QIBA FDG-PET Qualification Update Call
Thursday, Feb 11, 2010
Call Summary

In attendance:
Andrew Buckler, MS (moderator)  Richard Wahl, MD
Constantine Gatsonis, PhD  RSNA
Paul Kinahan, PhD  Susan Anderson, MLS
David Raunig, PhD  Joe Koudelik
Daniel Sullivan, MD

General Discussion-Briefing Document
- Opportunity exists to provide the FDA’s Biomarker Quality Review Team (BQRT) with imaging guidance
- Formal QIBA objectives needed based on key leadership insight and bio-statistical support
- FDG-PET has FDA approval now as a radiopharmaceutical; need more specific focus on quantitative, not qualitative, aspects; claim language will be critical
- FDG-PET already in clinical use to assess clinical response; briefing document should not ask for what already exists
- First phase of a 2-part process (consultation phase) with FDA for FDG-PET qualification has begun
  1. Specific briefing document being prepared for FDG-PET; what has already been done and lay-out of expected steps to acquire a “full data package” to serve as a discussion document between FDA and sponsors
  2. Feedback from briefing document to guide design/development of the full data package

Background information needed:
- FDA interested in prediction value of biomarkers, besides drug efficacy and surrogacy endpoint in clinical trials
- FDA favors narrow focus, such as mechanisms and tumor biology

Claims
- Claims needed for clinical response; need to identify classes of therapies, summarize evidence, and assemble a document for FDA with areas that are considered doable
- Need to understand the community interest to determine scope of QIBA requests
- Clinical claims may have more supportive data than drug development claims
- Clinical care needs a firm foundation set by quantitation
- More stakeholder attention may come from broadening scope beyond clinical trials; utility for vendors needed
  - Collected data can be used by vendors to strengthen more claims leading to reimbursement
- Feedback needed to determine scope
  - Assay development
  - Assay validation
Data issues
• Impossible to acquire enough data to prove efficacy completely; a fundamental problem to be addressed
• Quantitation leading to improved clinical practice is our hope; is this safe to assume FDA is thinking the same?

Approval vs Qualification
• Approval = for clinical use
• Qualification = qualified to be used in multiple ways
• FDA use parallel pathways for approval and qualification; a linear process may not be needed
• The bar for clinical use may be lower than for drug development; qualification of a biomarker for “proof” is much more difficult
• Qualification of FDG-PET is the endpoint; to be addressed at the April 2010 FDA/SNM/RSNA meeting

Proposed Timeline/Milestones
• March 2010 - Send request letter to FDA
• April 13-14, 2010 – RSNA/SNM/FDA Workshop, Bethesda, MD
• June (+) 2010 - Host meeting with FDA BQRT

Next Steps:
• Continue discussion on FDA briefing document and full data package
• Accuracy of measurements needs discussion
• Qualification of drug development vs. clinical implementation: should both be pursued?
• FDG-PET Qualification calls to continue for 4 (+) weeks; next call to be scheduled for Thursday, Feb 18 at 1 PM CST