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

In attendance:

John Sunderland, PhD (Co-Chair)	Martin Lodge, PhD	Timothy Turkington, PhD	**RSNA**
Miguel Ochoa Figueroa, MD, PhD	Nancy Obuchowski, PhD	Richard Wahl, MD	Joe Koudelik
Howard Higley, PhD	Mitsuaki Tatsumi, MD	Jeffrey Yap, PhD	Julie Lisiecki

Moderator: Dr. Sunderland

Logistics planning for a Clinical Trial:

- Drs. Sunderland and Perlman had discussed logistics for a clinical trial on April 3rd
- FDG-PET BC leadership want to move forward with a test-retest prospective multi-center clinical trial; Dr. Sunderland outlined proposed next steps
- FDG-PET BC Leadership are trying to determine ways to obtain external funding, but are also making plans to crowd-source the trial, relying upon QIBA volunteer sites
- Help from stakeholders will also be explored:
    - Dr. Sunderland to follow up with Mr. Tervé at Keosys to ask for in-kind support of infrastructure and clinical trial software
        - Keosys is an imaging CRO with a clinical trial suite and is a supporter of QIBA conformance
    - Dr. Wahl to follow up with Dr. Pisano at the American College of Radiology (ACR) regarding trial infrastructure support that might be available through a partnership with ACR's Imaging Core Lab
    - Dr. Yap to follow up with Dr. Knopp regarding available Imaging and Radiation Oncology Core (IROC) - related resources and access to sites that may be willing to participate in the proposed clinical trial
    - Dr. Higley suggested contacting the NCI / CIP funded network with QIN ties with the idea of piggy-backing onto an existing clinical trial that is validating software tools
        - Nuclear medicine QIN members that are also QIBA members might be helpful liaisons
    - MIM Software is also a QIBA supporter, but does not have all of the clinical trial infrastructure support that would be needed as a partner

What is needed:

- An official request letter describing the prospective test/retest study will be sent to selected sites
- 8 - 10 sites will be needed that can follow the QIBA FDG-PET/CT Profile and checklist and enroll at least 10 - 12 subjects
- The first baseline scan would be paid for by insurance as standard-of-care; the second scan could be regarded as "research" and covered by the participating sites (this is the bulk of funding requested for the entire study)
- Dr. Yap noted the challenges faced regarding subject enrollment and follow-up scanning, and recommended that only research scanners be used
    - Standard-of-care (clinical use) scanners may not provide the desired results (more difficult to change protocols, i.e., follow the QIBA FDG Profile and protocol)
- The study would be labeled as a clinical trial and require IRB approval, data de-identification, etc.
- It might be possible to obtain funding from industry sponsors for the second scan
- Dr. Obuchowski confirmed that a smaller sample size (e.g., 50 vs. 100+) would provide sufficient data for a comprehensive statistical analysis

Self-attestation:

- Although checking QIBA conformance may be challenging, it would be an opportunity to test methodologies and hypotheses
- It would be ideal to perform site audits if resources were available, but site self-attestation statements were deemed acceptable for this study
- This self-attestation would be accomplished using checklists, possibly formatted as a Google document

Next Steps:

- RSNA staff to send out the draft letter to those on the call, along with the FDG-PET BC co-chairs and scientific liaison and any other contacts provided by Dr. Sunderland
- This letter would outline the proposed trial and ask for support, in order to make certain that suitable resources are in place to collect the necessary data
- Once finalized, the letter would then be sent to targeted QIBA-related institutions
- Dr. Sunderland to contact Dr. Jackson regarding proposed trial infrastructure support that might be available from partnership with ACR's Imaging Core Lab
    - Dr. Wahl to discuss this possibility with Dr. Etta Pisano at ACR and report back to the group
- Dr. Higley suggested that Dr. Sunderland send the letter to Dr. Robert Nordstrom at ACR/QIN to target QIN interested members
    - QIN network has many tools undergoing validation and may be willing to financially support or provide volunteer site resources to this test/retest trial
- Dr. Wahl to look into possible international affiliates who might aid the effort, such as QIBA colleagues in Korea
- Finalize a detailed trial design with a checklist for Profile conformance
- Dr. Yap to follow up with Dr. Knopp regarding available Imaging and Radiation Oncology Core (IROC) related resources
- Develop case report forms (RedCap) and reader manual
- Dr. Sunderland, along with Drs. Subramaniam and Wollenweber, intends to draft a ½ page proposal for the QIBA letter to pharma, asking for the necessary monetary support for the proposed clinical trial

Nuclear Medicine Schedule:

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

4/9	SPECT BC: TC^{99m} @ 2pm CT
4/12	PET Amyloid BC
4/19	I-123 BC - TBD by co-chairs
4/26	NM Coordinating Committee @ 9 am CT
5/3	FDG-PET BC
5/14	SPECT BC: TC^{99m} @ 2pm CT
5/10	PET Amyloid BC
5/17	I-123 BC - TBD by co-chairs
5/31	NM Leadership - TBD
