

CTSA Clinical Trials/UPICT WebEx
May 7, 2009
11:00 AM (CDT)
Draft Call Summary

In attendance:

Gary Dorfman, MD (moderator)
Denise Aberle, MD
Harris Ahmad, MD
David G. Brown
David S. Channin, MD
Cecil Charles, PhD
David Clunie, MBBS
Patricia Cole, PhD, MD
James J. Frost, PhD, MD
Yaorong Ge, MD
V. Ghahraman
DeJane Hussey
Robert Jeraj, PhD
Tin Lee
David Miller

Richard Patt, MD
Eric Perlman, MD
David Raunig
Yuanxin Rong, MD, MPH
Rathan Subramaniam, MD
Daniel Sullivan, MD
Alice Tarantal, PhD
Annick Van den Abbeele, MD
Jeffrey Yap, PhD

RSNA

Linda Bresolin, PhD, MBA
Fiona Miller
Susan Anderson
Mary Cerceo

Agenda

- Status of current work
- Partnership with QIBA VolCT Technical Committee with proffered protocol
- Nomenclature (Dr Channin)
- Proposed instructional version of template (Dr Patt)

Draft template for UPICT protocol (Dr Dorfman)

- Template nearing final form after revisions by Dr Dorfman and others
- Extracted protocols should soon be available for extended subgroup review
- Dedicated UPICT Wiki being established for review and discussion of template/protocol iterations
- Working with QIBA VolCT Technical Committee on extraction of VolCT protocol.

Nomenclature

- Possible confusion between 'protocol' related to UPICT and 'clinical trial protocol'?
- Dr. Channin suggested substituting the phrase 'medical imaging act' for imaging procedure, imaging data acquisition
 - Industry uses terms 'image acquisition', 'image analysis'; avoid the generic term 'data' and use 'metrics' to stress numerical analysis or qualitative descriptors.
- The UPICT concept is that:
 - The clinical trial protocol is the largest entity (the 'book')

- The imaging protocol is a 'chapter' in the book; a UPICT protocol will not be a comprehensive compendium of all the imaging done in a clinical trial but will address modalities separately.
- Dr. Channin suggested an alternate concept and recommended establishing common nomenclature for all activities related to an imaging event.
- Determining the audience will determine the language level; there are several audiences including:
 - Imaging trialists and other constructing the imaging section of a clinical trial
 - Sponsors, reviewers and those approving trials, payers
- Nomenclature must be accessible and understandable by technologists and other personnel; will use common terms and will use standard nomenclatures such as IHE, DICOM, HL7 language as appropriate.
- Goal is to use language for scientists, not informaticists
- Where appropriate, a synonym library will be used.
- Linda Bresolin will compile terms for the glossary for review
 - Drs Dorfman, Cole and Channin will assist in glossary compilation.
 - Present and future opportunities for mapping of terms will be noted.

Benchmark or Instructional Template (Dr Patt)

- Will include guidance and clear explanations of points to consider before imaging.
- Important to non-imagers who are adding imaging to a clinical trial and will assist sites that are not experienced in clinical trials.
- Potential utility for pharma, NIH and FDA Dr Patt will draft and circulate for comments

Next Steps:

- Linda Bresolin will work on draft of glossary and share with committee for comments
- Dr. Patt will draft the instructional template and share with committee for comments
- Considering a fall in-person meeting for committee
- RSNA staff will prepare wiki site and passwords for UPICT group
- Next WebEx Thursday, June 4, 2009 at 11:00AM (CDT)