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

In attendance:

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 **RSNA** Joe Koudelik Julie Lisiecki

# Moderator: Dr. Mozley

# **Call Scheduling**

- The next SPECT BC meeting is scheduled for July 21<sup>st</sup>
- If needed, an ad hoc I-123 Profile Task Force (TF) call may be scheduled for Tuesday, June 27<sup>th</sup> 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:
  - The first Tuesday of the month will be for I-123 (Drs. Seibyl and Dickson)
  - The second Tuesday of the month will be for the Technetium Profile (Tc <sup>99m</sup>) (Drs. Dewaraja and Mozley)
  - Current participants interested in participating on one or both of these committees are asked to make their preference known by responding to RSNA Staff (<u>jlisiecki@rsna.org</u>) or Dr. Mozley (<u>mozley@gmail.com</u>)
  - 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 6<sup>th</sup>: 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
  - o 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 30<sup>th</sup>
- A NM CC vote will be needed prior to June 30<sup>th</sup> to approve this move to the Technical Conformance phase on July 1<sup>st</sup>
- 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 giba@rsna.org
  - Volunteers willing to moderate BC or TF calls would be appreciated
    - Please email the SPECT BC co-chairs if interested: <u>yuni@umich.edu</u>; <u>mozley@gmail.com</u>; <u>jseibyl@mnimaging.com</u>
- 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:
  - o October, Vienna: EANM annual meeting
  - o December, Chicago: RSNA annual meeting

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 <u>QIBA@RSNA.org</u> if their attendance is not reflected on the call summaries. <u>QIBA wiki</u>