

QIBA Quantitative PET Technical Committee
Minutes of discussion, 30 Jan 2010 1-3pm, Albuquerque, NM

Attending:

Richard Frank, MD, PhD (co-chair), Paul Kinahan, PhD (co-chair), Richard Wahl, MD (co-chair), Paul Christian, Eric Perlman, MD (via tcon)

Agenda:

1. FDA Meeting
 - 1.1 Approach
 - 1.2 Talks
 - 1.3 Briefing Document
 - 1.4 Action items
2. Manufacturer Road Show
3. Profiles

Discussion:

1.1 Approach

- Imaging Biomarker Qualification Process (IBQP) approach presented by Andrew Buckler on 28 Jan 2010 T-con reviewed.
- Proposed alternate, potentially faster, approach of proceeding with de facto current path, e.g. based on pointing out that RECIST is already used, and vCT and PERCIST are obvious extensions (although FDA may not accept the RECIST extension idea).
- Above alternate method will be in parallel with development of IBQP, and will facilitate development specific use-case of IBQP since there will be a ready source of needed data for the 'Review Process' phase of the IBQP.
- Proposed terminology is going from 1D (RECIST) or 2D (WHO) to 3D (vCT) and 4D (PERCIST), so for both vCT and FDG PET/CT (or PERCIST). There is less ambiguity in the measurements and thus improved accuracy and precision. Not completely accurate, but very likely a useful bullet point to engage FDA with.
- The two-prong approach may also be useful for QIBA vCT group, possibly QIBA as a whole until IBQP becomes established.
- Want to emphasize cooperative working relation with pharma and manufacturers.

1.2 Talks

- Richard Wahl in Plenary, Paul Kinahan in acquisition breakout. Brief discussion on this with FDA rep after meeting.

1.3 Briefing document

- Very important, as FDA plans to use meeting as a basis for proposed guidelines in 2011 or 2012
- This is not the Briefing document of the IBQP, but rather a model for how it will be used
- Getting feedback from FDA on this is also important
- Need to add section on Profiles

1.4 Action items

- Richard Frank to summarize two-prong approach and sent to QIBA and cVT groups
- Paul Kinahan to section up Briefing document for review
- RSNA to merge (non-overlapping) sections and send out for second round
- Paul Kinahan to check with Eric Perlman in 1-2 weeks for FDG-PET UPICT status