QIBA Transition FDG-PET Subcommittee Update October 8, 2010 2 pm CDT

Call Summary

In attendance:RSNA Staff:Paul Kinahan, PhD, (Moderator)Timothy Turkington, PhDJoe KoudelikRichard Frank, MD, PhDJeffrey Yap, PhDJulie LisieckiAndrew Buckler, MS

Purpose of today's call:

- Close-out of the existing FDG-PET sub-groups and restructure around our quantitative imaging goals
- Three areas to pursue:
 - Profile Writing
 - Road Show / corporate visits
 - o Information packet for the FDA (led by Dr Frank and Mr Buckler)
- Need to merge and prioritize list of vendor "asks" from all five current sub-groups
- Prioritization based on continued discussions and vendor feedback
- Dr Kinahan requested a paragraph from each subcommittee chair summarizing findings/results of their group's work. Links to any studies/ results would be appreciated. This paragraph will be part of a 5-paragraph summary presented to the whole group and posted on the QIBA WIKI.
- Consider contingency relationships to avoid adverse affects on the long-term outcomes of some of the related projects

Potential 3 new work groups:

- Profile Writing work group
- Road Show work group
- Information packet for the FDA work group (led by Dr Frank and Mr Buckler)

NIBIB Contract:

- 1.2 million over 2 years for sub-grant within technical committees (no salary support salaries, except post-docs, and engineers)
- Necessary to keep track of resources/expenditures for government reporting
- Consider projects that have an impact *and* get vendors directly involved e.g., Road Show, Profile writing projects
- Plan to work on an information package for FDA biomarker approval
- Part of the planning for new projects will need to take into account the feedback that received from the Road Show / vendor comments, which will help determine more specific actions

Road Show: Wording to consider for talking with vendors:

- "Here's what you need"
- "Here's how it should be done"
- "We need these capabilities"
- Follow up with why it should be done this way tie this to the Profile-writing process
- Stress the level of acceptability and emphasize competitive advantage
- Focus on "tweaking" existing systems, not building new product
- Clinicians and scientists can support these Profile Claims; thus emphasizing buying power (i.e., a business case)
- Bulls-eye approach needed: "Ideal", "Target," and "Acceptable" acceptable"; either the product is or is not compliant
- Plan for success and deal with the unexpected. Stress the idea of writing committees; work towards consensus

After conversations with vendors:

- Whether vendors assign people to certain committees or not will be a reality check for the Road Show team
- Vendors themselves will emphasize where they want their focus to be; what serves the common good
- Vendor engagement may vary; some may only want to meet minimum requirements (Bulls-eye approach); let vendors decide at what level they wish to participate
- Vendors are interested in their potential gain vs. the effort required
- Need for modality committees to be formed including academic + pharma representation
- Name committee for groups developing from Road Show interaction keep names simple and specific to encourage vendor members to join for the long term

Next steps:

- Paragraph from each subcommittee chair summarizing findings/results of their group's work to close-out groups
- Dr Kinahan to follow up via email with other subcommittee chairs regarding direction of the groups
- Poster work for RSNA 2010: Separate tasks and assign people appropriately:
 - Technical content
 - o Presentation/ graphical content production
 - One overall FDG-PET Subctte informational map proposed for RSNA 2010 instead of input from five sub-groups; additional discussion needed on next call
- Next FDG-PET Subctte call will be scheduled for November via poll; informational email to sent out in interim