

QIBA PET-Amyloid Biomarker Committee
Friday, September 10, 2021, at 9 AM CT
Draft Call Summary
Additional notes provided by Ms. Matthews

In attendance:

Dawn Matthews, MS, MBA (Co-chair)
Norman Foster, MD
Timothy J. Hall, PhD
Adriaan Lammertsma, PhD

Nancy Obuchowski, PhD
Jean-Luc Vanderheyden, PhD
Richard Wahl, MD, FACR
Dean F. Wong, MD, PhD

RSNA

Joe Koudelik
Julie Lisiecki

Moderator: Ms. Matthews

Manuscript update

- The manuscript has been assigned a manuscript number for review by the [Alzheimer's and Dementia](#) Journal, a positive step

Profile Updates

- Two task force meetings were recently held to discuss the Technically Confirmed (feasibility questionnaire) feedback received from Iowa and WUSTL, and how to address this feedback in the Profile
- Some suggested language regarding calibration and what is good and expected practice vs. what is required to achieve the Profile claim will be updated, particularly for community-based sites
- Adjustments will be made regarding reliance on the Hoffman phantom, as few sites have this phantom, and the BC does not want to make this an obstacle to Profile conformance
- Once updates to the Profile have been made and results compiled from the testing sites, a vote will be held regarding advancing to the Technically Confirmed Stage; we have two questionnaires in hand, pursuing third
- Some help from Dr. Obuchowski to adjust the claim language and DRO section wording will be needed/requested
- Guidance from pharma on implementing the Profile would be welcome; Pharma interest would capture CMS interest regarding FDG-PET usage
- Once at Technically Confirmed stage:
 - Transition efforts to the Tau Profile (some current committee members have expressed interest; other members not yet on committee are interested in Tau)
 - Arrange for task force to assist in translation for Pharma use
 - Pursue harmonization and dissemination efforts: ADNI, pharma, academic institutions, CROs

Harmonization with ADNI (Dr. Foster)

- Dr. Foster encouraged the group to make a strong case that quantitation is valid and important in this area of research and recommended strengthening ties with ADNI to demonstrate Profile relevance in the field
- ADNI has already established standards across sites; harmonization with ADNI could be helpful (examples would include if ADNI would recognize/support or incorporate into ADNI4 recommendations)
- Ms. Matthews explained that a gap analysis was conducted with the ADNI protocol and the PET Amyloid Profile in 2018, and the two documents harmonize well and some recommendations from ADNI were adopted for the QIBA Profile, and that in addition, the Technical Conformance questionnaire includes for reference a column that identifies those items that are already required by ADNI
 - Dr. Foster volunteered to reach out to Bob Koeppe and/or Bill Jagust at ADNI to facilitate the BC's wish for alignment
 - Agreement on standardization may prove challenging
- The QIBA Profile has a strength in that it will be referred to in a peer-reviewed publication soon

Outreach to Stakeholder Audiences

- The following stakeholders were identified: pharma, imaging CROs, academic institutions, clinical community
- While citation in a peer-reviewed publication will be helpful, how to promote the Profile must be considered
- Reaching out to drug companies and CROs was suggested, as they make quality decisions regarding PET amyloid acquisitions

- Decisions to continue may be dependent on feedback from these groups
 - It was also noted that pharmaceutical companies such as Novartis, Roche (Dr. Greg Klein), Merck, and Pfizer may be interested in the Profile and have internal experts who may drive image data acquisition and analysis requirements
 - CROs that could implement the Profile include ADMdx, IXICO, Invicro, and BioClinica
- It is critical to demonstrate to the FDA that QIBA members and other influencers in the field are using the PET Amyloid Profile to promote adoption of consensus standards
 - An advocate /champion for this effort would be helpful
 - Dr. Foster suggested publishing a summary article on the feasibility questionnaire used for the Technically Confirmed process

Clinical Trial Confirmation of Profile

- Dr. Wahl suggested expanding use of the PET Amyloid Profile to clinical trials via an appropriate study
- Dr. Lammertsma suggested reaching out to EARL
- Dr. Hall mentioned that he is working with two researchers at UW, Drs. Sterling Johnson, and Brad Christian, who are leading the ABCD Study, which is a brain imaging study for Alzheimer's Disease patients in the Down Syndrome population
 - The PET Amyloid Profile would work very well with this study and Dr. Hall has asked UW researchers to do a gap analysis with their protocol, similar to the gap analysis that was conducted with ADNI

Next steps

- Ms. Matthews to reach out to Dr. Seibyl regarding introduction to Invicro
- Ms. Matthews to send ADNI-QIBA gap analysis to Dr. Foster
- Dr. Foster to reach out to Drs. Jagust and Koeppe to pursue ADNI alignment

Action items (ongoing)

- Dr. Smith or Ms. Matthews to add a Profile note indicating that data are simulated for HIPAA regulations
- Ms. Matthews to reformat the Profile checklist from Excel to Word for ease of use
- Co-chairs to summarize response to finalizing feasibility questionnaire and incorporating Mr. O'Donnell's suggestions

Next call – Oct 8th at 9 am CT