

QIBA Quantitative PET Committee

Thursday, February 25, 2010

10 AM CST

Call Summary

In attendance:

Paul E. Kinahan, PhD (co-chair)
Richard L. Wahl, MD (co-chair)
Andrew Buckler, MS
Paul E. Christian
David A. Clunie, MBBS
Patricia E. Cole, PhD, MD
Constantine Gatsonis, PhD
John Hoffman, MD
Yuying C. Hwang, PhD
Gary Kelloff, MD
Dennis Neslon, PhD

Eric S. Perlman, MD
Yuanix Rong, MD, MPH
Ling X. Shao, PhD
Barry Siegel, MD
Daniel C. Sullivan, MD
John G. Wolodzko, PhD

RSNA

Susan Anderson, MLS
Joe Koudelik

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

- Based on establishing the needed pieces/parts to showcase order in the QIBA approach, not necessarily a formal approach leading to PET qualification as a biomarker
- A catalyst to organize for a future, more formal FDA meeting; an opportunity to polish the group's approach

FDA papers under preparation (Mr Buckler)

- Need clarification of specific FDA "ask"; "ask" must be made with care as to avoid FDA pushback or backward momentum; risk to be mitigated by focusing on quantitation and avoiding clinical aspects; use of a conservative approach proposed
 - Take care to avoid possible PET setback in the field
- Discussion that a *bad* proposal would cause more backward movement than *no* proposal
- Statistical quantitation based on cases needed to qualify PET as a biomarker (metadata analysis vs. existing work vs. work yet needed)

Briefing Document Overview; "Qualification Process" slide

- *Request Letter* – begins the process
- *Briefing Document* – consultative phase
 - Briefing Document to bring forward all supporting evidence and a summary of current activities, as well as map of anticipated future steps acceptable to the FDA process
 - Pre-consultation to establish reasonable FDA expectations for the QIBA process
- *Full Data Package* – review process

Action items

- Need for a Briefing Document beyond the Profile
 - 1-Literature analysis current of field
 - PERCIST work is appropriate now, more needed in the future; need to transfer results into context of the Briefing Document
 - 2-Present efforts in the field need to be summarized; clinical trials data needed to build evidence
 - 3-Steps need to be mapped out to build process
- Map out necessary steps to build sufficiency of cases in effort to establish FDA qualification approval basis
- Literature search underway beginning with Dr Wahl's experience with PERCIST
- Dr Perlman to transfer results from the PERCIST document to the Briefing Document
- Need to summarize claims / scope of what QIBA is pursuing in regards to PET biomarker qualification
- Need to compare central vs. site-specific quantitative analysis as part of Profile
 - QIBA could assist with improving localized site-specific readers

Manufacturer Road Show

- Carefully structured "ask" list for manufacturers needed with carefully chosen discussion points; to be presented to manufacturers as a concerted effort
- The "ask" list can be reviewed by manufacturer committee members
- Visits will be made to companies individually

UPICT Protocol and Profiles

- Profile and protocols are related
- Profile - what is current state and where QIBA wants to be; referred to in the Briefing Document
- Manufacturers need controlled conditions to understand QIBA's requests; need to identify main quantitative question
- QIBA Subcommittees couple results and determine performance Claim levels, then incorporate into Protocol
- UPICT PET Protocol Extraction based on whole body PET - single and multi- center clinical trials based on oncology; extraction of articles, presentation of commonalities and notation of appropriate literature in progress
 - Dr Perlman 30% done with main outline; more commonalities encountered than exceptions
 - Consensus language still needed based on four extraction documents
 - Dr Yap extracts and ACRIN SOPs to be included in extractions
 - European (The Netherlands) opinion is that quantitation analysis is too difficult for individual sites; to be performed at one central lab with experience; centralized vs. site-specific quantification analysis a cost issue to be addressed
- UPICT is specific to clinical trial setting
- Proffered protocol ongoing work is posted on UPICT Wiki, http://upictwiki.ctsa-imaging.org/index.php?title=Draft_Proffered_Protocols

Next Steps/Reminders:

- Dr Perlman to transfer results from the PERCIST document to the Briefing Document
- Need to summarize claims / scope of what QIBA is pursuing in regards to PET biomarker qualification
- QIBA Annual Meeting scheduled for May 25-26, 2010 at Hyatt Regency O’Hare, Rosemont, IL
- Next Q-PET Committee call scheduled for March 25 at 10 AM CDT

Imaging Biomarker Qualification Process (slide referred to on the call)

Kindly submitted by Mr. Andrew Buckler

