

CTSA Clinical Trials Group Update WebEx

Thursday, August 6, 2009
11:00am CDT

Call Summary

In attendance:

Gary Dorfman, MD (Chair)
David Brown
Vahe Charhraman
David Clunie, MBBS
Patricia Cole, PhD, MD
James J. Frost, MD, PhD, MBA
Vahe Ghahraman
Yuying Hwang, PhD
Donna Letizia
Tin Lee
P. David Mozley, MD

Kevin O'Donnell
Eric S. Perlman, MD
Yuanxin Rong MD, MPH
Yung Chin
Daniel Sullivan, MD
Walter Wolf, PhD

RSNA staff

Fiona Miller
Susan Anderson
Joe Koudelik

Introduction and agenda (Dr. Dorfman)

- Review of 08.03.09 UPICT draft template (Full version, Major Headers version and Major and First-level Headers version of document)
- Proposed UPICT meeting in conjunction with the Imaging Biomarkers Roundtable, afternoon of Wednesday, Nov 4, 2009

Evolution of UPICT Template

- Dr Dorfman expressed thanks to all who offered comments and suggestions on the three draft templates on the UPICT Wiki (http://upictwiki.ctsa-imaging.org/index.php?title=Main_Page)
 - Mr O'Donnell, Dr Dorfman and Mr Buckler incorporated comments and harmonized with QIBA Profiles and IHE conventions
 - Plan to post this new version on Wiki as Version 1.0
 - The template is not meant as an imaging charter, site manual, site protocol or CRO SOP, but will serve as protocol for imaging in a clinical trial.
 - The template can incorporate all types of modalities, e.g. static anatomic, physiological, kinetic
 - The draft template will be tested as workgroups begin extracting protocols

Template review

Section:

- *0. Executive Summary*—250 words or less, an “abstract” to provide a general sense of the protocol
- *1. Context*—interface between imaging protocol and the rest of clinical trial, includes study calendar issues and exclusion criteria
 - Text discusses two forms of Exclusion Criteria but doesn't specify Inclusion Criteria
 - --consider Inclusion Criteria as 1.7.x, e.g. able to comply, not able to comply
- *2. Site selection, etc.* -- related to trial-by-trial basis

Following sections are based chronologically on subject enrolled in trial and how the resultant data would flow through system, based on image-related events only

- 6. *Individual Subject Imaging–related Quality Control*- not QC related to modality but rather to individual
- 7. *Imaging*- related to data acquisition and reconstruction
- 8. *Image Post-processing*—maybe different platform from analysis and interpretation
- Sections 8-9-10 may be most useful and may undergo further revision
- 11. *Archival and Distribution of Data*-- should highlight central management of imaging data i.e., mechanics of data transfer
- 12. Quality Control –amalgamation of separate QC areas from preceding headings
- Appendix G Model-specific instructions and parameters includes inputs for platforms being use; “cookbook-like” instructions for models and versions, to achieve the desired output
- Workgroups will begin extraction of protocols into template, e.g. [ADNI protocols](#)
- Goal is to have mature product for meeting with FDA in 1Q2010

Next Steps

- Section 1.7.x: consider specifying Inclusion Criteria
- Section 2.1 and 2.5 need “Other” category” to include pharmacists, radiochemists, etc.
 - Also add order QC
- Sections 7.1.1-7.1.3: Comments welcome on whether section should be contracted or expanded
- Section 7.2.4 Model specific parameters: include energy and risks associated
- Dr Wolf and others to supply wording for Section 7.1.2, e.g. ‘framing rates’
- Dr Clunie will supply wording for Section 11. Archival and Distribution of Data
- Dr Dorfman will contact Workgroups who will extract protocols into template
 - Dr Frost will participate in workgroup
- E-poll group members for interest and availability for f2f on Nov 4 afternoon (4 hrs) following Nov3-4 IB Roundtable meeting in Chicago area