
  - 1. Start
  - 2. Digital data submitted
  - 3. DDSI submitted
  - 4. Color isodoses submitted
  - 5. All data received
  - 6. Digital data review ITC
  - 7. Sent to RPC for review
  - 8. ITC process complete
  - 9. Finished
- Status (success/failure)
- Date
- Comment



# ITC Standard Operating Procedures

- Anna Eccher joined ITC staff in April 2006 as Dosimetry Data Coordinator.
- She working with Roxana Haynes to learn data processing procedures and is reviewing and revising SOP documents as she learns the procedures.

#### ATC • Advanced Technology Consortium

Providing support in quality assurance and data management for radiation therapy clinical trials

### ITC Standard Operating Procedures

- ITC internal Wiki used to maintain SOP documents.
- Data Processing Procedures
  - General procedures for all protocols (complete)
  - Protocolspecific procedures (work in progress)



#### ITC Standard Operating Procedures

 Example: Registration of New Case in ITC Database and Chart

#### 4.0 Procedures

Providing support in quality assurance and data management for radiation therapy clinical trials

ATC • Advanced Technology Consortium

#### 4.1 Case registration is sent via email from the cooperative group.

• Print a copy of this email for the case chart.

#### 4.2 Locate ITC Code for Institution entering case.

#### 4.3 Log case registration into ITC QA Database.

- 1. Use study number, e.g. 0413 and Click on box SELECT NEW CASE
- 2. Enter the following case attributes:
  - o Protocol case number
  - o Patient initials
  - o Physician name
  - o ITC code for Institution entering case
  - o Registration Arm of Treatment

#### 4.4 Prepare a study folder to contain the case chart.

- Use appropriate folder, e.g. Hot Pink used for 0413.
- Print an adhesive label and attach it to the folder. Use the format \*0413c0024\*, where
  o 0413 is the protocol number,
  - o c signifies case (separates protocol and case numbers), and
  - o 0024 is the case number.

#### 4.5 Log case registration into the ITC Event tracking database.

Make sure to designate the case as Rapid Review or Timely Review, as appropriate.

4.6 If this case is a *Rapid Review* (an Institution's first case on a given treatment modality), send the following or similar note to the Institution via email:

"You have registered a case on B39/0413 which is the first case registered by your institution for the modality you are planning on using for this patient. Please note that this

ATC AdvancedTechnologyConsortium

## Timeline for Documenting ITC Data Security

- 5/30/2006 SOP draft documents
  - Standard Operating Procedures
  - 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

ATC AdvancedTechnologyConsortium Providing support in quality assurance and data management for radiation therapy clinical trials

ATC Compliant	Treatment Planning Systems			Exchange	Treatment Modality					
ATC Compliant Treatment	Vendor	System	Version <sup>*</sup>	Format	3DCRT	IMRT	Seed Brachy	HDR Brachy	Protons	
	<u>CMS</u>	Focus/XiO	3.1	R	$\checkmark$	$\checkmark$	$\checkmark$			
Planning	<u>Elekta</u>	RenderPlan 3D		R	~					
Systems		PrecisePlan	2.01	D	$\checkmark$	$\checkmark$				
(as of June 22, 2006)	<u>Nomos</u>	Corvus		R		++				
	<u>Nucletron</u>	Helax TMS		R	1	$\checkmark$				
		TheraPlan Plus		R	$\checkmark$					
		PLATO RTS	2.62	D	1					
D DICOM DT Objecte		PLATO BPS	14.2.6	D				$\checkmark$		
<b>D</b> = DICOM RT Objects	<u>Philips</u>	Pinnacle <sup>3</sup>		R	1	1				
R = RTOG Data		AcqPlan	4.9	R	1					
Exchange Format	<u>Rosses</u> <u>Medical</u>	Strata Suite CTPlan	4.0	R			1			
	<u>RTek</u>	PIPER	2.1.2	R			1			
	<u>Varian</u>	BrachyVision	6.5 (Build 7.1.67)	D				1		
		Eclipse	7.1	D	$\checkmark$	$\checkmark$				
Bosch – June 2006		VariSeed	7.1	D			~			

### ITC Work With Vendors/Users Toward ATC Compliance

- 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 yet 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 11May2006 (CT, RS, RP, and RD). Only the CT was readable 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.
- ITC has received TomoTherapy Hi-Art digital data from UC Davis using Tomo Research Workstation and is reviewing for ATC compliance.

## IHE-RO Technical Committee Meeting April 24-28, 2006 at ITC, St. Louis, MO

#### Topics addressed

- Review of Draft Transactions Document for 2006 demonstration
- Plans for 2006 Connectathon and Test Tools
- Scope of Work for 2007
  - Extension of RT Plan object (IMRT, electrons)
  - Image registration
  - Treatment delivery scheduling
  - Data Retrieval (DICOM Query/Retrieve) for RT objects