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)
- Terry Brown
- Eric Perlman, MD
- Joe Koudelik
- John Sunderland, PhD (Co-Chair)
- Martin Lodge, PhD
- Mitsuaki Tatsumi, MD
- Julie Lisiecki
- Nancy Obuchowski, PhD
- Timothy Turkington, PhD

RSNA

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:**

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<th>Date</th>
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<td>07/10</td>
<td>TC $^{99m}$ Profile @ 2pm CT</td>
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<td>07/20</td>
<td>I-123 Profile</td>
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<td>FDG-PET BC</td>
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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.