

QIBA PET-Amyloid Biomarker Committee

Friday, August 13, 2021, at 9 AM CT

Call Summary

Primary notes provided by Dr. Smith

In attendance:

Dawn Matthews, MS, MBA (Co-chair)

Anne Smith, PhD (Co-chair)

Tammie Benzinger, MD, PhD

Norman Foster, MD

Gregory Klein, PhD

Adriaan Lammertsma, PhD

Jonathan McConathy, MD, PhD

P. David Mozley, MD

Nancy Obuchowski, PhD

John Sunderland, PhD

Dean F. Wong, MD, PhD

RSNA

Julie Lisecki

Notes from Moderator: Dr. Smith

1. Organize a meeting to delve into the details of the Technically Confirmed (feasibility questionnaire) feedback received from Iowa and WUSTL, and how this may change the Profile
 - a. Suggested invitees:
 - i. John Sunderland
 - ii. Tammie Benzinger (plus her WUSTL colleagues that helped)
 - iii. Dawn Matthews
 - iv. Anne Smith
 - b. RSNA staff to aid with setting up and hosting the call
2. John Sunderland mentioned that there are several upcoming AD Clinical Trials from Pharma, and suggested broadening the MOU between SNMMI and QIBA
 - a. The goal would be to inform and facilitate the use of our QIBA Profile in these clinical trials
 - b. John mentioned that perhaps the MOU could be broadened such that QIBA and SNMMI could approach Pharma together to make this happen
 - c. Note that I cc'd Alex and Gudrun on this summary, since they are the ones involved in these discussions
 - d. John Sunderland, Dean Wong, and John McConathy would be happy to discuss as well
 - i. John McConathy also suggested that we work with the ACR Commission on Research on this topic as well; he has connections there
3. Anne and Dawn will meet on Monday to make final edits to the Manuscript
 - a. Will contact Adriaan by Tuesday if we need any clarification from him
 - b. Plan to submit the manuscript to [Alzheimer's and Dementia](#) Journal next week (perspective category)
 - c. Attached is the latest version with edits included from Dawn, Greg Klein, and Tammie
4. Dean, if you could send your edits by Tuesday (even earlier if possible), that would be great! Please used the attached version to make the edits.

Additional notes

- Dr. Sunderland emphasized that the Profile must be focused on a target audience and specific use case
 - Suggestion to focus on the primary endpoint and clinical benefit, e.g., reduction in amyloid plaque
 - Adoption of this Profile may encourage creation of a CPT code for reimbursement for amyloid imaging and quantification
 - Use of the PET Amyloid Profile for clinical trials with support of QIBA leadership and via planned harmonization efforts between RSNA-QIBA and SNMMI, with possible involvement from ADNI
- A small group will streamline the Profile with focus on the claim, and remove remnants from the FDG-PET Profile
- Drs. Benzinger and Sunderland completed the feasibility questionnaires at their respective institutions in the work toward Technically Confirmed (Stage 3)
 - The Profile will be moved to Technically Confirmed in a parallel path with the manuscript; any updates can be added to the manuscript as reviewers' comments are addressed
 - A significant challenge is the lack of access to amyloid tracers, even at large academic institutions
- Dr. Smith and Ms. Matthews met with Dr. Pierce to finalize DRO changes
 - Orientation of the T¹ image is fine
 - DICOM headers and subject names will be updated for grey cortex to white matter ratios
 - Information in the DICOM headers is simulated but looks real; some adjustments are being made to clarify that data are simulated/de-identified to avoid any misconceptions

- 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 or looping them into the conversation, as they may not be aware of how far this QIBA effort has come
 - 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. Klein suggested that the QIBA Profile could be implemented in interventional studies
- Dr. McConathy offered to broach discussions with the ACR Commission on Research to increase molecular imaging efforts in hopes of getting some support for the QIBA effort

Proposed Tau Biomarker Committee

- A Tau BC (with new leadership) will not be considered until the objectives of the PET Amyloid BC are complete

Action items (ongoing) – aim to complete by September call

- 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 finalize feasibility questionnaire and discuss Mr. O'Donnell's suggestions

Next calls – Sept 10th at 9 am CT (PET Amyloid BC); August 20th at 9 am CT (Nuclear Medicine CC)

Call to be planned with smaller group do discuss more detailed updates to the Profile based on feasibility questionnaire feedback