

QIBA FDG-PET Biomarker Committee (BC) Call

07 April 2017 at 9 AM CT

Call Summary

In attendance:

Rathan Subramaniam, MD, PhD, MPH (co-chair)

John Sunderland, PhD (co-chair)

Scott Wollenweber, PhD (co-chair)

Orest Boyko, MD, PhD

Janice Campbell, PhD

Abhinav Jha, PhD

Paul Kinahan, PhD

Martin Lodge, PhD

Nancy Obuchowski, PhD

Amy Perkins, PhD

Eric Perlman, MD

Ramkumar Saptharishi, PhD

Anne Smith, PhD

Na Sun, PhD

Jeffrey Yap, PhD

Richard Wahl, MD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Sunderland

Paper Status (Dr. Kinahan)

- The manuscript to be submitted to *Radiology* is being updated with comments received from the feasibility testing project: the Profile is now Technically Confirmed (Stage 3)
- A draft should be available for BC review prior to the QIBA Annual Meeting
- Some assistance is needed with determining authorship; a request may be made to BC members via a Google form to self-nominate for authorship

QIBA Multi-Center FDG-PET/CT Clinical Trial Proposal

- A small clinical trial is being planned to test performance of the claim with functional validation
 - The goal is to move closer toward claim confirmed status with the Profile (Stage 4)
 - Approximately 5 sites with 10 patients per site may be recruited; interested volunteers are asked to contact Dr. Sunderland: john-sunderland@uiowa.edu.
- The group is in Stage 3 now; the Technically Confirmed stage
- Stage 5 would be the Clinically Confirmed stage

Other factors for consideration

- Some additional review of the objectives for the clinical trial may be needed
- The primary objectives are solidly established
- Secondary objectives may require some wordsmithing with regard to lesion number and size inclusion criteria
- Lesions with an SUV^{max} of less than 4 will be analyzed, with diameters of less than 2 cm
- Assumption #2 within the protocol will require careful consideration
- Protocol directions were based on measurements for within lesion variability
- Bootstrap statistical assumptions were made at the subject level – not the lesion level
- The number of lesions to include on a given patient must be limited
 - The general rule of thumb was 2 lesions per patient
 - If there were more extreme cases, such as 5 lesions per patient, the sample size would require adjustment

Action items

- Dr. Obuchowski to follow up with Dr. Sunderland regarding citations for the clinical trial study
- Dr. Kinahan to follow up with potential authors regarding authorship for the proposed *Radiology* article
- Drs. Sunderland, Subramaniam, and Wollenweber to draft a poll for scanner manufacturers to determine reconstruction capabilities and other pending questions

Nuclear Medicine WebEx Schedule:

4/14 Amyloid BC

4/21 SPECT BC

4/28 NM Leadership (TBD)

5/5 FDG-PET BC

5/12 Amyloid BC

5/19 SPECT BC

5/26 NM Leadership (TBD)