

**CTSA IWG Clinical Trials/UPICT
WebEx**

Thursday, March 4, 2010
11:00 AM (CT)

Draft Call Summary

In attendance:

Gary Dorfman, MD (Chair)
Andrew Buckler, MS
Patricia Cole, PhD, MD
James J. Frost, MD, PhD, MBA
Vahe Ghahraman
Michael Graham, MD, PhD
Yuying C. Hwang, PhD
Carolyn Meltzer, MD
Kevin O'Donnell
Eric S. Perlman, MD

Daniel L. Rubin, MD
Haren Rupani, MD
Adam J. Schwarz, PhD
Rohit Sood, MD, PhD
Orhan Suleiman, MS, PhD
Jeffrey T. Yap, PhD

RSNA

Fiona Miller
Joe Koudelik

Review progress to-date

SNM PET harmonization meeting (June 3, 2010)

- To be held immediately preceding SNM meeting in Salt Lake City
- Gathering of all major players, including UPICT representative(s), to develop a harmonized protocol for PET to be acceptable by all clinical trials worldwide
- Invitees to include European groups, ACRIN, RSNA, Japanese and Korean groups (Dr Eric Perlman included)
- The Netherlands harmonization protocol/paper may be used as a starting point
- Goal that resultant publication will be state-of-the-art and well-regarded worldwide
 - Opportunities for co-authorship for those offering significant contributions
- Dr Dorfman offered use of PET extraction in UPICT template and provided an overview of the UPICT template and extraction process

The FDG-PET extraction update

- The FDG-PET extraction has been posted on UPICT wiki for comments and suggestions; current focus is on FDG-PET for oncology
 - http://upictwiki.ctsa-imaging.org/index.php?title=Draft_Proffered_Protocols
- Dr Perlman explained the team's work process:
 - Concurrent 'multi-extraction' from several documents including ACRIN SOPs, two European studies and other articles (e.g. Hallett, Shankar and Yap articles)
 - Each extraction into template is designated a different font color
 - Additionally, the original articles or documents are marked-up with comments where text has been used or where questions arise
- Statement needed identifying commonalities between documents; areas of relative harmonization and differences needed
- Draft consensus PET protocol to be developed by April 2010 FDA/SNM/Workshop
- Original CTSA/UPICT template working well as framework; no need to modify

- Boilerplate advisory text needed in areas instead of “N/A”; based on current expert opinions; Drs Dorfman to discuss with Dr Perlman off-line
- Encourage UPICT working groups within QIBA Quantitative MRI and CT Committees to extract material proposed, as well as ADNI 1&2
- QIBA Quantitative (Technical) Committees creating reference documents based on technical issues and details; to be extracted as well
- Base-line and most current versions of extractions to be posted for reference as Wiki “watch-pages”
- Dr Perlman to email PET Working Group details to Dr Michael Graham for reference

CTSA/UPICT Wiki

- Reorganization of CTSA / UPICT wiki to streamline navigation to be considered
- RSNA staff posting updates to wiki prior to group calls; new work product to be posted weekly
- RSNA staff to explore wiki tool to e-notify group members when documents have been updated

Next Steps:

- Emphasis on completing PET extraction by April 2010 meeting with FDA/SNM/RSNA; completed extraction needed by end of May 2010
- Drs Graham and Perlman to discuss the June f2f meeting details off-line
- RSNA staff to explore addition of wiki update notification tool
 - If available, send instructions re activation
- Mr Buckler and Mr O'Donnell to discuss off-line prospects of finding a “motivated equivalent” to Dr Perlman within the QIBA Q-CT Committee (working group)
- All working groups welcome to participate; email Dr Dorfman interest (e.g. QIBA Q-CT and Q-MRI)
- Dr Perlman to email PET Working Group details to Dr Michael Graham for reference
- Next call scheduled for April 1 at 11 am CDT (12 pm EDT); save-the-date to be sent