QIBA SPECT Biomarker Committee (BC) Friday, October 21, 2016, 9 AM (CT)

Call Summary

In attendance: RSNA

P. David Mozley, MD (Co-Chair) John Seibyl, MD (Co-Chair) John Dickson, PhD Abhinav K. Jha, PhD Paul Kinahan, PhD Robert Miyaoka, PhD Nancy Obuchowski, PhD Eric Perlman, MD Pierre Tervé, MS Richard Wahl, MD Brian Zimmerman, PhD Joe Koudelik Julie Lisiecki

Moderator: Dr. Mozley

Transition from I-123 to Tc 99m

- The October 21st meeting of the SPECT BC is the last planned BC t-con of the year
- Ad hoc task force calls may be scheduled if needed
- The BC plans to resume a full call schedule in February 2017, with new Profile focus on Technetium (Tc ^{99m}) and test-re-test studies
- Volunteers willing to moderate task force calls or biomarker committee meetings would be appreciated
 - Please email the SPECT BC co-chairs if interested: yuni@umich.edu; Moz@Endocyte.com; jseibyl@mnimaging.com
- Previous meeting agendas and work products are available in the group's <u>Dropbox folder</u>
 - Task Force calls in the new year will be held twice a month to reduce the load on volunteers:
 - The first Tuesday meeting will address brain (I-123)
 - The second Tuesday meeting will address oncology (Tc ^{99m})
 - There will be greater reliance on individual work and fewer calls overall

I-123 Profile

- Plans for publication of the Profile in manuscript form were discussed
 - o This will not take place until after the public comment process is complete
- Any additional edits at this point will be placed in the open issues section; there will be no more tracked changes allowed

Discriminatory Claim

- The discriminatory claim was discussed at the recent Process Committee and Steering Committee meetings
- The Steering Committee was cautious and discussed the possible legal ramifications of pursuing a clinical cut-off value as a claim
- Since the perception of risk was relatively low, it was ultimately decided that the SPECT BC would include the discriminatory claim (#1C) as a test pilot to explore the possibility of future discriminatory claims for other BCs, including a caveat that this claim has not been fully approved
- Use of this claim type may be an incentive to other organizations to use QIBA Profiles in a clinical context
- Some fears were expressed regarding any minor miscalculations with precision and confidence levels which could create some risk in clinical decision-making processes
- However, as it was pointed out during discussion, risk is inherent in clinical practice, as physicians must also question themselves, and the same risks exist

Authorship

- Active Biomarker Committee participants have been added to the Profile authorship list in alphabetical order
- If preferred, a Committee member may remove their name and re-save the document in the Dropbox folder
- RSNA Staff to add affiliations on the poster and within the Profile appendix

Public Comment Audience

- There has been some variation in the distribution process for public comment between Profiles
- Distribution often begins within a modality community, extends to all QIBA (900+ members), and then moves to external
 organizations outside of QIBA
- If additional subject matter experts are to be included, specific email addresses must be provided to RSNA staff: jlisiecki@rsna.org
- RSNA Staff will collate responses via a Google spreadsheet on the QIBA wiki
- Dr. Mozley would like a wide-ranging public comment process including contacts at the following organizations:
 - o QIBA-Japan, EIBALL, SNMMI, EANM, MDS, AAPM and others that may be clinically relevant
 - All are welcome to provide comments and distribute to other interested colleagues

RSNA 2016 Reminders: If you have not yet done so:

- 1. Please RSVP for the QIBA Working Meeting on November 30th and
- 2. Please sign up for QIBA Poster Meet-the-Expert Sessions (Please select tab at bottom for your BC).
 - a. Google forms save automatically as your responses are entered. Thank you.
- 3. QIBA BC posters are due to RSNA on Monday, October 31st in a print-ready PowerPoint format

Other helpful links: Posters from RSNA 2015 | QR code generator

Nuclear Medicine WebEx Schedule

Oct 28: NM CC @ 9:00 am CT (Friday)

Nov 04: FDG-PET BC **Nov 11:** Amyloid BC

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. QIBA wiki