QIBA FDG-PET Technical Committee Update
February 4, 2011 at 9 am CST
Call Summary

In attendance:
Paul Kinahan, PhD (Co-chair)
Richard Wahl, MD (Co-chair)
Andrew Buckler, MS
Patricia Cole, PhD, MD
Howard Higley, PhD
Blaine Horvath, RT
Dennis Nelson, PhD
Eric Perlman, MD
Jeffrey Yap, PhD
Brian Zimmerman, PhD

RSNA:
Joe Koudelik

Call agenda:

- Reminder of regular calls for alternating Fridays (Dr Kinahan)
  - FDG-PET "general business" call to alternate with the FDG-PET Profile Authoring Writing Group
- QIBA grants update (Dr Kinahan)
- Formation of Clinical Effectiveness Review Ctte (Dr Kinahan)
  - To coordinate (collect and review) data coming out of QIBA efforts and support the use of FDG-PET in clinical trials; statistical support still needed
- UPICT update (Dr Perlman)
  - Protocol development milestones presented
  - Consolidated vs. Consensus terms discussed
  - List of protocol technical issues (knowledge gaps) needed for addressing by Tech Ctte
- FDA Briefing Documents update (Dr Higley and Mr Buckler)

(abstract) BRIEFING DOCUMENT TO THE FOOD AND DRUG ADMINISTRATION

Qualification of FDG-PET/CT as an Imaging Biomarker Predicting Response to Cancer Therapy for Patient Management and Oncologic Drug Development
Version 1.1 January 30, 2011

Overall Hypothesis and Claim

FDG-PET/CT scans are sensitive and specific for detection of FDG-avid malignant tumors. FDG-PET scans reliably reflect glucose metabolic activity of cancer cells and can be measured quantitatively and with high reproducibility over time. Quantitative longitudinal changes in tumor FDG activity during therapy predict clinical outcomes (e.g., overall survival (OS), progression-free survival (PFS), etc.) earlier than changes in standard anatomic measurements. Therefore, tumor response or progression as determined by tumor FDG activity will be able to serve as an endpoint in well-controlled phase 2 and 3 efficacy studies of cytotoxic and targeted therapies in FDG-avid tumors in both primary lesions and metastatic disease. In tumor/drug settings where the phase 2 trials have shown a statistically significant relationship between FDG-PET response and an independent measure of outcome, changes in tumor FDG activity can then serve as the primary endpoint for regulatory drug approval in registration trials.

Next Steps:

- Dr Cole to review Briefing Document and provide feedback to Dr Kinahan
- RSNA staff to forward "Pharma Data Request Letter" to FDG-PET TC members on today's call for feedback
- Agenda items for next FDG-PET TC update call:
  - Pharma Data request Letter
  - Template/schema update (Mr Buckler)
  - List of protocol technical issues (knowledge gaps) needed for addressing by Tech Ctte
- Next call scheduled for: Friday, Feb 18th at 9 am CST