QIBA FDG-PET Biomarker Committee (BC) Call
02 August 2019 at 9 AM CT
Call Summary

In attendance:			**RSNA**
John Sunderland, PhD (Co-Chair)	Eric Perlman, MD	Timothy Turkington, PhD	Joe Koudelik
Howard Higley, PhD	Anne Smith, PhD	Richard Wahl, MD	Julie Lisiecki
Nancy Obuchowski, PhD	Mitsuaki Tatsumi, MD	Jeffrey Yap, PhD	

Moderator: Dr. Sunderland

General Update:

- QIBA staff has emailed the SIG/QIBA letters to pharma, and will follow up with printed letters
- SIG/QIBA leadership will provide status updates regarding responses and next steps

***Radiology* Manuscript update**:

- The BC wants to publish the results of the QIBA FDG-PET Profile to get QIBA Profiles into the literature so that they are referenced and used by the medical community
- The group would like endorsement from the National Clinical Trials Network (NCTN) at the National Cancer Institute (NCI) to include the Profile as a requirement or benchmark for FDG clinical trials, but the first step must be to get details about the Profile into the literature
- BC leaders have received an updated draft of the manuscript and are working toward resubmission
- There was an issue with the formatting of the references; substantial editing work is required
- Forgoing the *Radiology* effort altogether was suggested, focusing instead on submitting the original manuscript to the *American Journal of Roentgenology (AJR);* the nuclear medicine and molecular imaging focused issue may be more suitable
- The deadline for submission in a special AJR-focused issue is December 1st, 2019
- 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
- The checklist will be updated and included with the article
- The current checklist is organized by Actor, e.g., site personnel, scanner, software, etc.; if NCI were to endorse the checklist, it might be necessary to reformat it in a way that is easier for NCI to promote and audit

Sustainability Implementation Group (SIG) Update: (Dr. Turkington)

- Ad hoc SIG calls are focusing on transforming mature Profile checklists into site conformance processes
- Three teams are working to develop conformance methods for Actors to verify that they do conform to the Profiles: DWI-MRI, CT Volumetry and FDG-PET (SUV)
- There are 2 BC representatives on these calls (Drs. Kinahan and Turkington for FDG-PET); Dr. Turkington asked for another volunteer to help with the effort and balance busy schedules
    - Dr. Yap volunteered
    - Dr. Sunderland recommended Dr. Martin Lodge (and volunteered himself, if needed)
    - Dr. Wahl recommended Dr. Richard LaForest (Washington Univ)
- Determining verification level (self-attestation vs full verification) and what the verification method would be is the current focus
- A system beyond self-attestation is needed, but QIBA volunteers would figure prominently as subject-matter-experts for verifying conformance, and building a large-scale sustainable model may be challenging
    - Does conformance within the clinical trial context differ from patient care (clinical standardization)?
    - Would conformance apply only to clinical trials or toward a more global clinical standardization?

- The ideal goal would be a broader application of QI to both clinical trials and clinical standardization either users are QIBA conformant or not (a binary approach)
- Facilitating a way to make QIBA conformance part of routine practice and not just in research only is the goal
    - Many clinical trials demand something different than what is done clinically, though quantitative protocols would be welcome to raise the performance bar

Checklist:

- The checklist will be adjusted for true clinical practice and will help to translate the work of QIBA into the clinical domain by setting a clinical standard for reliable quantitative data
- A QIBA qualified site (non/academic) will be required to use the "QIBA method" at all times, providing proof that Profile conformance builds confidence amongst clinical partners
- Two items must be finalized in the checklist:
    - Identification of the normative rows that can be self-attested vs.
    - Rows that must be evaluated, perhaps via use of a calibrated phantom
- Defining the paradigm is the challenge – QIBA needs to decide whether clinical trials are the focus or a more global view of clinical practice which also encompasses clinical trials
- To begin this task, the small group will work on parsing out the list of "must-do" items to adapt the checklist
- This will help to translate the best practices for clinical trials into mainstream clinical practice, which is why research is done - to ultimately improve patient care
- In addition, a detailed harmonized standard would make data more comparable across clinical trials
- Some effort is needed to distill the checklist language into a 6 -7page clinical trial manual for acquisition sites; this 3rd document would require periodic updates
- Self-attestation is akin to a site survey claiming conformance with the QIBA Profile
    - It is also used to make certain that a site is verified, audited, and tested to ensure conformance to the Profile
    - This must be an active process to demonstrate that sites are complying
    - An online registry will be developed to show the sites that have been verified as conformant

Checklist Task Force:

- A temporary task force may be needed to help with the checklist translation effort, making the language clearer for clinical trial use
- Recommended volunteers included: Drs. Lodge, LaForest, Sunderland, and Yap
- Drs. Turkington and Kinahan would also be available as liaisons working with the SIG on this effort
- RSNA Staff will follow up with a doodle poll for the next small group call with Dr. Zahlmann

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:*

8/13	SPECT TC^{99m} BC @ 2 pm CT
8/16	NM Leadership
8/23	NM Q3 Coordinating Committee
9/06	FDG-PET BC
9/10	SPECT TC^{99m} BC @ 2 pm CT
9/13	PET Amyloid BC
9/20	SPECT I-123 BC – TBD
9/27	NM Leadership – TBD

RSNA Staff attempt to identify and capture all committee members participating on WebEx calls. However, if multiple callers join simultaneously or call in without logging on to the WebEx, identification is not possible Call participants are welcome to contact RSNA staff at QIBA@RSNA.org if their attendance is not reflected on the call summaries.