

QIBA SPECT I-123 Biomarker Committee (BC) Call
Friday, August 17, 2018, 9 AM (CT)
Call Summary

In attendance:

John Dickson, PhD (Co-Chair)
John Seibyl, MD (Co-Chair)

Rachid Fahmi, PhD
Robert Miyaoka, PhD

P. David Mozley, MD
Nancy Obuchowski, PhD

RSNA Staff

Joe Koudelik
Julie Lisiecki

Moderator: Dr. Dickson

QIBA Poster for RSNA 2018

- BC members agreed that the Ioflupane poster would be refreshed, updated, and resubmitted for RSNA 2018
- Dr. Seibyl to update the Ioflupane poster by the end of September using the PowerPoint version on file in Dropbox
- The TC99m BC will be focused on Profile work and may not be ready to draft a poster yet but will likely produce one for RSNA 2019

Profile Work and Timelines

- The BC's goal is to have an updated Profile draft by 3Q2018 (September) and are considering re-sending the update for a second public comment in order to get more exposure, especially among software vendors
- Conformance testing for both Profiles is planned to be completed serially though Ioflupane is aiming for conformance testing to begin in 1Q2019
- Once initial conformance testing is complete, the Profiles will be "parked" and made available for use
- The Profile writing team agreed not to modify the Profile based on the current template in order to "stay the course"

DRO in the Profile

- Text in question includes the following sections:
 - 3.10.1 – Image Analysis
 - 4.8 – Assessment Procedure: Total SPECT Performance (Image Certification and Interpretation)
 - It is uncertain that this section will remain
 - Text for the DRO will reconstruct "shall" statement as a within subject Coefficient of Variation (**wCV**) statement of scale or value of 8%, as described in section 2
 - Section 4 reflects what it takes to meet the claims in section 2
 - Section 4 to be revised to make the image analysis conformant with the wCV specification in section 2
 - The upper bound of the confidence interval should be less than 8
 - Additional discussion of confidence intervals can be found in section 4.6
 - It was recommended that section 4.8 be revised: to remove the part that demands +/- 3.5 from the last sentence

Profile Claims and Questions

- Profile technical conformance claims were discussed
 - The claims were believed to be sufficient as long as there is contrast and the ability to differentiate between the patient and the control
- A concern was raised by Dr. Obuchowski regarding the claims: what is being tested is not what is stated in the claim
 - Recent testing reflects reproducibility; this may require further discussion
- Mr. O'Donnell had suggested reducing the number of actors down from the current 27 to a smaller number and checking for inconsistencies between actors
- Image QC and periodic QC needs to be addressed per Mr. O'Donnell
- A two-part DRO with control and disease features deemed useful to make a linearity assessment

Profile Updates

- Dr. Dickson has completed significant editing of the Profile; Dr. Seibyl will review edits and make final updates, keeping it in Dropbox for BC members to review
- The Image QC and Periodic QC sections with comments from Mr. O'Donnell have been addressed

Next steps

- Section text updates will be discussed during the next t-con
- Information on how the DRO can enhance the Profile to be discussed on the next call, Friday, October 19th
- Linearity and how it should be defined may be another topic of discussion