In attendance:

- Paul E. Kinahan, PhD (co-chair)
- Richard L. Wahl, MD (co-chair)
- Andrew Buckler, MS
- Paul E. Christian
- Igor Grachev, MD, PhD
- John Hoffman, MD
- Lisa R. Karam, PhD
- Eric S. Perlman, MD
- Ling X. Shao, PhD
- Daniel C. Sullivan, MD
- Scott D. Wollenweber, PhD
- John G. Wolodzko, PhD
- Jeffrey T. Yap, PhD
- Brian E. Zimmerman, PhD

FDA documents (Mr Buckler)

- FDA Request Letter and Briefing Document being drafted
- Request Letter begins FDA biomarker qualification (consultative) process; FDG-PET to be first example submitted
- Request Letter formalizes the process for FDA to form a Biomarker Qualification Review team (BQRT), which will use Briefing Document as primary material
- Draft Request Letter in circulation for feedback and comment; generic language used to broaden beyond one specific disease or purpose; final language to be adjusted based on outcome of qualification study/efforts
- Relationship with the current NIH OBQI (Oncology Biomarker Qualification Initiative) trials is being discussed
- QIBA action to support Request Letter based on quantitative PET, not qualitative PET
- Focus to be on oncology for FDG-avid tumors and well controlled quantitative studies (being defined by adherence to QIBA Profile)
- SUV and change in SUV wording needed
- No explicit link between the April 13-14, 2010 FDA/SNM/RSNA meeting and these QIBA qualification documents; April meeting is a catalyst to build momentum
- QIBA to forward both Request Letter in April (target) and Briefing Document to FDA by June/July 2010

Multiple agency collaboration

- Stronger voice heard from collaborating organizations, e.g. QIBA, SNM, EANM, ACRIN, and oncology groups like ASCO and CALGB, etc
- Need sense of collaborative effort/process
- QIBA reflects inclusion of multiple stakeholders

Strategy

- Need to breakdown overall QIBA scheme into smaller, manageable, “doable” steps
- Multiple stages need to be identified and assessed; individual groups to focus on “project blocks”
• Request Letter language needed based on:
  - Oncology
  - FDG-avid tumors
  - Quantitation

• All interested groups beyond QIBA welcome to participate

• Mr Buckler to forward draft FDA Request Letter and Briefing Document to all Q-PET Committee members for feedback and comment

• Mr Buckler to forward a flowchart outlining the process needed, as well as project plans and proposed schedule

• Feedback requested

Next Steps:

• Mr Buckler to forward draft FDA Request Letter and Briefing Document to all Q-PET Committee members for feedback and comment

• Mr Buckler to forward a flowchart outlining the process needed, as well as project plans and proposed schedule

• Next Q-PET Committee call scheduled for April 29 at 10 AM CDT

Imaging Biomarker Qualification Process (slide referred to on the call)
Kindly submitted by Mr. Andrew Buckler