

QIBA Q-CT Committee Weekly Update

Monday, January 24, 2011

11 AM CDT

Call Summary

In attendance:

Andrew Buckler, MS (QIBA Program Director)
P. David Mozley, MD (CT Co-chair)
David Clunie, MBBS
Charles Fenimore, PhD
Paul Garrett, MD
Michael McNitt-Gray, PhD
James Mulshine, MD
Kevin O'Donnell
Guillaume Orioux
Nicholas Petrick, PhD

Anthony Reeves, PhD
Yuanxin Rong, MD, MPH
Ganesh Saiprasad, PhD
Binsheng Zhao, PhD

RSNA

Fiona Miller
Joe Koudelik

Profile Development – Survey Information Gathering

- Advanced disease volumetric CT Profile on the Wiki for reference
 - Version 1.4.1 in Field Test
 - Version 1.5 (that will ultimately turn into v2) posted
- Early disease (or perhaps more specifically small nodule) Profile to resume development under Dr Mulshine's guidance
- Strong opinion/feedback for all Profiles needed
- Need to further develop the "Collect Feedback" process on Wiki
- Dr Mozley's EPIG calls/forum deemed a means to broadcast information and ask for pharma feedback for Protocols and Profiles we develop. (However in this case the "Collect Feedback" step is intended for those that have actually used the version we have in Field Test)
- Mr Buckler to lead development and broadcast efforts for the survey with expert content assistance from Drs Mozley, McNitt-Gray, Schwartz, and Mr O'Donnell
- Survey Questions:
 - How did you find the protocol? (i.e. did it make sense)
 - Did the protocol impact your trial?
 - Was the protocol helpful in achieving your goals? (i.e. protocol critical to accomplishing goals)
- Responses expected to vary depending on where the respondent fits within the clinical trials process (e.g. operations staff, data analysis, etc)

Profiling and Protocol Logistics

- Authoring software tool to help with merging Profile and protocol like-content being looked into
- FDG-PET and Vol CT Early Stage Profile writing groups to utilize soon

FDA Imaging Biomarker Qualification Request Letter Update

- Request letter submitted and reviewed by the FDA BQRT
- Briefing document requested based on VolCT Claims stating what we consider the biomarker to be and its performance
- Claim also exists for device manufacturers based on full data package
- Claims to translate directly into practice of medicine
- Mr Buckler provided an overview of Briefing Document sections
 - 100+ pages, 5 sections, 2 sections relate most directly to work of the technical committee
 - Document outline based on FDA requests
 - Feedback welcome for all sections

Next Steps:

- Drs McNitt-Gray and Zhao to further develop and converge Vol CT Claim language
- Group 3B topic of next call: *Clinical Efficacy and Utility* by Dr Laurence Schwartz
- Next call scheduled for Monday, Jan 31, 2010 at 11 am CST