

QIBA Quantitative PET Committee Update

Thursday, March 25, 2010

10 AM CDT

Call Summary

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

RSNA

Fiona Miller
Susan Anderson, MLS
Joe Koudelik

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

