QIBA FDG-PET Qualification Update Call

Thursday, Feb 11, 2010
Call Summary

In attendance:

Andrew Buckler, MS (moderator)
Constantine Gatsonis, PhD
Paul Kinahan, PhD
David Raunig, PhD
Daniel Sullivan, MD
Richard Wahl, MD

RSNA

Susan Anderson, MLS
Joe Koudelik

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

- Qualification activity of clinical research

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