

CTSA Clinical Trials/UPICT WebEx
April 2, 2009
11:00 AM (CDT)
Draft Call Summary

In attendance:

Gary Dorfman, MD (moderator)

Andrew Buckler, MS

Kavita Garg, MD

Gordon Harris, PhD

Luna Hilaire, PhD

DeJane Hussey

Mary Ann Bishop-Jodoin (QARC)

Michael Knopp, MD, PhD

Wen-Lin Luo

P. David Mozley, MD

Bradford Navia, MD, PhD

Eric Perlman, MD

David Raunig, PhD

Orhan Suleiman, PhD

Daniel Sullivan, MD

RSNA

Linda Bresolin, PhD, MBA, CAE

Fiona Miller

Joseph Koudelik

Mary Cerceo

Overview of progress made at the 3/29-3/31 CTSA/IRAT Meeting and Discussion and review of the draft template for UPICT protocols:

Purpose and work flow (Dr. Dorfman)

- Two types of protocols
 - 1. Meets vetting threshold from existing trials (e.g. ACRIN, CALGB, CROs, and industry)
 - Broad variety of formats
 - Harmonized look to assist in searching for protocols
 - 2. Similar protocols may be used to build a consensus protocol, or to create a new protocol to meet an identified need.
- Protocols will be put into a uniform template to assist those searching to identify, compare or contrast.
- Users will be able to extract or modify information.
- Protocols will be linked to profile claims.
- Meta-tags and annotations w/bibliographies will also be provided to simplify and streamline searching.

- x. 1 Utilities and Endpoints of Imaging Tests within the Clinical Trial
- x. 2 Pre-enrollment Imaging Tests
- x. 3 Timing of Imaging Tests within the Clinical Trial Calendar
- x. 4 Off-protocol and Off-schedule but On-protocol Imaging
 - Interface domains between imaging protocol and the rest of the trial.
 - Particulars can be changed to meet needs.
- x. 5 Not all subject, inclusion, exclusion criteria related to the imaging portion of the trial itself
- x. 6 Imaging: change to one section to be about subject only. Move from x.7 and x.8 into x.6

- x. 7 is data acquisition, parameters.
- x. 13 summary of all documentation; ability to see all the source documents
- Baltimore group discussed ADNI MRI protocol, Boellaard FDG PET (Netherlands) protocol, ACRIN 6678 VolCT protocol, ACRIN FDG PET and underpinning SOPs

Template Suggestions/Goals

- Some areas are unclear or redundant; definition of terms should be made more obvious.
- Draft template should be loaded on CTSA WiKi for user comment over a 1-month review period.
- Consider posting thematic questions.
- Hold WebEx call at end of comment period to address comments in an organized fashion
- Dr. Perlman suggested data acquisition be separated from post processing and image interpretation.
 - Consider reorganizing around patient/ subject: pre-,intra- and post-imaging
- Avoid making a template for an entire clinical trial.
- Add interface on the front end for timing, off protocol imaging, or on protocol imaging.
- Subject recruitment, selection criteria and other non-imaging attributes could be topic of another group project e.g., collection of Top- 10 list of useful practices and technologies or things to avoid from sites that have success in rapid trial accrual.
- Consider convening a face- to- face meeting in October 2009 with Extended PhRMA Imaging Committee in Bethesda; meet with the FDA, academics, NEMA, bio and governmental - all stakeholders needed.
 - For this meeting define the process; have several extracted protocols and templates posted.
- Dr. Mozley suggested populating the template with the FDG-Pet, ACRIN 6678 and ADNI protocols, and extending the timeline on responses
- Once the reformatted template is posted, committee will invite others to comment.
- Editorial comments:
 - If the proffered protocol is written/used for one purpose, there could be a potential problem if it is used for another purpose. Perhaps a disclaimer should be written under editorial comments. Should be informative of context of the protocol.
- More discussion of editorial control and comment is needed:
 - Consider weighted feedback
 - Process for review of comments
 - Possible inclusion of disclaimer
- The committee goal is to include clinical trial protocols that any site could replicate.

Next steps

- Dr. Dorfman to send Dr. Linda Bresolin the latest draft of the protocol template. Linda will annotate prior to posting.
- Load revised template on CTSA WiKi for group feedback
- Next CTSA/UPICT WebEx May 7, 2009 at 11AM (CDT)