QIBA FDG-PET/CT Update WebEx
Monday, November 17, 2008
2:00 pm CST
Draft Call Summary

In attendance:

Richard Frank, MD, PhD (Co-Chair)
Helen Young, PhD (Co-Chair)
Paul Christian
David A. Clunie, MBBS
Patricia E. Cole, PhD, MD
Constantine Gatsonis, MD
John M. Hoffman, MD
Yuying C. Hwang, PhD
Paul Kinahan, PhD
Eric Perlman, MD
Daniel Sullivan, MD
Timothy Turkington, PhD
Jeffrey Yap, PhD
Fiona Miller (RSNA)
Susan Anderson (RSNA)
Joe Koudelik (RSNA)

General Discussion

- Dr. Kinahan noted that Vol-CT is focusing on lung cancer and also includes FDA group data for data generation
- The FDG-PET/CT group will focus on identifying issues and what data has been accumulated and is available
- Dr. Kinahan made two assumptions
    - This group is not attempting to state how to improve the FDG-PET/CT field
    - This group is not looking to advance imaging techniques with advanced tracers or dynamic imaging (currently beyond the scope of most academic centers)
- Continue to encourage vendor participation
- System and protocol characterization
    - Whether protocols are determined ahead of time
    - Tracking co-variates
- Growing interest to use FDG-PET/CT as a pharmacodynamic biomarker to study treatment response - issues remain:
    - Reliability
    - Accuracy
    - Working across all vendor platforms is key
- Vendors are interested, but need convergence with pharma use and clinical trials

Discussion of flowchart--*Pattern for PET SUV Measurements as a Biomarker*

- Change wording in 4th chevron to Quantitation: RI delineation and SUV computation

- **Precursor Specifications section:**

- Look at fit-for-purpose role for biomarker
- Discussion of surrogate endpoint
    - Delineate 1) biological effect/pharmacodynamic effect for individual therapies and 2) surrogate endpoint in clinical therapy
    - When identifying precursor specifications, precision and accuracy of measurements is critical

    - Aim is delineation of how to do better measurements across platforms
- **SUV Issues in Staging/re-staging**
    - When do SUVs matter?
    - Is SUV reproducible?
    - Initial staging requires SUV - two images would be useful
    - Re: SUV change analysis, include assessment of reproducibility/repeat retesting/variability; there are 3 studies on this
- Hardware and software
    - Include whole blood glucose as a DICOM field--there is not a space on console but can now enter as a comment
    - Include residual activity/post-injection assay
    - QIBA could make status field recommendations to manufacturers

ISSUE table

- Add Administration/Assays under Basic Calibration?
- Edit ISSUE table to include a 4th column for Group/Subcommittee(s) responsible
- Define Status fields including *Not addressed*; *Mixed* (e.g. 1 out of 3 vendors); *OK*

Action items:

- Subcommittee leaders to edit their applicable section on ISSUE table; there will not be a 1-1 match with the five issues (Basic Calibration, Covariates, Protocol, Processing, Analysis)
- Each subcommittee leader should provide Dr. Frank with 2 slides on their Objectives and Accomplishments for the QIBA Informational Meeting (Monday, Dec 1, 2008 at 10:30 AM – 11:30 AM, Room S-103-C&D)
- Dr. Frank to update the flow-chart submitted by Dr. Kinahan