QIBA SPECT Biomarker Committee (BC) Friday, August 18, 2017, 9 AM (CT)

Call Summary

In attendance: RSNA

P. David Mozley, MD (Co-Chair)Abhinav Kumar Jha, PhDRichard Wahl, MD, FACRJoe KoudelikYuni Dewaraja, PhD (Co-Chair)Robert Miyaoka, PhD (Co-Chair)Brian Zimmerman, PhDJulie Lisiecki

Rachid Fahmi, MSc, PhD

Moderators: Dr. Miyaoka and Dr. Mozley

Call Scheduling:

- The next SPECT BC meeting is scheduled for September 15th
- An I-123 Profile Task Force (TF) call will be scheduled for Tuesday, September 5th at 2 pm CT to review comments
- An additional call may be needed mid-September for I-123; RSNA Staff to coordinate with Dr. Dewaraja
- As TF calls resume, they will be scheduled as follows:
 - o First Tuesday of the month: I-123 (Drs. Seibyl, Dickson, and Miyaoka)
 - o Second Tuesday of the month: Technetium Profile (Tc 99m) (Drs. Dewaraja, Miyaoka, and Mozley)
 - Technical scribes may be needed for these calls. If interested, please respond to Dr. Mozley (mozley@gmail.com)

Ioflupane Checklist:

- The group is progressing the Consensus I-123 Profile (Stage #2) toward the technically confirmed phase
- Tasks remaining include:
 - Reviewing groundwork project progress / results
 - o Reviewing Mr. O'Donnell's post public comment remarks and naming the updated version of the Profile, v2.0
 - Dr. Seibyl to focus on incorporating Mr. O'Donnell's edits
 - Creating a conformance checklist
 - o A multi-site trial would be ideal, but might not be feasible
 - Multiple sites are to be recruited to use the Profile in their clinical work
 - Dr. Seibyl's institution has volunteered to act as a site
 - · Additional recruits are needed
 - Dr. Dewaraja to ask Dr. Frey about possibly being a conformance testing site
 - A comparison of imaging site protocols to the Profile deemed necessary to identify any process variation
 - It was also suggested that this protocol comparison could be performed by chief technologists instead of medical physicists
 - IRBs / ERBs will be informed that this will be QQ / QC, and will therefore be exempt from standard operating procedures for human subjects research
 - o Revision of the Profile and claims with
 - New groundwork data
 - Input from QIBA stats about claims
 - Feedback from conformance testing sites
 - Deadline for the new Profile version will be the f2f meeting at RSNA 2017 on December 1st
 - o By December 31st, version 2.0 should be posted to the QIBA wiki
 - This will occur before the conclusion of conformance testing; so, naming convention should be discussed

^{99m} TC use cases under consideration (from PowerPoint slides):

- Various proposed use cases for the Technetium Profile were discussed as follows:
 - o Dr. Mozley, et al: IV small molecule drug conjugates, e.g., ^{99m}Tc labeled DUPA for PSMA chemo or radiotherapy of prostate cancer
 - quantitative PK of large biological molecules

- Dr. Dewaraja: intra-arterial MAA for treatment planning of, e.g., 99Y particles for hepatocellular carcinoma or somatostatin receptor radiotherapy (carcinoid metastases to liver)
- o Dr. Miyaoka: ^{99m}Tc MAA lung perfusion SPECT/CT for lobular functional lung assessment for surgical lobectomy and/or external beam radiation therapy planning.

Potential recruits to aid with the following areas include:

Software:

- New recruits: MIM Software and Median Technologies
- o Keosys, Siemens, and GE would be encouraged to continue
- Action: The QIBA BC needs a primary point of contact for each actor

• Pharma:

- Progenics, Inc. is known to have a ^{99m}Tc labeled DUPA PSMA compound in Phase III
- There might be others with slow-moving biologics that can be labeled with ^{99m}Tc
- O Question: Are there any in the public domain?

Academia:

- o MD Anderson, Memorial Sloan Kettering Cancer Center (MSKCC), and Moffit need to be called back to action
- o Others?

Groundwork project results have been accepted for oral presentation at RSNA 2017:

I-123 (Drs. Dewaraja and Dickson):

• "Impact of Total Counts on Iodine-123 Ioflupane SPECT Quantification" by Niedbala J, Lim H, Ackermann R, Hubers D, Obuchowski NA, Dickson J, Dewaraja Y.

New members

- All are encouraged to recruit new members regularly; new names can be sent to qiba@rsna.org
- Volunteer moderators for BC or TF calls would be appreciated
 - o Please email the 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>

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

NM WebEx Schedule

8/25	NM Leadership
9/1	FDG-PET BC
9/8	PET-Amyloid BC
9/15	SPECT BC
9/22	NM Leadership (TBD)
9/29	NM Coordinating Ctte?

SPECT Task Forces	
9/5	I-123 Profile Comment Resolution
9/12	TC 99m Profile Development

SAVE-THE-DATE:

