**QIBA FDG-PET Technical Committee Update**

Friday, September 2, 2011 at 9 AM CDT

Call Summary

| **In attendance:** | | **RSNA** |
|---|---|---|
| Paul Kinahan, PhD (Co-chair) | Eric S. Perlman, MD | Fiona Miller |
| Richard Baumgartner, PhD | Rathan Subramaniam, MD | Julie Lisiecki |
| Andrew Buckler, MS | Daniel C. Sullivan, MD | |
| Paul L. Carson, PhD | John J. Sunderland, PhD | |
| David A. Clunie, MBBS | Timothy G. Turkington, PhD | |
| Patricia E. Cole, PhD, MD | Scott D. Wollenweber, PhD | |
| Constantine Gatsonis, PhD | John G. Wolodzko, PhD | |
| Howard Higley, PhD | Jeffrey T. Yap, PhD | |
| Martin A. Lodge, PhD | Brian E. Zimmerman, PhD | |

**Agenda Topics:**

1. The summaries from the August 19th and 26th meetings were approved.

2. Call for participants in multicenter reader variability study
   - more information needed for the invitation, including an introduction to the project from Dr. Wahl
     extended discussion of the reader variability study including:
     - need to determine the paradigm that most accurately reflects how readings would be done in a clinical trial
     - consideration of identifying lesions with an arrow or other marking to minimize variance
     - need to decide whether this is a hypothesis-driven or observational study
       - if the former, a clear hypothesis needs to be identified
     - For consideration: Is the study trying to prove that there is a difference in reads or that there is NO difference?
       - Specific wording required for study design

3. Update on Y2 proposals - T-cons have been scheduled to discuss project proposals from Drs. Yap and Hoekstra.

4. FDA Draft Guidelines on Imaging in Clinical Trials
   - Fits with QIBA standardization efforts
   - Primarily of Phase- 3 but has application for all trials
   - Implication that software and equipment should be FDA-approved
     - Consider enquiring about the validation process for software used for analysis
   - Dr. Yap will circulate bulleted summary of pertinent points
   - Consideration should be given to providing a cohesive response from QIBA
     - Could incorporate response prepared after April meeting
   - Individuals welcome to respond to guidance document – open for public comment until early October;
     5. 1st Annual Progress Report will be due by October 2011 –

**Next steps:**
- Dr. Yap's to provide highlights of the FDA draft guidance document
- Original QIBA response to the FDA meeting
- Dr. Wahl to provide updated study design with more specific details by next call (9/16).
- Dr. Gatsonsis to follow up with Dr. Wahl regarding a draft protocol

**Next call:** QIBA FDG-PET Technical Committee call on September 16th at 9 am CDT; There will be NO call on September 9th.