

QIBA SPECT TC^{99m} Biomarker Committee (BC) Call

Tuesday, September 11, 2018, 2 PM (CT)

Call Summary

In attendance:

Robert Miyaoka, PhD (Co-Chair)

Yuni Dewaraja, PhD (Co-Chair)

John Dickson, PhD

David Mirando

P. David Mozley, MD

Nancy Obuchowski, PhD

Richard Wahl, MD, FACR

Johannes Zeintl, PhD

RSNA Staff

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Miyaoka

Profile Work

- Dr. Miyaoka reviewed language in sections 3.2, 3.6, 3.9, and 3.10 for committee discussion
- There was some discussion regarding the longitudinal trial design

Discussion Regarding Longitudinal Trial Design

- Section 2.3 from Clinical Trial Utilization (Amyloid Plaque Profile)
- Template from Amyloid Plaque profile
 - Section 2 Clinical Context and Claims
 - Section 2.1 Clinical Interpretation?
 - Section 2.2 Discussion?
 - Section 2.3 Clinical Trial Utilization
- Group to try to identify a similar Tc-99m SPECT application.
- Section 2.3 from Clinical Trial Utilization (Tc-99m SPECT Bone Scan?)
 - Powering clinical trial to measure rate of progression of bone metastasis (volume of disease or rise in max SSUV?)
 - Powering clinical trial to measure response bone metastasis to treatment intervention (decrease in volume or drop in max SSUV)
 - Minimal detectable increase for individual subject
 - Confidence interval for an individual's true change

Timeline

- The BC would like to have a first draft of the Profile out by the end of 3Q2018
- It is the goal of the group to work toward public comment by the end of 4Q2018
- The group aims to start work on conformance testing by the 1Q2019 and make significant progress by the QIBA Annual Meeting in June 2019

Work Assignments for section editors / mini-task forces per Dr. Miyaoka:

- claims sans CVs: Moz/Nancy, et al (mozley@gmail.com); target deadline: **end of 1Q2018**
- image acquisition: Yuni Dewaraja, et al (yuni@med.umich.edu); target deadline: **end of 1Q2018**
- image recon: Eric Frey, et al (efrey@jhmi.edu); target deadline: **end of 2Q2018**
- image analysis: Robert Miyaoka, et al (rmiyaoka@uw.edu); target deadline: **end of 2Q2018**
- QA: Denis Bergeron/Brian Zimmerman, et al (denis.bergeron@nist.gov); target deadline: by f2f meeting 2018

Next steps

- All are asked to look over the section written by the PET Amyloid BC to help with longitudinal claim design ([Section 2.3 – Clinical Trial Utilization](#)).

Next call – 2nd Tuesday of October (October 9, 2018 at 2 pm CT)