QIBA FDG-PET Biomarker Committee (BC) Call

05 January 2018 at 9 AM CT Call Summary

In attendance: RSNA

John Sunderland, PhD (Co-Chair)
Rathan Subramaniam, MD, PhD, MPH (Co-Chair)
Scott Wollenweber, PhD (Co-Chair)
Chris Crisman, MBA

Jeff Kolthammer, PhD Martin Lodge, PhD Nancy Obuchowski, PhD Amy Perkins, PhD

Eric Perlman, MD Anne Smith, PhD Richard Wahl, MD, FACR Xiaoyou Ying, PhD Joe Koudelik Julie Lisiecki

Moderator: Dr. Sunderland

Paul Kinahan, PhD

Radiology Article Update (Dr. Kinahan)

- About half of the recommended edits have been drafted
- Dr. Kinahan is working on completing the paper edits before forwarding to the BC leaders for review,
 followed by resubmission to Radiology editors

Proposed White Paper on the Case for Quantitative PET (Dr. Lodge)

- An introduction to quantitative imaging with practical details on how Profiles are used
- Need high-level context regarding importance of Profiles, not detailed Profile specifics
- Need input from physician leaders and oncologists; need "clinician champion" to promote quantitative PET
- Need details on imaging biomarkers for cancer
- Must have a broader appeal, including a review of all applications, especially those identified as effective clinical use cases of quantitative PET through examination of literature and reports
- It may also be interesting to conduct a survey to determine to what extent SUV values are reported clinically
- A future goal would be to work toward reimbursement for quantitative PET via CMS, but first the use cases and implementation must be made in a meaningful way
- Leadership will work on focusing the questions in order to organize a core group for limited groundwork
- The co-chairs to draft an email to the FDG-PET/CT BC regarding suggested proposals for groundwork and supporting literature searches
- In addition, Dr. Lodge has contacted *JNM* to gauge interest in a phantom study article, and hopes for feedback in two weeks

Claim Confirmed Clinical Trial Efforts

- The BC is trying to move forward with the claim (claim confirmed stage) and would like to test the claim in a clinical trial; ideally a multi-center trial.
- Funding is needed for this effort
- Although initial funding requests to ECOG-ACRIN were declined, the BC is cautiously optimistic about the possibility of applying to the ACR Foundation for funding
- Funding is needed for follow up scans for approximately 100 subjects at \$1,500 = \$150,000
- Application for ACR Foundation funding is due by the end of February
 - o The trial design can be focused after the application has been completed
 - o If accepted, the trial would be run by ECOG-ACRIN
 - o The BC hopes to make the trial design more general and inclusive to include lymphoma, for example
 - o Dr. Kinahan to follow up with the FDG co-chairs on this application

- It was suggested that Dr. Mankoff, Chair of the ACR Foundation's Experimental Imaging Sciences
 Committee, be contacted, as a letter signed by committee chairs will be required after study protocol review is approved
- o Follow up guidance from Dr. Obuchowski will also be needed for protocol design
- Team to work offline and get approvals from different committees, as well as to consider possible organ systems
- Dr. Wahl suggested offering a modest \$3,000 honorarium to 5 readers to provide incentive
 - Reads can be done remotely through the cloud system, but time must be allocated
 - It was suggested to include \$15k in the overall budget (\$3K x 5 readers)...this was <10% and deemed acceptable</p>

Proposed Cross-modality PET-MRI Profile

- Next steps were discussed for a PET-MRI collaboration to enhance the existing FDG-PET/CT Profile
 - o BC members will need to decide which sections of the Profile require modification, as inclusion of PET-MRI would cross all areas, including physics
 - Dr. Perlman requested that the PET-Amyloid BC leaders be included
 - The co-chairs asked that RSNA Staff send out a <u>request</u> for volunteers on the FDG-PET/CT BC and also include leadership from the MR Biomarker Committees to gauge interest

Sustainability for future groundwork

- All are asked to think beyond the usual government funding sources for new ideas
- BC members are asked to identify needed groundwork projects and potential ways to raise funds
- Suggestions included:
 - Leveraging ongoing studies
 - Add-ons to other clinical trials
 - Reaching out to organizations conducting complementary research and foundations
 - The FDG-PET checklist might be used in a pilot project for clinical trials, if approved
- Dr. Kinahan mentioned that QIBA is also considering ways to bridge the gaps between QIBA and QIN
- Dr. Wahl encouraged the group to consider a "QIBA Compliance fee" for stakeholders, e.g. software companies, as a potential fund-raising mechanism before it becomes impossible to monetize

Nuclear Medicine WebEx Schedule:

01/12 PET Amyloid BC

01/19 SPECT BC

02/02 FDG-PET BC

02/09 PET Amyloid BC

02/16 SPECT BC

02/23 NM Coordinating Ctte CC

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