QIBA FDG-PET Biomarker Committee (BC) Call

01 June 2018 at 9 AM CT Call Summary

In attendance:

Rathan Subramaniam, MD, PhD, MPH (Co-Chair) Scott Wollenweber, PhD (Co-Chair) Terry Brown Cris Crisman, MBA Howard Higley, PhD Paul Kinahan, PhD Martin Lodge, PhD Nancy Obuchowski, PhD Amy Perkins, PhD Eric Perlman, MD Fabien Ricard, MD, MS Mitsuaki Tatsumi, MD Timothy Turkington, PhD Jeffrey Yap, PhD Brian Zimmerman, PhD

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Joe Koudelik Julie Lisiecki

Moderator: Dr. Wollenweber

Overview of the QIBA Annual Meeting

- Topics discussed included the following:
 - Plans for a three –year clinical trial:
 - Who might be a partner
 - How might the trial be organized
 - How can a clinical trial be funded
 - Will the group need to consider sun-setting or can the course of work be changed if funding is not available in order to continue with our efforts

Claim Confirmed Clinical Trial Efforts (Dr. Subramaniam)

- Two potential partner organizations for a clinical trial have been approached:
 - An application for ACR Foundation funding (\$300, 000) was submitted on February 25th
 - The foundation will review the proposal within the next two weeks and their decision will be made known to the group at the next BC meeting in July
 - An additional funding request presented to the *Imaging Core Laboratory Group* of the ECOG-ACRIN Cancer Research Group was recently denied; official notification is expected soon
 - Concerns cited included the struggle to accrue patients for such a trial
 - Some suggestions for directions and trial modifications were provided by Dr. Schnall, including:
 - Selection of one cancer type (not lung) with a review of the lesions that the original lung cancer study did not review
 - Use of a single disease component, rather than multiple disease components, including metastatic sites
 - If the focus is on a single cancer type, roughly 100 subjects would be needed, and the question could be answered by comparing the variability to an already published ACRIN lung study
- Another proposal was put forth by Dr. Perlman:
 - If funding remains a hurdle, it might be possible for the BC members to collaborate on a multi-site study volunteering their time
 - Infrastructure would be need for second acquisition scans
 - The second FDG-PET dose might be donated by industry
 - Perhaps a partnership with an imaging core lab might be possible to analyze all images
 - Or as Dr. Schnall suggested, a single-disease site could be used to complete the study

- Dr. Yap questioned how the Profile compares to the current standard-of-care; i.e., does QIBA performance justify the extra effort?
 - If the Profile demonstrates a substantial reduction in variability, accreditation providers (e.g., ACR) may take notice and integrate into their existing programs
- Mr. Crisman made the observation that oncology doctors are very interested in quantitation and that this area of study has even more need for accuracy and resolution of variability to impact clinical decisions
- QIBA could control for more factors including:
 - o multiple cancers
 - o additional variability
 - o variability even within one patient, e.g., with uptake variability
 - The QIBA FDG-PET/CT Checklist is only 3 pages long and incorporates those key items which have been deemed truly relevant for conformance
 - Use of the checklist in a clinical trial would be extremely helpful to provide ongoing feedback for the next version of the Profile

Dr. Vanderhoff (?)

- Dr. Perlman mentioned a recent presentation by Dr. Vanderhoff at a PINTAD meeting where he detailed the use of SUR, a different measurand that has many features and may act as a surrogate marker
- It could possibly mitigate some of the technical specifications in tracer uptake time across time points
- Dr. Perlman to follow up with Dr. Vanderhoff regarding sharing his slide deck, as well as possible availability to be a guest speaker on a future FDG-PET BC WebEx

Action Items for Next Call:

- The next call will focus on future plans for the committee, depending on the outcome of the ACR Foundation decision
- Dr. Perlman to follow up with Dr. Vanderhoff
- Dr. Kinahan to circulate updated proposed paper for *Radiology* for review and comment by the BC co-chairs
- Dr. Sunderland to invite Dr. LaForest to lead the PET-MRI Profile TF

Nuclear Medicine WebEx Schedule:

06/08 PET Amyloid BC06/15 I-123 Profile Writing TF06/29 NM Coordinating Committee

SPECT TF call:

06/12 TC^{99m} Profile TF @ 2pm CT

07/06 FDG-PET BC

07/13 PET Amyloid BC

- 07/20 I-123 Profile Writing TF TBD
- 07/27 NM Leadership TBD

SPECT TF call:

07/10 TC ^{99m} Profile TF @ 2pm CT

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