QIBA SPECT Biomarker Committee (BC) Friday, March 17, 2017, 9 AM (CT)

Call Summary

In attendance:

Yuni Dewaraja, PhD (Co-Chair) P. David Mozley, MD (Co-Chair) John Dickson, PhD Rachid Fahmi, MSc, PhD Paul Kinahan, PhD Gregory Klein, PhD Robert Miyaoka, PhD Nancy Obuchowski, PhD Kevin O'Donnell, MASc Amy Perkins, PhD Eric Perlman, MD Richard Wahl, MD Johannes Zeintl, PhD Brian Zimmerman, PhD **RSNA** Joe Koudelik Julie Lisiecki

Moderator: Dr. Mozley

I-123 Profile Comments

- Overall, comments were very positive and helpful
 - The co-chairs have already begun labeling and bucketing the comments received
- Public comments for the I-123 Profile will be addressed on Tuesday TF calls, starting in April
- A new Profile focus on Technetium (Tc ^{99m}) and test-retest studies will begin to work in parallel on the TF calls
 - o Two TF calls will be scheduled at the beginning of the 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})
 - Default for 3rd and 4th Tuesdays is no meeting
- There will be greater reliance on emails and individual work, resulting in fewer calls overall
- Volunteers willing to moderate task force calls or biomarker committee meetings would be appreciated
 - o 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 Dropbox folder

QIBA Public Comment Process (Mr. O'Donnell, QIBA Process Committee Chair)

- Mr. O'Donnell provided an overview of the <u>QIBA Profile Stages</u>
- The current Profile is in Stage #2; the "consensus" stage; plans are to move toward feasibility testing once comments are resolved
- Comments have been collected by RSNA Staff, collated, and sent to the all BC members for review
 - Reminder that the committee should be open to all feedback
- Now that comments have been received, they can be sorted as follows:
 - 1. Accepted
 - 2. Rejected (with documentation)
 - 3. Resolved
- "Shalls" are pass / fail criteria
 - o If the shalls are completed, a Profile user is conformant; if not, they are non-conformant
- "Shoulds" are items that should be placed in the front of the resolution table for further discussion
 - Comment resolution team to ask the question, "Can one reliably achieve the claim if one doesn't do this?"
- The timeline for resolution of these comments is open-ended

Tools

- Mr. O'Donnell encouraged the group to use tools that work best for the group, such as Dropbox, Google docs, or email
- However, it was suggested that a relatively recent document be posted to the QIBA wiki page for public reference
- A resolution document or spreadsheet with numbering was also recommended, so that comments can be easily sorted and filtered by criteria in order to make the resolution of comments more manageable
 - RSNA staff is working on collating these comments into spreadsheet format for ease of filtering/sorting/prioritizing

Comments from JRS

- The group will try to schedule some follow up WebEx calls with Japanese colleagues to discuss more complex issues
- Dr. Mozley to draft a letter of gratitude to the JRS members
- Comments from Japanese colleagues included suggestions for a Profile for cardiac imaging

Groundwork related to the I-123 Profile

- Some comments cannot be resolved until groundwork has been completed
 - Comments related to groundwork will be "deferred for now"
 - Version 1.0 will be based on the outcome of SPECT groundwork projects
- Dr. Miyaoka reviewed progress on his groundwork project
 - o Patient MRI images have been collected and segmented with NeuroQuant® software
 - A first pass has been completed with the DRO
 - o There are some questions about the cerebral spinal fluid
 - Disease putamen can be adjusted to have some gradient
 - The project is ready to move into the next phase with the simulations
 - Needed: A good scalar value for update with cerebrospinal fluid (CSF)
 - Dr. Miyaoka to follow up with Dr. Seibyl offline for some recommended CSF values
 - Dr. Miyaoka also to follow up with Dr. Obuchowski offline regarding software analysis numbers

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