QIBA FDG-PET Profile Writing Group Update

Friday, January 14, 2011 at 9AM CST

Call Summary

In attendance

Ronald Boellaard, PhD (Chair)
Paul Kinahan, PhD
Andrew Buckler, MS
Patricia Cole, PhD, MD
Eric Perlman, MD
Ling Shao, PhD
Daniel Sullivan, MD

RSNA

Joe Koudelik
Julie Lisiecki

FDG-PET Writing Group Format

- Need to identify representatives from all stakeholder groups to serve on this writing group
- Suggestion to keep the group membership open to allow for greatest stakeholder activity and input
    - Entire FDG-PET Tech Ctte encouraged to participate
- Vendor compliance is the end-goal
    - Create a standard that device manufacturers would market QIBA compliant products and services; manufacturers need to want this engagement
- Stakeholders still needed include physician/scientist representatives (e.g., Drs Elliot Siegel, Richard Wahl, Otto Hoekstra)

FDA Biomarker Qualification

- FDA imaging biomarker qualification meeting planned; open format, but no details yet
- FDA requested "Briefing Document" being prepared for FDA review and feedback
    - Describes how FDG-PET could be used as a quantitative and qualitative biomarker in clinical trials and patient care
- Biomarker Profile development and) Qualification are two separate processes
- Qualification uses the Profile to define what is being qualified
- Protocol, Profile, Briefing Document all need to be consistent and tie to another;

UPICT Template (Protocol) vs. Qualification vs. Profile

- Profile goal:
    - A definition of what the biomarker is
    - A tool to provide information
    - A standard on how to perform quantitative imaging in the future; looks at performance characteristics, e.g., what level of noise is acceptable?
    - How equipment should be used for quantitative imaging
    - Include protocols
- Tight coupling between UPICT protocol and Profile needed
    - Protocol content affects Profile content
    - Reference UPICT template for protocol section numbering/ formatting
    - Same version numbering system proposed
    - Same section headers may be used across the UPICT Template (protocol) and Profile
- Profile focus on information for specific products
- Need Profile criteria and product specifications based on phantom data
- Profile = Product specifications and PET criteria
- Automated sharing of document sections need updating; copy/ paste would take a long time
- Updated Protocol to be circulated before each call as reference

- UPICT protocol in advanced stage
    - Wordsmithing changes occurring
    - To be posted to Wiki when finished
- Content of Profile is focus of this group; document format is secondary
- Mr Buckler exploring content authoring/sharing tool for Consider posting Profile template on Wiki
- Need to create metrics and identify specific performance characteristics

Next Steps:

- List of Profile items discussed (flagged) and vendor "Asks" needed for distribution to broader Tech Ctte
- Drs Boellaard and Perlman to review "Ask" list
- Dr Boellaard to examine core UPICT Template (protocol) details and cut/paste into Profile sections for group feedback
- Profile core detail document to be completed and distributed to full FDG-PET Tech Ctte for broader feedback
- Dr Kinahan to pull and compare major section headings across both UPICT Template (protocol) and Profile
- Dr Boellaard to provide update of Profile Authoring t-con during next FDG-PET Tech Ctte "general business" t-con
- Dr Boellaard to prepare agenda for next call, scheduled for Friday, January 28, 2011 at 9 am CST
    - Dr Perlman to provide brief update on status of the PET Protocol (UPICT Template)