

QIBA FDG-PET Technical Committee Update Call

Friday, January 7, 2011 at 9 am CST
Call Summary

In attendance:

Paul Kinahan, PhD (Co-chair)
Richard Wahl, MD, PhD (Co-chair)
Ronald Boellaard, PhD
Andrew Buckler, MS
Michael Casey, PhD
Paul Christian
Patricia Cole, PhD, MD
Howard Higley, PhD
John Hoffman, MD
Dennis Nelson, PhD
Ling Shao, PhD

Daniel Sullivan, MD
Valerie Treyer, PhD
Timothy Turkington, PhD
Scott Wolodzko, PhD
Jeffrey Yap, PhD
Brian Zimmerman, PhD

RSNA

Fiona Miller
Joe Koudelik

Re-establishing Regular Calls

- Alternating FDG-PET Technical Committee “general business” calls with PET Profile Writing proposed for 9 AM CST every Friday; Dr Boellaard to lead the Profile Writing Group
- PET Profile to use the IHE model for reference; strategy needed to best pursue Profile development
- Next few calls to study high-level project plan (Gantt chart items)

UPICT/PET Protocol

- UPICT protocol not final, but extraction of vendor “asks” helpful in developing the Profile content
- Protocol to be posted to Wiki for reference

PET Work Plan Overview

- Deliverables and associated timelines discussed
- Work Plan and Profile v1.0 to be completed by May 2011
- Profile Claims need to be confirmed
- FDG-PET Profile and the FDA biomarker qualification process may share many Claims
- Groundwork evidence to identify any potential PET knowledge gaps and provide feedback to help Profile development
- Monthly snap-shots of PET Work Plan to be Wiki posted
- “Ad Hoc Standards” to be added to Work Plan

FDA Data Package Updated

- Briefing document being prepared based on communication with FDA BQRT
- Additional t-cons required to further discuss FDA BQRT feedback/responses with definitive Claim statements of what FDG-PET can predict; examining consensus for Claim language
- Objective is to get Briefing Document to FDA within six weeks and schedule a f2f meeting soon after; proposed to forward draft product to Steering Cttee in one week for feedback
- Focus to be qualification for FDA document; Claim to be more general, leaving room for additional possible uses
 - Scientifically: Use specific QIBA Claims
 - Strategically: Use general Claims for FDA use
- Profiling efforts to be part of data submission
- Clinical Effectiveness a possible new PET subcommittee
- Need to identify data in support of this; further development needed

NIBIB/QIBA Contract Update

- All funding proposals reviewed by individual Technical Committees, then selections forwarded to Modality Committees for ranking
- Steering Committee call of Jan 11th to review scoring, narrow down projects and request proposal follow-up details if needed
- Steering Committee to meet f2f Jan 28th to make final funding decisions
- Any proposal modifications to be re-submitted to Fiona Miller (RSNA) by Friday, Jan 21, 2011

Overall QIBA Activities Update

- QIBA Steering Committee f2f meetings (Aug and October 2010) used to discuss and revise the process
 - Statement of major goals (26 original objectives reduced to 8)
- Revision to governance structure made
 - Clear process, defined membership and authority needed for making financial decisions
 - Technical Committee remains open to all interested
 - Modality Committee possesses defined membership and Profile approval authority
- Corporate Visits
 - GE visit in October 2010 to ascertain industry point-of-view concerning quantitation
 - Philips, Toshiba and Siemens visits planned for winter/spring 2011

Next Steps:

- Monthly snap-shots of PET Work Plan to be Wiki posted
- UPICT (Profile) and FDA Briefing Document to be discussed on next call
- UPICT/PET Protocol Writing Group Update next week by Dr Boellaard (Jan14th)
- Email FDG-PET Tech Ctte co-chairs any agenda suggestions for the Jan 21st call