

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

In attendance:

Gary Dorfman, MD (Chair)
Denise Aberle, MD
David Brown
James Frost, MD, PhD
Kavita Garg, MD
Yaorong Ge, MD
Wen-Lin Luo
P. David Mozley, MD
Kevin O'Donnell
Eric Perlman, MD
David Raunig

Vahe Ghahraman
Linda Velasquez, MS
Jeffrey Yap, PhD

RSNA
Linda Bresolin
Fiona Miller
Susan Anderson
Joseph Koudelik
Mary Cerceo

CTSA IWG website (<http://www.ctsa-imaging.org>)

- Two approaches to website:
 1. Directly at <http://www.ctsa-imaging.org>, then select 'Imaging in Clinical Trials/UPICT.'
 2. Through the RSNA website, <http://www.rsna.org/>, choose the 'Science' tab and choose 'CTSA IWG Imaging' to be directed to the CTSA IWG main page
From the CTSA IWG main page, select 'Imaging in Clinical Trials/UPICT.' A link is also provided to the UPICT Wiki, <http://upictwiki.ctsa-imaging.org/>

CTSA IWG/UPICT Wiki (<http://upictwiki.ctsa-imaging.org>)

- The UPICT Wiki is a web-based workspace and supporting infrastructure to facilitate the submission, vetting, and annotation of Proffered Protocols in a transparent and inclusive manner.
- Will include:
 - a web-based resource library of annotated Proffered Protocols that have been used to support clinical trials within institutions, cooperative groups, and trials consortia that meet a minimum set of criteria
 - a web-based workspace and infrastructure to facilitate the iterative authoring and periodic review of Consensus Protocols in a transparent and inclusive manner
 - a web-based environment to facilitate the interaction among clinical trialists and imaging scientists within academia, industry, and agencies
- Three templates are currently posted for comment and review: the UPICT template, QIBA vCT template, and the QIBA FDG-PET CT template. The templates are posted in two formats:
 - The first format is a PDF document for reference. This document cannot be edited but it is possible to copy sections from it.
 - The second format is an editable version of the same document.
- The committee is requested to read and compare the three templates and comment on the following from the view of the imaging protocol in a clinical trial:
 - Which has the best organizational structure and flow?

- Are there gaps in the templates?
- Are there redundancies in the templates?
- Consider from the point of view of the technologist, the clinical trialist, the regulator and others who may use the protocol.
- Comments that indicate approval for any or all templates are welcome.
- When commenting or editing a template, please add your initials to the text for ease of identification.
- The goal is to have a single template across all modalities although the language may differ by modality
- The template is not intended to replace the imaging charter, site manual or spec documents from the manufacturer

QIBA (Mr. O'Donnell)

- QIBA is promoting the use of biomarkers in clinical trials
- Clinical practice needs a 'plug and play'; we are ultimately targeting a detailed set of specs
- A midpoint of progress is distribution in clinical trials; UPICT group and infrastructure would be useful as a review community and a distribution method
- Also working in DICOM committees for a modality system, e.g. suite of protocols for different vendors

Next steps

- Dr. Dorfman requests that the committee comment on/edit the templates on the Wiki.
- The next UPICT WebEx is August 6, 2009 at 11:00AM (CDT)