QIBA Q-PET Committee Update November 8, 2010

Call Summary

In Attendance

Paul Kinahan, PhD (Co-chair)
Richard Frank, MD, PhD (Co-chair)
Richard Wahl, MD (Co-chair)
Andrew Buckler, MS
Patricia Cole, PhD, MD
Constantine Gatsonis, PhD
Michael Graham, MD, PhD
John Hoffman, MD
Blaine Horvath, RT

Eric Perlman, MD
Daniel Sullivan, MD
Valerie Treyer, PhD
Timothy Turkington, PhD
Brian Zimmerman, PhD

RSNA

Fiona Miller Joe Koudelik

Modification to QIBA FDG-PET Subcommittees (Dr Kinahan)

- Previous FDG-PET subcommittees have made significant contributions
 - List of gaps identified and will be communicated to vendors
- Proposed was to close-out the subcommittees with 1-2 paragraph summaries/ reports due by year's end, to be posted on the Wiki
- Next activities to focus on protocol and Profile drafting; documents recognized by all modality experts as a basis to move forward
- Vendor input needed to advise FDG-field in meaningful ways
- Profile to identify and articulate requirements via Claims and details via Profile specifications
- "QIBA method" provides commercialization path for committee groundwork to proceed; small enhancements towards the long-range vision of quantitative future applications
- A QIBA Profile based on an IHE model; IHE model to work as example only; an influence on the QIBA process but not an IHE domain itself
- Dr Boellaard to initiate FDG-PET draft Profile and circulate among FDG-PET Committee members for review and feedback

FDA Full Data Package

- QIBA cosponsoring FDG-PET qualification with NCI and fNIH
- Groundwork needed to complete data package based on Roadmap stemming from the Imaging Biomarkers Roundtable Meetings
- Three stages to characterization and standardization
 - Technical characterization (Profile is active effort here)
 - Clinical performance standards (data exists now)
 - Clinical efficacy
 - Group to engage in activities to strengthen statistical power of data for FDA data package
 - Includes PERCIST efforts re: collecting data and modifying groundwork
- Performance aspects of Profile being done by UPICT writing groups
- Physics and medical biology are combined in the UPICT template
- Analysis Committee proposed to validate published methods on PET analysis
- Need to systematically validate numerous datasets with different methods
- More insight on how GE plans to work closer with QIBA anticipated by year's end
- Ability to compare across systems is crucial

FDG-PET Clinical Effectiveness Committee

- Clinical efficacy may be focus of FDG-PET Technical Committee application for QIBA funding
- Drs Sullivan, Kinahan, Frank, Wahl, and Mr Buckler to get the group up-and-running
- Still need 1 pharma rep to join the group

NIBIB Contract Update

- Approximately \$1.2 million per year for two years; \$600k for administrative support/ \$600k for QIBA activities/ projects
- One page application form, data sheet and budget justification forms in development; forms to be finalized and circulate to all modality committees within two weeks
- Dec 16, 2010 deadline for FDG-PET Modality Committee to submit finalized proposals to QIBA Steering Committee for review and consideration

QIBA Modality Committee Poster for RSNA 2010

- One poster per modality proposed
- 10-slot Meet-the-Expert (MTE) Doodle poll to be circulated for FDG-PET members for possible participation at RSNA 2010

Vendor Roadshow Update (Drs Sullivan and Kinahan)

- October 26, 2010 visit to GE in Milwaukee lead to vigorous discussions with numerous people
- Range of agreement in many areas; QIBA approach generally supported by GE management
- Issue raised that QIBA Profiles may hold vendors accountable for things outside of vendor control, e.g., how experiments are performed and what effects caused by biology
- FDG-PET group discussion focused on science of SUV and whether it is possible to standardize across vendors

IEEE Meeting Overview

- Discussion with GE, Philips and Siemens reps; overall agreement with QIBA ideas
- Modest pushback concerning resource allocation experienced
- 3-Carrots Profiles are to hold-out to vendors to engage them to comply
 - Reimbursement
 - o FDA compliance
 - Product specification (ie, need to claim some advantage) all needed by manufactures
- Vendor buy-in is critical
- Various vendor platform readouts reflect variability due to biology, but readout read differently by different vendors support the need to pursue these activities
- Longitudinal quantitation is the root of the effort; need to know whether a measurement is accurate

Next Steps:

- Dr Perlman to provide an update on the UPICT template being used by the FDG-PET/CT writing group
- Tech Ctte to follow new call schedule; yet to be determined