Status of Implementing ATC Method 3 at NCIC CTG

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National Cancer Institute of Canada Institut national du cancer du Canada Clinical Trials Group

Groupe des essais cliniques



Overview

- NCIC CTG Data Warehouse Goals
- Progress & Challenges since last ATC meeting
- MA.20 Accrual
- MA.20 Goals for next 6 months
- ROQAC Vision
- Summary and Conclusions
- Questions for ATC
- Questions

Goals of NCIC CTG Data Warehouse

- Use internet technology to facilitate
 - Rapid real-time reviews for MA.20
 - Distributed review of clinical trials
- Minimize impact on central office staff
- Minimize technical expertise required by end user
- Extend solution to support Dicom-RT data objects for 3D-CRT and IMRT protocols

Progress (since Jan-05 ATC meeting)

- Meetings
 - Weekly ROQAC MA.20
 - Every 6th week ROQAC
 - Semi-annual NCIC CTG
 - Conference calls with RCET & ATC as needed
- Completed testing of NCIC CTG Test Server
- Moved software to Production Server for user testing
- User Documentation completed
 - MA.20 submission manual
 - MA.20 reviewers manual
 - NetSys Installation and configuration manual
 - FAQ
- Released NCIC CTG Data Warehouse for MA.20 clinical use May 30, 2005 (<u>letter</u>)



Progress cont'd (as of June 21, 2005)

- All MA.20 centres to be re-credentialed
- 3 credentialed institutions
 - Vancouver Island Cancer Centre
 - Juravinski Cancer Centre
 - Tom Baker Cancer Centre
- 5 Dry Runs in progress
 - Cross Cancer Institute
 - Thunder Bay Regional Health Sciences Centre
 - Toronto Sunnybrook Regional Cancer Centre
 - Nova Scotia Cancer Centre
 - Peter MacCullum Cancer Centre (TROG)
- Dry Run reviewers
 - Technical: 4 volunteers
 - Clinical: Reviewing centres



Challenges Post-Production Server

- IS support at the submitting institutions
- Time to climb the learning curve
- Data security issues (common concern)
- Establish Standard Operating Procedures (SOPs)
 - New user registration and privilege assignment
 - Installation procedure for RCET software and required source code and software packages
 - Moving test server into production
 - Bug reporting and resolution



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MA.20 Submitted Cases

10 cases submitted for rapid or final review

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MA.20 Accrual to June 13, 2005

- Total Accrual •
 - Accrual = 1315
 - Partial June Accrual = 22
- NCIC/Canadian
 - Accrual = 1171
 - Partial June Accrual = 16
- CTSU •
 - Accrual = 52
 - Partial June Accrual = 2
- ~35 patients per month
 TROG (AUXT)
- 472 accruals remaining
- ~13 months

- - Accrual = 92
 - Partial June Accrual = 4



MA.20 Goals (July to December, 2005)

- Perform rapid reviews for credentialed institutions
- Perform final reviews for credentialed institutions
- Educate submitting institutions
 - Hands-on assistance with credentialing
 - CARO presentation, September
- Credential more institutions
 - Canadian institutions
 - Top accruing centres to MA.20 from the US
 - Australia
- Develop distributed and redundant personnel infrastructure to
 - Perform technical dry run reviews

- Perform clinical dry run reviews

ROQAC Goals (July to December, 2005)

- Pilot Project to re-evaluate submission of Dicom-RT and RTOG data objects to NCIC CTG Data Warehouse (Method 4)
- Select NCIC CTG protocol to use as test of 3D data sets using RCET technology
- Develop QA goals for NCIC CTG for next 5 years (e.g. 'Vision Statement')
- Establish guidelines to access NCIC CTG Data Warehouse for non-NCIC sponsored trials
- Grant application with ATC/RCET to provide continued support and development of infrastructure & operating procedures (hardware, software, personnel) at NCIC CTG

Summary and Conclusions

- NCIC CTG data warehouse is being used clinically for MA.20 rapid real-time and final review
- Pilot Project will evaluate Method 4 for NCIC CTG protocols
- Collaborative Grant application between NCIC CTG & ATC/RCET to assist with development and clinical support of NCIC CTG Data Warehouse

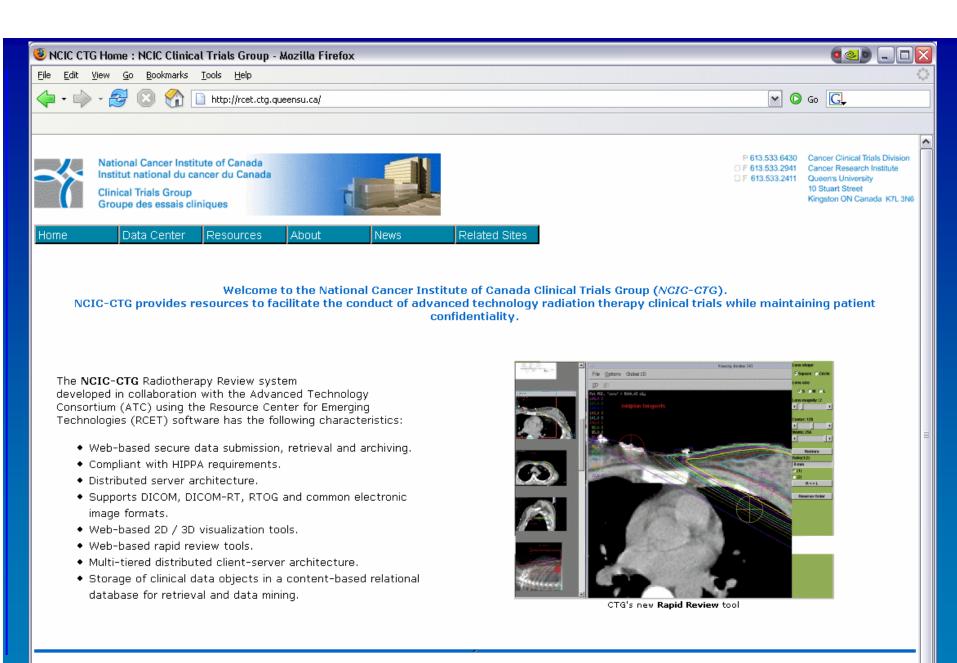


Questions for ATC

- Can NCIC CTG use the QARC IMRT questionnaire for a Canadian survey ?
- Old Questions
 - How are software changes made to RCET software in Kingston, Gainsville, and St Louis merged ?
- Other Questions ???







Best Viewed with <u>Netscape 7.01</u>, <u>FireFox 1.0</u> or Internet Explorer 6.0 SP1

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Radiotherapy Review System developed in collaboration with the <u>Advanced Technology</u> <u>Consortium</u> using the <u>Resource Center for Emerging Technologies</u> software If you have any questions, comments or suggestions, please contact our <u>Systems</u> A dministrator

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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
- NCIC CTG is too reliant on volunteers: Liz Elliot, Lam Pho, Sonia Schellenberger, Wendy Parulekar, Colin Field







RCET Support

- Bug fixes
- Request for access to RCET
- WebSys
- ?



Outstanding Items - RCET / NetSys

- 1. Remove, or password protect, log files which contain confidential information
- 2. Add user verification during NetSys download
- 3. Addition of appropriate MA.20 dataset to NetSys download for training
- 4. Problem with Case ID not being unique across NCIC protocols - temporary solution DR_CALM0007. Other protocols will reuse case #.



Use version 3 of the rapid review tool - done