QIBA PET-Amyloid Biomarker Committee
Friday, June 11, 2021, at **9 AM CT**
Call Summary

In attendance:		**RSNA**
Dawn Matthews, MS, MBA (Co-chair)	Lindsay Quandt, MS, MBA	Joe Koudelik
Anne Smith, PhD (Co-chair)	Richard Wahl, MD, FACR	Julie Lisiecki
Tammie Benzinger, MD, PhD		

Moderator: Ms. Matthews

FDA Approval of Aducanumab (Aduhelm)

- Due to the FDA announcement, it is the perfect time to get the manuscript and Profile ready for possible use in upcoming clinical trials to demonstrate drug efficacy
- The Profile needs a few minor edits, and it is almost at the Technical Confirmation stage
    - One more site is needed to complete the feasibility testing questionnaire and then voting would proceed at the BC and CC levels to publish as Technically Confirmed
    - Drs. Minoshima and Foster were invited to participate
- Dr. Benzinger provided an overview of the FDA briefing on Aducanumab, which will be distributed to the BC
- Dr. Wahl emphasized that getting the Profile to Technically Confirmed (Stage 3) is critical and time-sensitive to be able to take part in upcoming clinical trials
- The FDA test only requires brain MRI imaging for baseline and follow up scans, and it is unknown what CMS will require or reimburse
- The advantage of including a PET Amyloid scan would provide proof that amyloid is present (amyloid load), especially since Aducanumab is being tested as an amyloid removal drug
    - The Profile could help to tie the baseline to therapy response
    - Additional detail regarding Centiloid measurements will need to be added to the Profile due to the FDA usage of these measurements

DRO updates

- Ms. Matthews had a follow-up conversation with Dr. Obuchowski regarding calculation questions
- A confidence interval of 95% is needed at Technical Confirmation, but can be reduced to 50% at the Claim Confirmation stage; further statistical clarification is needed
- Pons is generally noisy and does not pass requirements; so, it is recommended that the whole cerebellum be used for refence, which corresponds to the FDA recommendation
- Permission is still needed from the University of Washington to use the original MRI patient scan that formed the PET-DRO
    - This T^1 image is needed for certain software packages to analyze data properly
    - An artificial MRI for image registration may need to be created (warped to the DRO) if permission cannot be granted, as this detail would be helpful for DRO users
    - Dr. Sunderland is trying to get in touch with Dr. Kinahan, and the image in question was shared with Drs. Sunderland and Pierce via Dropbox

Publishing the PET Amyloid Profile

- The BC is drafting a collaborative paper for peer-reviewed publication to promote QIBA and the Profile
- Language to be added regarding the FDA approval of Aducanumab to the manuscript and the Profile
- Details on barriers to Profile implementation are needed
- International reviewers are asked to note differences between their methods and the U.S. version
    - Dr. Lammertsma to add European process/regulation differences
    - Dr. Minoshima to follow up with a colleague at J-QIBA to ask him to review
- Two volunteers requested to read through the entire Profile (internal BC review)
- Previously, it was decided that the group would target the *Alzheimer's and Dementia* journal, as it has the highest impact score and best targets their audience

Action items (ongoing) – *aim to complete by July call*

- Dr. Smith or Ms. Matthews to add a Profile note indicating that data are simulated to ensure that no questions are raised pertaining to HIPAA regulations
- Drs. Sunderland and Smith to follow-up with Dr. Kinahan re: a T^1-weighted MRI for the DRO
- Dr. Vanderheyden to contact United Imaging colleagues to evaluate DRO and inquire about the manuscript
- Dr. Lammertsma to add European differences and contact Australian colleagues: Christopher Rowe, MD, and Victor Villemagne, MD, as well as Simon Cherry, PhD
- Dr. Minoshima to ask Japanese colleagues to read manuscript and point out any Japanese differences
- Dr. Sunderland to contact Korean colleagues to read manuscript and note and differences
- Ms. Matthews to reformat the Profile checklist from Excel to Word for ease of use
- Co-chairs to finalize feasibility questionnaire and discuss Mr. O'Donnell's suggestions

Next call – July 9th at 9 am CT