QIBA PET Amyloid Biomarker Committee (BC) Call

11 May 2018 at 9:00 AM CT Call Summary

In attendance:			RSNA
Dawn Matthews, MS, MBA (Co-Chair)	Adriaan Lammertsma, PhD	Nancy Obuchowski, PhD	Joe Koudelik
Anne Smith, PhD (Co-Chair)	P. David Mozley, MD	Jean-Luc Vanderheyden, PhD	Julie Lisiecki

Moderator: Ms. Matthews

Profile Updates:

- Updated Profile documents have been posted to the wiki including the following:
 - 1. 18F-labeled PET Tracers Targeting Amyloid as an Imaging Biomarker 2018-05-02
 - 2. QIBA Public Comments and Responses 2018-05-02
 - 3. QIBA PET-Amyloid DRAFT Profile with tracked changes 2017-06-15
- Eighty-eight comments have been addressed from the public review process, which closed on September 15, 2017

Claim:

- Reference literature was updated to align with guidelines
- The Profile cites one technical performance claim
- Claim considerations have been updated with strongly stated caveats
- Clinical trial examples using wCV and assumptions from the literature have been updated
- Additional details can be found in previous meeting slides which are posted to the wiki:
 - 1. October 12, 2017
 - 2. February 9, 2018
 - 3. April 13, 2018

Full Dynamic Modeling:

- · Claim considerations have been revised for clarity
- Appendix 1 for Kinetic Modeling was added
- Additional details can be found in previous meeting slides which are posted to the wiki:
 - 1. March 9, 2018
 - 2. April 13, 2018

PET-MR:

- PET-MR considerations are now included in the Profile
- Text updates have been implemented
- Additional details can be found in previous meeting slides which are posted to the wiki:
 - 1. March 9, 2018

References:

- References have been added for the reference region and kinetic modeling
- In the reference section, a by-topic grouping was used but items were sorted by the first author's last name

Variability:

There is narrowed variability guidance, which is less of an issue with newer scanners

- The axial uniformity guideline was tightened in the Profile update; however, the Profile claim is based on reference literature that did not constrain axial variability to a more rigid standard that within 10%, even though the Profile recommends a tighter constraint
- A <u>vote</u> for eligible BC voters is active until May 21st to publish the <u>PET Amyloid Profile</u> as <u>CONSENSUS</u>, Stage 2 of Profile development
- BC members should begin thinking about feasibility testing of the Profile and contacting possible testing sites that may have ties to ADNI in efforts to promote faster Profile integration within clinical trials
- Ms. Matthews to follow up with Dr. Koeppe regarding contact information for the Hoffman phantom

Next steps:

• BC members will consider any remaining loose ends regarding the phantom section or other sections of the Profile and will prepare for conformance testing

NM WebEx Schedule:

06/01	FDG-PET BC	
06/08	PET Amyloid BC	
06/12	SPECT TF: TC ^{99m} @ 2pm CT	
06/15	I – 123 Profile TF	
06/22	NM Leadership - TBD	