QIBA FDG-PET Biomarker Committee (BC) Call

07 June 2019 at 9 AM CT

Call Summary

In attendance:			**RSNA**
Rathan Subramaniam, MD, PhD, MPH (Co-Chair)	Jayant Narang, MD	Fabien Ricard, MD, MS	Joe Koudelik
Scott Wollenweber, PhD (Co-Chair)	Nancy Obuchowski, PhD	Mitsuaki Tatsumi, MD	Julie Lisiecki
Adriaan Lammertsma, PhD	Amy Perkins, PhD	Timothy Turkington, PhD	
Martin Lodge, PhD	Eric Perlman, MD		

Moderator: Dr. Subramaniam

General Updates:

- The BC submitted a funding proposal for the SIG/QIBA letter to pharma, which outlines the primary objectives of a multicenter test-retest study (clinical trial)
- QIBA leadership are working to obtain specific pharma contact names and addresses, as well as to develop an appropriate timeline for distribution of the letter and accompanying project proposals
    - There will probably be some discussion at the QIBA Annual Meeting
- At the 2019 Spring ECOG-ACRIN meeting, Dr. Kinahan spoke with leadership from the ACR Foundation, and it was discovered that the FDG-PET application for funding was not submitted to the committee for consideration since the ACRIN Chair did not deem it worthy
- Dr. Subramaniam intends to pursue application for an RO1 grant, in parallel with the QIBA pharma efforts and self-funding mechanisms for BC members

Manuscript update:

- BC leaders have not yet received an updated draft
- Forgoing the *Radiology* effort altogether was suggested, focusing instead on submitting the original manuscript to *AJR (American Journal of Roentgenology);* the nuclear medicine and molecular imaging focused issue may be a more suitable
- The checklist could be updated more robustly and included with the article
- The deadline for submission in a special AJR-focused issue is December 1st, 2019
- Current editorial leadership at AJR is receptive to this publication, as it has a more clinical-oriented readership
- Time is of the essence, as a new *AJR* editor will be appointed next year, and it is unknown how a new editor might receive the article
- Dr. Subramaniam has the email with the first draft and *Radiology* reviewer comments for reference

Sustainability Implementation Group (SIG) Update:

- Dr. Turkington provided an overview regarding a recent ad hoc SIG call, focusing on efforts to transform mature Profile checklists into site conformance processes
- There are many aspects to consider and it is important to obtain early feedback from pharma and manufacturers regarding whether or not they would intend to use a QIBA conformance process to determine if sites would participate in trials and what is needed to achieve quantitative PET
- However, there is a delicate balance in asking for feedback, as no process is yet in place to demonstrate how this might work, creating a chicken-egg problem
- It is not yet known exactly how one could prove that a site has met the requirements set forth in the Profile
- Three Profiles are being considered for initial pilot studies: FDG-PET, CT Volumetry, and DWI-MRI
- Detailed steps are needed to outline the conformance process

- Dr. Turkington was uncertain regarding whether CROs would pay to be evaluated for participation in trials, but noted that trial sponsors might be willing to pay to ensure quality data

- Dr. Lammertsma noted that EARL certification (similar to what is being described by the SIG) is standard practice in Europe
    - No participants can enter a clinical trial without prior certification, monitored by EARL
    - Even among high-performing academic centers, up to 50% variation in scanner output was discovered, which led to this performance initiative
- EARL is an initiative governed by the European Association of Nuclear Medicine (EANM), and is referred to as EANM Research Ltd
- The purpose of the EARL accreditation program is to promote harmonization efforts aimed at using FDG-PET as a quantitative imaging biomarker in multi-center research
    - This will help to enhance the comparability of data acquired by molecular imaging
    - Presently, the accreditation is required for oncology and will soon be used with brain trials
    - There is a fee for accreditation, and often trial sponsors (Pharma) may cover the costs

- Dr. Perlman referred to the April FDG_PET BC call summary and asked about follow up efforts with ACR and IROC
    - Dr. Wahl was to follow up with Dr. Etta Pisano at ACR
    - Dr. Yap was to follow up with Dr. Knopp at IROC
        - Updates regarding these efforts would be appreciated, though it was mentioned that Dr. Knopp will be at the QIBA Annual Meeting, and perhaps some conversations can take place regarding certification pathways
- It was emphasized that more time must be spent on developing ACR partnerships and sharing QIBA resources, including checklists, other documentation, and gap analysis of the Profiles vs. ACR accreditation

Proposed Agenda for NM Modality Discussions at the QIBA Annual Meeting:

1. Sponsorship of funding for a clinical trial
2. Development of a conformance paper based on the checklist
3. How to implement the checklist in an accreditation process (ACR) or inclusion in a clinical trial network (ECOG-ACRIN)

Logistics planning for a Clinical Trial:

- Dr. Subramaniam to follow up with Dr. Obuchowski at the f2f meeting, because he would like to include her in the RO1 proposal
- Dr. Perlman mentioned that he spoke with Dr. Sunderland on April 3rd regarding logistics planning for the proposed clinical trial
    - He reiterated his interest in helping to develop the case report forms and a reader manual
    - He mentioned that Dr. Sunderland intends to use RedCap for the case report forms as a tool
    - These items are fundamental pieces of a trial and will need to be developed whether funding is obtained or not
- Dr. Subramaniam is hopeful that various methods of support may become available but is leaning primarily toward an RO1 mechanism

Next Steps:

- Finalize a detailed trial design with a checklist for Profile conformance
- Develop case report forms (RedCap) and reader manual

Nuclear Medicine Schedule:

*The next scheduled QIBA calls will be as follows at **9 am CT** unless otherwise noted:*

7/12	PET Amyloid BC – TBD
7/26	NM Leadership – TBD
8/2	FDG-PET BC
8/9	PET Amyloid BC – TBD
8/23	NM Q3 Coordinating Committee

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