QIBA FDG-PET Biomarker Committee (BC) Call
02 November 2018 at 9 AM CT
Call Summary

In attendance:

Richard Wahl, MD, FACR (Moderator)	Jeff Kolthammer, PhD	Eric Perlman, MD	**RSNA**
Orest Boyko, MD, PhD	Adriaan Lammertsma, PhD	Fabien Ricard, MD, MS	Joe Koudelik
Chris Crisman, MBA	Martin Lodge, PhD	Anne Smith, PhD	Julie Lisiecki
Howard Higley, PhD	Nancy Obuchowski, PhD	Mitsuaki Tatsumi, MD	
Edward Jackson, PhD			

Moderator: Dr. Wahl

Estimation of what remaining groundwork is needed

- The proposed clinical trial is the highest priority in efforts to progress to Profile Stage 4: Claim Confirmed
- Point-spread function was to be addressed in the proposed trials
- Parallel projects suggested could focus on the harmonization of PET images from multiple sites and the reconstruction requirements for matching spatial resolution; both remain significant technology gaps in the current Profile
    - Post reconstruction smoothing could be quite difficult
    - It may be too late to alter the Profile to accommodate this, though future versions of the Profile could incorporate new specifications
    - New generation scanners are hitting the marketplace with digital detectors, etc.
        - Will new protocols be needed?
            - Drs. Lammertsma and Boellaard (experts in this area) to discuss the performance characteristics of these new scanners offline
        - Future Profile versions may need to incorporate this detail

Dr. van den Hoff

- Dr. Perlman mentioned Dr. van den Hoff's work again and suggested that it might be helpful to the Profile
- He has studied overcoming tracer uptake time variability and SUV vs. SUVmax to determine which measurement would be more robust

Other parameters in need of resolution

- Less time dependent and less scanner dependent measurands are needed
- How to address low dose without sacrificing performance must be addressed; what is the lower limit in counts that still produces good images?
- Noise and resolution parameters should be explored to determine if groundwork in those areas may be beneficial
- Older research papers may also be worth exploring to see if anything has been overlooked in the pursuit of harmonization
- Dr. Smith suggested looking at infiltration and the quality of the injection
- Mr. Crisman offered to review injection protocols with Dr. Kinahan to eliminate variability and also offered to donate devices, though he has not yet received a response
    - It would be helpful to add something to the Profile regarding injection protocols
    - Drs. Smith and Wahl agreed that the injection infiltration would be a worthwhile pursuit
- Dr. Obuchowski mentioned the possibility of creating a statistical model
    - Different reconstruction factors that affect the numbers could be added to the model
        - 4 – 6 different hypotheses that could be tested outside of a trial might be good to test first

- Mr. Crisman also proposed trying to go beyond proving repeatability and considering seeking funding form payers (insurance, e.g. Aetna, Humana) to improve the quality of diagnostic tools
    - This would consider the overall treatment of patients as payers are more concerned with ongoing treatment
    - This was deemed an intriguing idea to pursue further

***Radiology* Article Update**

- Substantial revisions are still needed to the manuscript; Dr. Kinahan continues to work on the draft
- If not accepted by *Radiology*, other journal options will be considered, such as the *Journal of Nuclear Medicine* (*JNM)* or the *American Journal of Roentgenology* (*AJR)*

PET/MRI Update

- Drs. LaForest and Hope are conducting a preliminary test-retest study utilizing the QIBA FDG-PET/CT Profile to identify sections that might require modification
- An update may be available by the next BC call, though it is uncertain if the group is ready to take on another Profile
- Dr. Smith noted that the onus would be on the user to demonstrate that values would be equivalent to PET/CT if using PET/MRI, and this could be difficult to document

RSNA 2018 / QIBA f2f Meeting Proposed Discussion Items

- Achieving Profile conformance and the issuance of a QIBA Conformant Mark
    - There has been interesting work and discussion in the QIBA lung nodule area – it would be helpful to consider how their work might be applicable to FDG-PET
- Profile stage and how to move forward, along with publication strategy
- Different scanner and reconstruction values
- Noise, infiltration, etc.
- Strategies to approach insurers regarding the value of QIBA image "quality assurance"

Clinical Trial Task Forces

- Volunteer effort will be needed to organize a trial; BC members are asked to volunteer for one of the following 3 groups by responding to RSNA Staff: Jlisiecki@rsna.org:
    1. **Trial Logistics Group** (led by Dr. Perlman)
    2. **QIBA Conformance Group** (led by Dr. Sunderland)
    3. **Data Definition Final Design Group** (led by Dr. Subramaniam)
- Final protocols are anticipated to be complete by the RSNA Annual Meeting
- It is imperative that progress be made on the protocol definitions and trials design
- Dr. Perlman mentioned that BC members need to discuss ways to engage other who are needed in order to create the necessary infrastructure
    - Institutions are needed to share data from patients, and volunteers will be needed to do the readings
    - A platform is needed for volunteer readers to access/read and store analysis results, and a web-based one would be ideal
    - In-kind donations from different organizations would be most appreciated
    - Potential targets must be identified as well as image management, e.g. *AG Mednet, Triad*?
    - Data storage needs to be considered; it needs to be determined if the QIDW is a possibility
    - Image display stations must also be selected, such as *MIM, Hermes*, or *TeraRecon*
    - It was noted that Dr. Knopp recently finished working with Imaging Core Lab to collect data for an fNIH study, and the data for 171 patients will be available at TCIA for additional analysis
        - It might be worthwhile to ask TCIA if they might be willing to collaborate

Action Items:

- All are asked to volunteer for Clinical Trial Task Forces by contacting RSNA Staff: jlisiecki@rsna.org
- The next call will focus on how to encourage Profile and Checklist use at clinical institutions
- Finalize a detailed trial design by the time of the RSNA Annual Meeting with a checklist for conformance
- Develop case report forms (RedCap) and reader manual

Nuclear Medicine Schedule:

11/09	PET Amyloid BC	**12/07**	NM Coordinating Ctte
11/13	SPECT BC: TC^{99m} @ 2pm CT	***12/11***	*No call for SPECT TC^{99m} BC*
11/16	I-123 BC	**12/14**	PET Amyloid BC
		12/21	*No call for SPECT I-123 BC*

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