

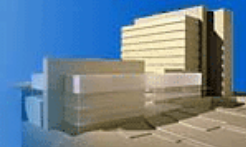
NCIC Report on the Use of ATC Method 3 and Experience Implementing Method 2B

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Institut national du cancer du Canada

Clinical Trials Group
Groupe des essais cliniques



Overview

- Method 3 and MA.20
 - Accruals and Credentialing
 - Progress over last 6 months
- Method 2B
 - Goals
 - Pilot Project & RAPI D study
 - Progress over last 6 months



Method 3 and MA.20

- Scanned and screen captured images
- NetSys_Image_Scanner
- Rapid Review using Java Applet



Total Accrual from 1999-Dec-14 to 2006-Jun-21

Centre	Hospital	Total Accrual
CAMN	Sunnybrook Health Sciences Centre	210
CAGH	Centre hospitalier universitaire de Sherbrooke	155
CALM	Juravinski Cancer Centre at Hamilton Health Sciences	152
AUXT	Trans-Tasman Radiation Oncology Group	149
CAMP	Univ. Health Network-Princess Margaret Hospital	124
CAHN	CHUM - Hopital Notre-Dame	103
CAGQ	CHUQ-Pavillon Hotel-Dieu de Quebec	100
USXU	Cancer Trials Support Unit	88
CATW	Cross Cancer Institute	86
CAVV	BCCA - Vancouver Island Cancer Centre	75
CANL	London Regional Cancer Centre	65
CATC	Tom Baker Cancer Centre	50
CAVA	BCCA - Vancouver Cancer Centre	40
CABN	QEI Health Sciences Center -	38
CAHC	McGill University - Dept. Oncology	32
CAKO	Ottawa Health Research Institute - General Division	31
CAPT	Northwestern Ontario Regional Cancer Centre	27
CAPN	Northeastern Ontario Regional Cancer Centre	24
CAER	Dr. Leon Richard Oncology Centre	21
CARM	CancerCare Manitoba	20
CAVF	BCCA - Fraser Valley Cancer Centre	20
CANG	Grand River Regional Cancer Centre	10
CASS	Saskatoon Cancer Centre	10
CALC	Niagara Health System	9
CAAJ	Dr. H. Bliss Murphy Cancer Centre	6
CAEJ	Atlantic Health Sciences Corporation	5
CAGS	CHA-Hopital Du St-Sacrement	0
CASA	Allan Blair Cancer Centre	0

TOTAL: 1650

MA.20 Accrual Required: 1787

	13-Jun-2005	18-Jan-2006	21-Jun-2006
Canadian	1171	1312	1413
CTSU	52	79	88
TROG	92	124	149
Total	1315	1515	1650
Institutions credentialed for electronic submission	3 + 5 in-progress	8 + 2 in-progress	10 + 3 in-progress
Registered Users	?	38	42
Electronic Submissions	?	27	43
Remaining accruals	472	272	137



MA.20 Progress

(17-Jan to 21-Jun-2006)

- Meetings:
 - weekly ROQAC MA.20
 - semi-annual NCIC CTG
- Credentialed centres
 - 2 more, 3 in-progress, 1 or 2 in-hibernation
- 4 more registered users
- 16 submitted cases
- 'Firewall' problems at a couple of centres
- Electronic Submission manual is 'too dense'



Method 2B Goals

- Upload and Download using WebSys
 - Dicom formatted CT studies
 - Dicom-RT formatted Structures, Plan, DRR, Dose, DVH
 - Added later: scanned images (JPG, BMP, TIFF)
- Passive 3D Review using NetSys
 - No editing of contours
 - No recalculation of DVHs
- Rapid Review using RR Applet ?



Pilot Project

- Draft Requirements
- Pilot Project Team Members
 - Wayne Beckham, Victoria (Eclipse)
 - Orest Ostapiuk, Hamilton (Pinnacle)
 - Colin Field, Edmonton (Eclipse, Helax, Tomotherapy)
- Investigating use of Wiki for manuals and documentation



QA support for RAPID study

Randomized Trial of Accelerated Partial Breast Irradiation

RAPID

A multi-centre randomized trial to determine if accelerated partial breast irradiation, utilizing 3D-CRT, is as effective as whole breast irradiation following breast conserving surgery in women with ductal carcinoma in situ or invasive breast cancer with negative axillary lymph nodes

- NCIC CTG commitment to support QA
- Support for Physician credentialing
 - 4 training cases
 - 3 test cases



Method 2B Progress

(17-Jan to 21-Jun-2006)

- Meetings
 - Gainsville meeting, March 31-April 1
 - NCI C CTG Spring Meeting, April 28-30
 - Weekly NCI C CTG & RCET teleconferences
 - Pilot Project team teleconferences
- ICTR 2006 conference
 - Interest from Germany, Italy, UK, Australia



Method 2B Progress - Software Testing

- WebSys 2.4.+
 - Eclipse interoperability problems
 - Phantom export / import
 - Copying of structures from one data set to another
 - 3D volume and export of original CT slices
- NetSys 4.0
 - Bugs identified
 - New version to be tested
- Rapid Review Applet
 - Limitations with viewing structures, beams, doses
- Robust Installers
 - remove previous versions, caches, applets, etc



Summary and Conclusion

- Method 3 and MA.20
 - Electronic submission is ticking along slowly
 - Accrual is almost complete
- Method 2B
 - needs more testing of WebSys, NetSys, and RR Applet with different TPSs and different planning techniques
 - Pilot Project team is ready to go
 - RAPI D protocol needs NCI C CTG support now !



Questions





MA.20 Goals (July to December, 2005)

Goal	Status
Encourage rapid & final reviews for credentialed institutions	<ul style="list-style-type: none">• Rapid reviews: 1• Final reviews: 22 + 11?
Educate submitting institutions <ul style="list-style-type: none">• Assistance with credentialing	<ul style="list-style-type: none">• 3 hr MA.20 Workshop 22-Oct-05 Montreal, attended by Jatinder and Vincent• CARO poster, Sep-05
Credential more institutions <ul style="list-style-type: none">• Canadian institutions• Identify top accruing centres to MA.20 from the US• Australia	<ul style="list-style-type: none">• focusing on Canadian centres (increased from 3 to 8)
Develop distributed and redundant personnel infrastructure to review technical and clinical dry runs	<ul style="list-style-type: none">• 4 Volunteer Dry Run Technical reviewers• Reviewing centres performing Dry Run Clinical review



ROQAC Goals (July to December, 2005)

Goal	Status
Pilot Project to re-evaluate submission of Dicom-RT and RTOG data objects to NCIC CTG Data Warehouse (Method 2B)	3D Pilot Project teleconference 29-Sep-2005 Waiting for installation of NetSys v 4.0
Develop QA goals for NCIC CTG for next 5 years (e.g. 'Vision Statement')	Being circulated to CTG Executive
Establish guidelines to access NCIC CTG Data Warehouse for non-NCIC sponsored trials	In progress
Grant application with ATC/RCET to provide continued support and development of infrastructure & operating procedures (hardware, software, personnel) at NCIC CTG	In progress (slowly)



Method 2B Development Task	Who	Jun-05 Timeline	Status
Select NCIC CTG protocol to test Method 2B	ROQAC & PIs	Now	• done: ABPI
Develop QA Process <ul style="list-style-type: none"> • QA requirements, tool specification • Personnel: Physics & dosimetry 	ROQAC & protocol PIs	Now	• in progress
Preliminary <ul style="list-style-type: none"> • Install latest version of WebSys & NetSys • Develop general users manual 	RCET & NCIC CTG ROQAC	Aug-Sep05	• in progress • waiting
Develop NCIC CTG Credentialing Process <ul style="list-style-type: none"> • Dry Run, phantom?, technical, clinical review 	ROQAC (with support of ATC)	Ongoing	• action needed (ala MA.20)
Pilot Study <ul style="list-style-type: none"> • Identify 'test' centres • Perform study for specific protocol with defined QA requirements 	Ask for volunteers ROQAC NCIC CTG	Oct/Nov-Dec05	• Victoria, Edmonton, Hamilton • on hold for NetSys v4.0
Estimate costs & identify funding sources (core support, protocol specific)	NCIC CTG RCET	???	• action needed
Identify & Fix problems <ul style="list-style-type: none"> • RCET? Kingston? 	Digital Data sub-committee, RCET, NCIC CTG	Oct05 to Feb06	• on hold for NetSys v4.0



Questions

- Old Questions
 - How will new and old database formats be merged ? E.g. How will MA.20 data be merged into new database structure ?
Is this an RCET concern ?
 - How are software changes made to RCET software in Kingston, Gainesville, and St Louis merged ?



- **User Permissions SOP**

- Standard Procedure for assigning/revoking user accounts and permission groups to the RCET production and test websites
- Standard Procedure for granting access to the RCET production and test servers
- Standard Procedure for usage of RCET user account at participating center
- Standard procedure for password aging system

- **User Permissions Work Instructions**

- Step by step Work Instructions for assigning/revoking user accounts and permission groups to the RCET production and test websites using the online administration tools
- Work Instructions for emailing new user an acceptance letter with instructions for software setup



Progress (21-Jun-2005 to 17-Jan-2006)

- 3+ Dry Runs in progress
 - Toronto Sunnybrook Regional Cancer Centre, Toronto, ON
 - Vancouver Cancer Centre, Vancouver, BC
 - Grand River Regional Cancer Centre, ON
 - Peter MacCullum Cancer Centre (TROG) ?
- Installation of NCI C CTG Developmental Server completely independent from Production Server



Progress con't (21-Jun-2005 to 17-Jan-2006)

- Establish Standard Operating Procedures (SOPs)
 - New user registration and privilege assignment for production and test systems
 - Password Aging
 - Installation procedure for RCET software and required source code and software packages
 - Moving test server into production
 - Needed:
 - Bug reporting and resolution
- 21CFR Part 11 testing and compliance



Jan 2006, Summary and Conclusions

- NCI C CTG data warehouse is being used clinically for MA.20 rapid real-time and final review
- Pilot Project will evaluate Method 2B for the NCI C CTG APBI protocol
- Collaborative Grant application between NCI C CTG & ATC/RCET to assist with development and clinical support of NCI C CTG Data Warehouse



Jan 2005, Summary and Conclusions

- Installation of the RCET infrastructure is not yet plug and play. Other groups should be made aware that dedicated resources must be provided:
 - 0.5 FTE systems support staff
 - Hardware/software cost to-date: ~\$50,000 CAD
- Better documentation and SOPs will facilitate distribution of RCET system to other groups
- NCI C CTG is too reliant on volunteers: Liz Elliot, Lam Pho, Sonia Schellenberger, Wendy Parulekar, Colin Field

