

QIBA FDG-PET Biomarker Committee (BC) Call

06 July 2018 at 9 AM CT

Call Summary

In attendance:

Rathan Subramaniam, MD, PhD, MPH (Co-Chair)

John Sunderland, PhD (Co-Chair)

Terry Brown

Martin Lodge, PhD

Nancy Obuchowski, PhD

Eric Perlman, MD

Mitsuaki Tatsumi, MD

Timothy Turkington, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Sunderland

Radiology Article Update

- Dr. Kinahan is working on revisions to the manuscript; substantial changes are still needed
- It would be ideal to have the manuscript ready for resubmission to *Radiology* no later than October
- If not accepted by *Radiology*, other journal options will be considered
- Dr. Kinahan will be asked to forward his current draft to the BC leaders to parse out sections to different team members for update to expedite the draft
- RSNA Staff to set up a doodle poll for ad hoc manuscript calls, once Dr. Sunderland has had a chance to speak with Dr. Kinahan and provide some text as well as a list of invitees for this ad hoc effort
- Calls could be scheduled bi-weekly to review outstanding items line-by-line to finalize the draft manuscript

Claim Confirmed Clinical Trial Efforts (Dr. Subramaniam)

- An application for ACR Foundation funding (\$300,000) was submitted on February 25th
 - The foundation is expected to review the proposal in September
 - Though the funding request presented to the *Imaging Core Laboratory Group* of the ECOG-ACRIN Cancer Research Group was denied, guidance from their comments may aid in the trial design
 - Concerns cited included the challenge of patient accrual
 - Dr. Subramaniam believes that 100 patients could be accrued across QIBA sites
- Inclusion criteria for the proposed trial must be determined
 - Some suggestions for inclusion criteria were:
 1. Relatively broad inclusion criteria, e.g., all solid tumors and lymphoma with limits on a particular type of cancer
 2. A narrower and more rigorous focus with choice of a single cancer
 3. A middle-of-the-road selection with the choice of 4 common cancers, e.g., melanoma, lymphoma, etc., with sufficient statistical data
 - Questions about these approaches included:
 - Will results be similar enough to combine and compare?
 - With different types of cancers, will we need to determine numbers for bias and precision for each prior to being able to compare results?
 - Would test-retest results be similar or highly variable?
 - Is self-attestation sufficient or would an audit function be needed?
 - What measures would be taken for items not collected in the DICOM headers?
 - A protocol and logistics for a proposed trial are needed to move forward
 - A commitment from sites with an estimate of patients would be needed
 - Dr. Subramaniam to distribute the current protocol for group review
 - Dr. Turkington to review the checklist categories for applicability to the trial
 - A scanner qualification with baseline measurement prior to the study would be requested to more easily determine if there are outliers once the study is complete

- Infrastructure for image storage would also be needed
 - Dr. Sunderland to contact the Clinical Trials Network (CTN) to gauge interest and also to contact Dr. Nelson regarding possible collaboration with MIM software
 - Dr. Subramaniam to follow up with ACR to see if they might be willing to provide space for DICOM images
- Consideration of whether or not one software platform or multiple platforms would be included in the trial design to measure additional variability
 - Partners to consider would be Siemens and MIM
 - A challenge could be created to include multiple software vendors
 - MIM has cloud-based operations which are archived in a central location – an ideal setup for a collaborative trial amongst sites
 - Dr. Sunderland to talk with Dr. Nelson
- A proposed deadline for having the trial design established would be RSNA 2018

Action Items:

- The next call will focus on the protocol and logistics for a proposed QIBA-led clinical trial
- Dr. Sunderland to contact Dr. Kinahan regarding the manuscript
- Dr. Kinahan to circulate updated paper for *Radiology* for ongoing ad hoc calls until revisions are complete

Nuclear Medicine WebEx Schedule:

07/10 TC ^{99m} Profile @ 2pm CT
07/20 I-123 Profile
07/27 NM Leadership - TBD

08/03 FDG-PET BC
08/10 PET Amyloid BC
08/14 TC ^{99m} Profile @ 2pm CT
08/17 I-123 Profile
08/24 NM Leadership - TBD

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