

CTSA Clinical Trials Group Update WebEx

Thursday, February 5, 2009
11:00am CST

Call Summary

In attendance:

Gary Dorfman, MD (Chair)
Denise Aberle, MD
Andrew Buckler, MS
Patricia Cole, PhD, MD
Sean Fain, PhD
Thomas FitzGerald, MD
Robert Ford, MD
James J. Frost, MD, PhD, MBA
Vahe Ghahraman
Luna Hillaire, PhD
DeJane Hussey
David Mozley, MD

Eric S. Perlman, MD
Orhan Suleiman
Daniel Sullivan, MD
Saara Totterman, MD, PhD
Linda Velasquez, MS, CCRC
Walter Wolf, PhD

RSNA staff

Fiona Miller
Susan Anderson
Mary Cerceo

Introduction and agenda (Dr. Dorfman)

- Vision of UPICT as central repository
- Identify imaging protocols, obtain permission to post
- Work towards UPICT recognition as the standard and coordinate activity
- January 2008 *European Journal of Cancer* on RECIST criteria

Deliverables

- Eight tasks/workgroups needed:
 1. Protocol Templates (Have limited to specific domains for CT, PET/CT, and MRI initially) start by extracting one protocol for each modality to complete a template and annotate, as an example
 2. Threshold/vetting criteria--define what is acceptable to be posted, e.g. FDA registration
 3. Annotations--how protocol has been used:
 - establish eligibility, establish disease baseline or response assessment
 - organ system addressed
 - disease addressed
 - type of trial, e.g. bio trial, pharma trial
 4. Workflow for vetting, annotating, posting and review of proffered protocols
 5. Workflow for consensus protocols--group will work together to optimize workflow; will test workflow at in-person meeting
 6. RSNA and CTSA-hosted website with protocol library and Web-moderated Discussion Forum
 7. Listing of ongoing protocol development efforts
 - Encourage collaboration
 - Increase awareness to avoid duplication of effort
 8. Support for early phase single institution imaging studies within CTSA

Discussion

- Template should accommodate the efforts of QIBA groups

- QIBA FDG-PET work will integrate well with Clinical Trials work; FDG-PET to provide a 2nd harmonizable image reconstruction algorithm which may be used in place of manufacturers' default

Identifying efforts on protocol harmonization

- Utility of creating a listing of ongoing protocol development but difficulty in identifying the efforts
- Once identified, invite other groups to participate in a collaborative and non-competitive effort
- Similar efforts identified by group:
 - Recent publication on protocol standardization across Dutch sites:
 - The Netherlands protocol for standardisation and quantification of FDG whole body PET studies in multi-centre trials. Eur J Nucl Med Mol Imaging. 2008 Dec; 35(12):2320-33.
 - NCI cooperative groups
 - QARC
 - ACRIN
 - ADNI (PET and MRI core groups). ADNI investigates consensus on profiles for instruments
 - Manufacturers have supplied specific directions for equipment
 - ADNI II will include reproducible product sequences
 - ISMRM (Dr. Hillaire will provide citation of publication on diffusion-weighted MRI)
 - Drs. Peter Choyke and Anwar Padhani will be useful contacts
 - Biomarkers Consortium
 - Used ACRIN acquisition protocol for FDG-PET (Dr. Sullivan will pursue)
 - SNM standardized protocols for multi-site PET imaging (Dr. Cole will pursue)
 - Duke efforts standardizing cardiac ultrasound in clinical trials?
 - Pam Douglas (Duke), June 2008 conference related to standardizing core labs (Dr. Sullivan will pursue)
- Encourage collaboration and use of UPICT template (Dr. Cole to discuss w/ADNI leadership)

Update on Workplan

1. Small working groups (sometimes of one person) will create "strawman" work products for items 1 - 5 above
2. Work with the RSNA staff on item 6 above
3. Work with specific volunteers on item 8 above
4. Have specific work product available for group review and refinement prior to March in-person meeting

In-person meeting: IRAT/CTSA Workshop, Baltimore, MD, Sunday, March 29-Tuesday, March 31

- The meeting will include two Clinical Trials group breakouts: Sunday, March 29, 4-8pm and Monday, March 30, 8am-12noon, http://www.iratnetwork.org/irats_meeting/
 1. Review and refine draft work product
 2. Review and refine example proffered protocols put into draft templates and annotated
 3. Discuss next steps and organize to implement workflows to rapidly process proffered protocols
 4. Discuss next steps and organize to implement items 6 - 8 above.

Next Steps

- Dr. Mozley will continue to recruit pharma persons to participate in project and attend March meeting
- Strawman or draft materials needed before in-person meeting

- Next call: Thursday, March 5, 2009, 11amCST