

QIBA PET-Amyloid Biomarker Committee (BC) Call

Friday, February 14, 2020 at 9 AM CT

Call Summary

In attendance:

Dawn Matthews, MS (Co-chair)

Anne Smith, PhD (Co-chair)

John Sunderland, PhD

Jean-Luc Vanderheyden, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Smith

Status of PET-Amyloid Profile Feasibility Questionnaire and Profile

- The questionnaire has been organized by actor and is ready for distribution, with the exception of DRO details
- Dr. Sunderland to follow up with Dr. Kinahan for final DRO details needed for Profile conformance
- It was noted that the FDG-PET Profile has an Appendix I, "QIBA FDG-PET/CT Imaging Site and Scanner Checklists," and the PET Amyloid does not yet have such a checklist, though it can be added once the feasibility questionnaire results are compiled
- Ms. Matthews to send finalized questionnaire to Drs. Subramaniam and Sunderland for feasibility testing (and one more site, TBD), which will lead to Technical Confirmed (Stage 3) for the Profile

Considerations for Technical Confirmation

- Getting the Profile to [Stage 3: Technically Confirmed](#) is the current goal
- The next step will be publishing the Profile as technically confirmed
- More details regarding advancing through Profile stages can be found on the QIBA wiki here:
 - <http://qibawiki.rsna.org/index.php/Process>
 - http://qibawiki.rsna.org/index.php/Technical_Confirmation_Process#Planning
- Once completed, the PET-Amyloid Profile to be promoted as a finished product

Helpful Industry News

- Dr. Sunderland discussed the possibility of an urgent need for the PET-Amyloid Profile in the near future if an experimental therapeutic agent being tested now demonstrates significant clinical benefits
- Eisai is developing a new anti-amyloid agent, which if used at an early stage can demonstrate the reduction of amyloid burden and minimize the subsequent proliferation of Tau in the neocortex, which can impact cognition
- The key factor needed would be determining how to identify patients before amyloid has developed too far
 - If these at-risk patients can be identified earlier, this could be life-changing in that the therapeutic drug would be able to slow disease progression
- The drug in development may be submitted for consideration to the FDA in the next year; the FDA is looking for more data to support the therapeutic claim
 - CMS reimbursement would need to be considered quickly if the drug is approved
- Questions regarding whether the US is ready for amyloid imaging would need to be addressed, as many centers are not prepared
- It was suggested that a white paper or review article that summarizes the amyloid Profile and the correct ways to perform amyloid imaging would be extremely useful and would position the QIBA PET-Amyloid Profile for adoption and use
 - Promoting the Profile as the overall best way to perform amyloid imaging, while addressing the importance of quantitative imaging, could result in a very popular "go-to" protocol status
 - Information regarding the DRO should also be included in the publication
 - Time and money saved by companies due to QI would also be helpful to note

Next Steps

- Actor-specific checklists to be distributed to participating sites
 - Ms. Matthews to contact Drs. Sunderland, Subramaniam, and Wahl
- Dr. Sunderland to follow up with Dr. Kinahan regarding DRO updates

QIBA Nuclear Medicine Schedule:

02/18	NM Q4 Coordinating Committee @ 1 pm CT
02/21	FDG-PET BC @ 11 am CT
02/28	NM Leadership @ 9 am CT – TBD
03/10	SPECT TC ^{99m} BC @ 2 pm CT
03/13	PET Amyloid BC @ 9 am CT
03/20	FDG-PET BC @ 11 am CT
03/27	NM Leadership @ 9 am CT – TBD