QIBA FDG-PET/CT Biomarker Committee (BC) Call
21 February 2020 at 11 AM CT (new time)
Call Summary

In attendance:

John Sunderland, PhD (Co-Chair)	Howard Higley, PhD	Martin Lodge, PhD	**RSNA**
Rathan Subramaniam, MD, PhD, MPH (Co-Chair)	Paul Kinahan, PhD	Nancy Obuchowski, PhD	Joe Koudelik
Ronald Boellaard, PhD	Adriaan Lammertsma, PhD	Tim Turkington, PhD	Julie Lisiecki
			Adeline Boettcher

Moderator: Dr. Sunderland

Encouraging Profile Adoption in the Community

- Dr. Sunderland discussed how the Profiles are currently "parked" on the QIBA wiki and are not being widely used
- He would like to encourage widespread use amongst pharma, CROs, the NCI Clinical Trials Network, and other organizations
- There is a global push from QIBA Leadership that the Profiles must be used in a meaningful way, e.g., as imaging guidelines
- How to get the Profiles into the community will be a focus of discussions at the upcoming QIBA Annual Meeting

Update on Funding Opportunity

- There was an RFA for Tool Development which seemed like it might be a good fit for the FDG-PET/CT Profile
    - As a pre-approved Letter of Intent (LOI) was required, it will not be possible for the BC to respond
    - If there is a new FDA cycle in the fall, more time would be available to seek approval of an LOI with a narrower context of use
- Dr. Higley noted that the rigor and detail for the application is extremely difficult and new regulatory guidelines (Section 507) are quite demanding
    - Dr. Higley to revise the original LOI by narrowing the use case

White Paper Proposed

- It was suggested that the team need to demonstrate the importance of prospective test-retest studies in a peer-reviewed white paper to improve their funding potential with ECOG-ACRIN or other foundations
- Such a paper will require review by Dr. Obuchowski to provide statistical validation
- Once complete, the paper could be used to support the value of the proposed FDG-PET clinical trial for future funding applications
- It was suggested that the paper could potentially be submitted to *Radiology*

Related Trials

- Dr. Subramaniam noted that there are two trials in the works, one funded by ECOG-ACRIN and the other by the NRG Oncology Foundation, which may be avenues to test the feasibility of the FDG-PET Profile checklist
- Dr. Subramaniam is preparing a SurveyMonkey questionnaire for the feasibility responses and wants to see what number of these study sites will be able to comply with the QIBA checklist
    - Feedback could result in trial protocol modifications
- The team is taking a softer approach with requesting these responses so as not to inhibit trial accrual
- Other funding mechanisms were discussed, but the team does not currently have the necessary bandwidth

***Radiology* Manuscript Update**

- The article published in *Radiology* by Dr. Kinahan and colleagues on "The QIBA Profile for FDG PET/CT as an Imaging Biomarker Measuring Response to Cancer Therapy," was published online on January 7, 2020
- A very complimentary editorial was also posted by Dr. Gary Ulaner

- The QIBA Profile for FDG-PET/CT as an Imaging Biomarker Measuring Response to Cancer Therapy has also been featured in a *Radiology* podcast: https://lnkd.in/eHzpymt
- This content has also been posted to the **QIBA LinkedIn** page. Parties interested in joining the QIBA LinkedIn page for QIBA updates should visit: https://www.linkedin.com/company/rsna-qiba

Other opportunities

- Dr. Sullivan and the immune modulation group at NIH are considering interest in test-retest studies and how to best involve pharma and CROs, lobbying on QIBA's behalf
- There may also be prerequisite qualification for sites in clinical trials, similar to PET accreditation with more formalized checklists

Harmonized Templates

- Dr. Sunderland urged the BC to consider what would be needed to lay out the groundwork for a potential model for clinical trials that could easily be adapted, i.e. a plug and play language template
- A clinical trial and clinical use tool kit for the FDG-PET Profile that distills the Profile into a more usable and adaptable format could be very helpful, not only for FDG-PET opportunities but other nuclear medicine Profiles as well
    - Approximately, 60-70% of the Profile would likely remain unchanged for a template
- There are other approved PET imaging agents in the approval pipeline and the QIBA nuclear medicine community needs to take this into consideration
- The BC intends to streamline the Profile drafting process by starting with an electronic template
    - Will need to perform a gap analysis for new tracers and biomarkers, such as PSMA and DOTATATE
    - This work needs to be done in concert with European and Australian colleagues, as well as other leaders in this clinical field
    - Drafting a table based on all the items that are different will provide an at-a-glance reference
- Quantitation is needed in Australia and Dr. Subramaniam anticipates a favorable response to partnership outreach
    - There is a need for global standardization of scanner validation approaches, which would be beneficial for everyone
- Dr. Boellaard has agreed to collaborate in aligning European protocols or making them mutually interchangeable
    - He will work on cross-calibrating accreditation programs not in conflict with the EANM
- Documents to be developed for the Appendix may include:
    - Harmonized / standardized protocol
    - Checklists that are radio-tracer specific
        - These smaller documents may prove to be more useful than the Profiles
- Per the *QIBA Mission*, "QIBA seeks to improve the value and practicality of quantitative imaging biomarkers by reducing variability across devices, sites, patients, and time," it is not clear that the Profiles are the best vehicle to achieve this mission
- Drs. Sunderland and Kinahan will need to present these ideas to address QIBA Leadership priorities at the upcoming QIBA Annual Meeting
- Dr. Turkington to investigate the practicality of the appendix approach, possibly using the appendix to create an abbreviated protocol
- It will also be necessary to have a consensus protocol checklist which Dr. Kinahan will create for ECOG-ACRIN
- Dr. Subramaniam will share the protocol that he wrote for a recent head and neck trial with the team in order to utilize some of the QIBA-specific language
- The goal will be to create a universal QIBA-UPICT-EANM-FDG template
- It is hoped that such a protocol will be more practical and will be implemented at community centers
- Drs. Boellaard and Sunderland to begin scanner validation discussions offline

Continuing discussion items:

- RO1 proposal for a clinical trial with FDG-PET/CT
- NCTN trials
- SPECT/CT protocols needed for clinical trials
- Establishing quantitative parameters for new PET/CT radiopharmaceuticals in clinical practice
- Implementing the FDG-PET/CT Profile in multi-center trials
- Scanner validation

Nuclear Medicine Schedule: *The next scheduled QIBA calls will be as follows:*

03/10	SPECT TC^{99m} BC @ 2 pm CT
03/13	PET Amyloid BC – TBD
03/20	FDG-PET BC @ 11 am CT
03/27	NM Leadership @ 9 am CT – TBD

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