QIBA FDG-PET/CT September Update
September 19, 2008
10AM CDT
Call Summary

In attendance:

Richard Frank, MD, PhD (Chair)
Michael Casey, PhD
Patricia Cole, PhD, MD
Constantine Gatsonis, MD
John Hoffman, MD
Yuying Hwang, PhD
Paul Kinahan, PhD
Steve Kohlmyer
Eric Perlman, MD
Richard Wahl, MD
Jeffrey Yap, PhD
Helen Young, PhD
Daniel Sullivan, MD
Fiona Miller (RSNA)
Joe Koudelik (RSNA)

Dr. Frank began with reminders concerning upcoming events:

QIBA Informational Meeting: Monday, Dec 1, 2008 at 10:30 AM – 11:30 AM, Room S103 C&D. The FDG-PET/CT group to report out on group progress. Main objective is to present progress on various tasks to a targeted group of invited people. Being an open meeting, Dr. Frank suggested committee members submit names of potential invitees for consideration.

Informational QIBA kiosk available at RSNA 2008
QIBA kiosk slide deck also appropriate for Dr. Patricia Cole to present/use at the DIA meeting in October, 2008 – Joe to send the slide deck to Dr. Cole (Done 9.19.2008).

General Discussion
Pharma and Academia Committee Involvement

- Need pharma and academia involvement concerning FDG-PET/CT leadership to help with group oversight, direction and to report-back to their own organizations (cross-communicating)
- New co-chairs introduced
    - Helen Young, PhD (Pharmaceutical Industry)
    - Sandy McEwan, MB (Academic Clinician)

Kevin O'Donnell's Groundwork and Profiles document overview provided
Paul Kinahan, PhD reported how the O'Donnell document accommodated work of his subcommittee

- Steps leading to the IHE process discussed
- Goal to bring pharmaceutical and manufacturers together
- Good mechanism so far – applicable to FDG-PET/CT to be determined
- Good mechanism to follow to help simplify the original matrix
- Pharmaceutical industry wants to know where the group stands now
- Good communication tool
- The Profile document mentioned the term "Claim"
    - Are claims to be submitted to the FDA for product approval?
    - Will our one committee FDA rep reach out to the FDA?
    - If data of this committee can expand product labeling, would this help the manufactures?
    - Will our committee's efforts result in claims for vendor products?

- Manufacturers are more focused on clinical demands
- Possibly dovetail efforts with those of other biomarker initiatives to help in qualifying biomarkers
- PET throughput is currently the main emphasis
- Opportunity to demonstrate importance of quantitative values on patient outcomes
- Response monitoring must be accurate and valid
- Vendors need to be encouraged to lend support in efforts in quantitative validation to move this process forward
- Subcommittee leaders to fill in (develop) the FDG-PET/CT profile for their specific tasks, then circulate among the larger committee

Jeffrey Yap, PhD
FDG-PET/CT as Internal Decision Maker

- Numerous cases where FDGPET has been be useful for internal decision making
- PET results are the product of outcomes
- There exists a gap now – the technology is better than what is being used now. Conventional response measurements may not always work.
- Modalities and drugs change fast – the FDA needs to accept this
- This Technical Committee could help position the value of the effort as an effective biomarker and a future predictor of tumor response

Yuying Hwang, PhD
Dr. Yuying Hwang, PhD (Amgen) provided a brief background and her involvement in Covariates Rationale. Dr. Hwang expressed her willingness to lead this subcommittee forward.

Helen Young, PhD (AstraZeneca)
Dr. Young provided a brief history of the use of FDG-PET in internal decision making at AstraZeneca. Dr. Young emphasized the need to advocate to the pharmaceutical industry for involvement and funding, eventually leading to the FDA confirmation of FDG-PET/CT as a qualified biomarker.

Constantine Gatsonis, PhD
Dr. Gatsonis has agreed to provide statistical advice to the group. He endorsed the need for reliable and reproducible measurements.

ACTION ITEMS:

- Invite Gary Kelloff (NCI-FDA liaison) to join the FDG-PET/CT Technical Committee
- Schedule the next FDG-PET/CT call for mid-October, followed by bi-monthly standing calls to prepare the RSNA 2008 report out activities
- Sub-committee Chairs to draft profiles document to be reviewed by next conference call
- Sub-committee Chairs to provide a slide for the December 1st QIBA Informational Meeting at RSNA