QIBA FDG-PET Technical Committee Update
Friday, May 13, 2011 at 9 AM CDT

Call Summary

In attendance:
Paul Kinahan, PhD (Co-chair)
Richard Wahl, MD (Co-chair)
Andrew Buckler, MS
Paul Christian
Howard Higley, PhD
Blaine Horvath, RT
Martin Lodge, PhD
Sonia Peason-White, PhD
Eric Perlman, MD
Ling Shao, PhD
Valerie Treyer, PhD
Timothy Turkington, PhD
Brian Zimmerman, PhD

RSNA
Joe Koudelik

QIBA FDG-PET Y2 Priorities

- QIBA Round-2 Funding Proposals
- Top-down analysis approach taken for Round-2 funding vs open solicitation done for Round-1
- Round-2 funds to be spent by the September 30, 2012 NIBIB contract deadline
- FDG-PET face-to-face Tech Ctte meeting in Chicago (April 19, 2011) identified four high priority projects:

1. Multi-site comparison of inter- and intra-reader variations in determining SUVs. This was identified as the top priority and Dr Wahl is taking the lead.
    a. 10 sites and 20 readers deemed acceptable for project scope
    b. Reader concordance data always important across variable workstations
        i. Wahl proposal to be circulated among ctte members for feedback prior to May 19 SC review
        ii. Follow-up with Dr Wahl needed to determine whether more than one cancer type is analyzed
2. Profile writing by either a direct contract for someone with expertise and/or a 2-3 day writing retreat
    a. Volunteer effort is limited; contracting a content expert to one month writing assignment possible
    b. Associating a 2-3 day writing retreat with a “vacation-type-location” also proposed
    c. Dr Shao volunteered for retreat and reaching out for greater industry participation
3. Integration of retrospective reviews of 2-3 groupings of clinical trial databases. This potentially includes the current Hoekstra and Yap proposal; T-con for details held on May 12th.
    a. Drs Hoekstra, Yap and Wahl to coordinate efforts and prepare smaller proposals based on response measurements in PET images in terms of SUV database analysis studies (outcomes deemed too large a project for the current QIBA resources)
    b. FDA concerned with clinical control vs randomized settings; database prioritization needed to identify clinical trial datasets (i.e., which data to analyze first)
4. Participation in a multi-society effort to define scanner parameters for trials based on image characteristics using a 'greatest common performance' criteria. This will ideally involve participation from the AAPM, NCI, EANM, SNM etc. Dr Kinahan is taking the lead.
    a. Leveraging QIBA support would help convince the NCI to possibly fund projects and contract discussions beyond Round-2 of NIBIB funding
    b. Profile would help articulate device dependent and independent parameters obtained in various ways, in efforts to achieve comparable performance (i.e., basic idea of QIBA mission)

- Two main goals of the FDG-PET Tech Ctte
    - Building Profiles (guidance docs)

    - Collecting groundwork data for FDA and other regulators to support validity of FDG-PET in response to treatment for clinical trials and clinical practice
- FDA will make a case for FDG-PET as a BM if linkages to outcomes are made
- Randomized clinical trial data to be used (FDA most interested in this)
- PERCIST to be used as a common report for both the Hoekstra and Yap projects; analysis with PERCIST with hard endpoints would be helpful
- Projects to focus on what is needed to make Profile successful with FDA
- Need criteria to select “high-yield-value” projects for Round-2 funding

Next steps:

- RSNA to circulate the Wahl proposal to the Tech Ctte members; feedback welcome before May 19 SC review call
- Dr Wahl to follow up with Dr Dorfman concerning PET call-outs for the Tech Ctte to review and forward the current PERCIST working group document to Dr Hoekstra and Yap for reference
- Dr Shao volunteered to assist with Profile development during the summer months
- Next FDG-PET TC call scheduled for June 24, 2011 at 9 am CDT