

QIBA Quantitative PET Committee

Thursday, January 28, 2010

10 AM CST

Call Summary

In attendance:

Paul Kinahan, PhD (Co-chair)

Richard Wahl, MD (Co-chair)

Andrew Buckler, MS

David Clunie, MBBS

Patricia E. Cole, PhD, MD

Yuying C. Hwang, PhD

Gary Kelloff, MD

Steve Kohlmyer

Eric Perlman, MD

Rathan Subramaniam, MD

Daniel C. Sullivan, MD

Scott Wollenweber, PhD

Jeffrey Yap, PhD

Brian E. Zimmerman, PhD

RSNA

Fiona Miller

Susan Anderson, MLS

Joe Koudelik

FDA/SNM/RSNA joint workshop, April 13-14, 2010

- FDA is addressing two purposes in a single workshop:
 - Requirement in PDUFA for guidance by 2011 (or later); information from this meeting may lead to white paper in interim
 - Clarify issues of radiopharmaceuticals in drug trials
- Day 1 of workshop to address standards in imaging acquisition in trials to include discussion of QIBA and IIBE;
- Day 2 of workshop to address PET in trials and practice and how QIBA and IIBE relate to PET
- A number of QIBA participants will be invited to participate as panelists; Dr Wahl will present on PET
- In preparation for meeting(s) with FDA, three manuscripts in preparation to address:
 - Quantitative imaging assay validation
 - Evidentiary studies to support coverage/reimbursement
 - Quantitative imaging biomarkers qualification as surrogate endpoint in clinical trials
- FDA follows multi-work streams for all biomarker qualification, e.g. blood serum, phenogenomics, etc; each stream/process should share a common language for all stakeholders
- Discussions with Mr Goodsaid at FDA led to chart (attached) which has been used for safety markers but not efficacy or imaging markers yet; suggestion was to start narrow and broaden scope over time
- The process is similar to EMEA process in Europe
- Suggestions related to draft:
 - 'Performance Characteristics' to replace 'Sensitivity & Specificity' term
 - Important not to treat imaging as a lab assay, i.e. associated with an interpretation
 - Could use multiple F and G categories in left column
 - Important to involve European participants in process and invite to April meeting
 - Refine term 'clinical' (practice vs. research) and substitute with 'human'

- In left column, reflect 'clinical' as well as research; although the emphasis is on research because clinical means drug approvals and trials
- Include pre-clinical, i.e. research should back-into pre-clinical qualification
- Mr Buckler reviewed a sample Table of Contents for vCT and PET which includes:
 - Literature review
 - Data acquired by QIBA collaborative, e.g. from Groups 1A,B &C
 - Broader retrospective data re-analyzed in support of current ideas/Claims
 - Future work planned to acquire needed 'full-data'
- Methods section lays out adaptation of IHE process and engaging manufacturing community with Profiles
- The Signoff Letter step is essentially a draft guidance on how biomarkers get used; in EMEA is called an 'advice' guidance
- Need discussion on timing of submission of request letter
- Involvement of a Sponsoring Collaborative is important
 - In validation pathway which is dominated by hardware/software, suppliers
 - In qualification pathway in which standards require supplier and user collaboration, e.g. Predictive Safety Testing Consortium (PSTC) a collaborative effort between pharmaceutical companies to generate data supporting biomarker qualification
- Discussion on whether FDG-PET could follow shorter path by literature review alone (PERCIST review)
 - Need to rethink stating need for clinical trials; may not be required for all biomarkers

Next steps:

- Mr Buckler encourages comments, suggestions and text for white paper drafts
- Committee will further discuss the chart during Saturday, Jan 30 f2f during SNM midwinter in Albuquerque and will submit comments to Mr Buckler
- Dr Wahl will review papers re: PERCIST
 - Dr Wahl will discuss effort with European participants at SNM