RSNA QIBA Meeting Summary
FDG-PET Technical Committee
4-5 PM November 30 2011

Attendees: Paul Kinahan, Richard Wahl, Richard Frank, Wenli Wang, Eric Perlman, Scott Wollenweber, Rathan Subramaniam, Andrew Buckler, Patricia Cole, Howard Higley, Blaine Horvath, Dennis Nelson

Major items discussed:

1. Y2 Multi-reader project
Rich Wahl asked that people consider participating in the Y2 Multi-reader project.
Rich Wahl also suggested that CROs may want to participate.

2. Y3 Projects
Paul Kinahan noted that a future agenda item will be to determine what project areas or gaps the TC thinks needs addressing if Y3 funding becomes available.
Andy Buckler noted that some 'challenges' (e.g. testing against standards by vendors or other parties) may be useful and furthermore may not need funding.
Dennis Nelson suggested that a suitable topic would be the definition or testing or measurement of SUV-peak measures, as these is no information on variability of such measures on different platforms. In the following discussion it was noted that the PET/CT DRO can provide a means to verify or test SUV-peak measures.

3. FDG-PET Profile
Eric Perlman presented the current status of the FDG-PET Profile. In the following discussion there was general agreement with the approach of using a 'compliant' and 'exceeds compliance' categorization, and that it was important to include relevant items in the 'exceeds compliance' category as a means to encourage future directions.
Paul Kinahan added that he had presented the same concepts to the MITA nuclear committee on Nov 28th at their RSNA meeting and there seemed to be general acceptance of the approach.

4. FDA Memorandum of Meeting Summary
Howard Higley presented excerpted sections of the FDA Memorandum of Meeting Summary (appended below) that are specific to the technical aspects of FDG-PET imaging. He also noted that further data from the ACRIN and CALGB trials will be presented to the FDA w.r.t. the biological relevance of FDG PET as a biomarker. In the discussion it was noted that the following comment from the FDA:

> "We recommend the applicant develop such operative definition(s) of the SUV measurement procedure(s), as well as a “good practices” guidance"

These two items correspond closely to the UPICT FDG-PET protocol and the QIBA FDG-PET Profile.

There was general agreement with the suggestion by Andy Buckler and Howard Higley that a necessary component of the response to the FDA will be the FDG-PET Profile

There was some discussion about the apparent misconceptions by the FDA about technical aspects of PET imaging. It was suggested by Andy Buckler that these be

addressed by providing data (peer-reviewed where possible) rather than tutorial material.

One specific point raised by Howard Higley was that one of the figures from the RIDER FDG-PET paper seemed to cause concern about the comparison between different FDG-PET image metrics. Paul Kinahan pointed out that this comparison was anecdotal and the Y2 Project under Jeff Yap is aimed to address this specific point in a statistically significant manner.

Action Items

1. Rich Wahl (?) to draft a letter to CROs requesting participation in the multi-reader study. Paul Kinahan to ask QIBA staff to add participation to next agenda.
2. Paul Kinahan to ask QIBA staff to add Y3 projects to next agenda.
3. TC members are encouraged to provide feedback to Howard Higley on the questions raised in the FDA response. Paul Kinahan to ask QIBA staff to add this to the next agenda.

Excerpt of MEMORANDUM OF MEETING SUMMARY

MEETING DATE:	Friday, June 17, 2011
TIME:	11:00AM – 1:00PM EDT
LOCATION:	WO Building 32/ Room 2162
TYPE OF MEETING:	Face-to-Face meeting to discuss sponsor-submitted Briefing document- FDA and Representatives of QIBA and FNIH/ The Biomarker Consortium

:::

Additional FDA Comments about SUV Measurement: SUV is defined as a concept fairly generally, in practice being applied in several different ways (e.g. SUV max, SUV peak). The measurement procedures may be also influenced by the operator subjective factors, as well as, the features of the graphical user interface. Overall this leads to a certain level of ambiguity regarding the SUV definition and its practical application. Since the biomarker qualification process requires the determination of specific decision thresholds, the SUV measurement procedure needs to be defined, unambiguously to a higher standard of specification. If several distinct measuring procedures are to be used they should be treated as distinct biomarkers unless proven their values are statistically equivalent. We recommend the applicant develop such operative definition(s) of the SUV measurement procedure(s), as well as a "good practices" guidance in order to reduce the variability due to operator subjectivity, or other factors such as differences in the instrumentation or the image visualization and analysis software.

Even if the instrumentation errors may be small compared to the variation due to the biological factors, however for a better understanding of the measurement process and a rigorous interpretation of its results there are a number of questions that require clarification. The instrument calibration studies carried out using phantoms (briefing document, page 38) show a nonlinear response with the sphere size and the type of scanner. This makes nontrivial the interpretation of the differences in SUV measurement, in particular when different scanners are involved. Since the clinical quantity of interest is the SUV difference (ΔSUV), what are the estimated errors of the SUV differences due to instrumentation factors? What type of inter-scanner calibration procedure is envisioned? How much the ΔSUV errors changes when more complex shapes are involved? We recommend the phantom and instrument calibration studies be further expanded in order to provide answers to these questions.

ACTION ITEMS:

1. Meeting summary will be drafted.
2. QIBA/FNIH will provide data and request further consultation as warranted.