QIBA SPECT Biomarker Committee (BC) Friday, June 16, 2017, 9 AM (CT)

Call Summary

In attendance: RSNA

Yuni Dewaraja, PhD (Co-Chair)
P. David Mozley, MD (Co-Chair)
John Seibyl, MD (Co-Chair)

John Dickson, PhD Eric Frey, PhD Paul Kinahan, PhD Robert Miyaoka, PhD Eric Perlman, MD Anne Smith, PhD Richard Wahl, MD, FACR Brian Zimmerman, PhD Joe Koudelik Julie Lisiecki

Moderator: Dr. Mozley

Call Scheduling

- The next SPECT BC meeting is scheduled for July 21st
- If needed, an ad hoc I-123 Profile Task Force (TF) call may be scheduled for Tuesday, June 27th at 2 pm CT, if any additional high priority public comment responses are received from QIBA Japan or other reviewers.
- As TF calls resume, they will be scheduled as follows:
 - o The first Tuesday of the month will be for I-123 (Drs. Seibyl and Dickson)
 - o The second Tuesday of the month will be for the Technetium Profile (Tc ^{99m}) (Drs. Dewaraja and Mozley)
 - O Current participants interested in participating on one or both of these committees are asked to make their preference known by responding to RSNA Staff (jlisiecki@rsna.org) or Dr. Mozley (mozley@gmail.com)
 - o Technical scribes may be needed for these calls. If interested, please respond to Dr. Mozley (mozley@gmail.com)

I-123 Ioflupane Profile: Next Steps

- A formal memo response was sent to QIBA Japan and other reviewers on June 6th: The group is awaiting any additional response
 - Absolute quantification was highly encouraged; however it is simply not possible to make this the minimally acceptable standard in multisite trials or ordinary clinical practice at the present time
 - Current groundwork projects may provide additional clarification of claims
 - Either claims will be shown to be not feasible or claims will be documented with "known issues"
- A cross section claim regarding system calibration may not be possible since bias is not known
- A discriminatory claim was re-purposed as a "Statement of Clinical Use" or a "Potential Clinical Use Case" which references clinical utility, thereby making the Profile more valuable in clinical practice
- In the meantime, cleanup of comments continues, to move the Profile to the next phase: Technical Conformance
- A clean version of the Profile will be used to create a checklist, and will be posted to the wiki on June 30th
- A NM CC vote will be needed prior to June 30th to approve this move to the Technical Conformance phase on July 1st
- Some additional review of passages within the Profile to continue on Dropbox by the team

New members

- All are asked to recruit new members regularly; new names can be sent to qiba@rsna.org
- Volunteers willing to moderate BC or TF calls would be appreciated
 - Please email the SPECT BC co-chairs if interested: yuni@umich.edu; mozley@gmail.com; jseibyl@mnimaging.com
- Previous meeting agendas, Profile versions, and work products are available in the group's <u>Dropbox folder</u>
- Opportunities to meet and recruit new members may present themselves at the following meetings:
 - October, Vienna: EANM annual meeting
 - December, Chicago: RSNA annual meeting