

## QIBA PET-Amyloid Biomarker Committee

Friday, October 9, 2020 at 9 AM CT

Call Summary

### In attendance:

Dawn Matthews, MS (Co-chair)

Satoshi Minoshima, MD, PhD (Co-chair)

Anne Smith, PhD (Co-chair)

Tammie Benzinger, MD, PhD

Rachid Fahmi, MSc, PhD

Norman Foster, MD

Adriaan Lammertsma, PhD

Nancy Obuchowski, PhD

Daniel Sullivan, MD

John Sunderland, PhD

Jean-Luc Vanderheyden, PhD

Richard Wahl, MD

Gudrun Zahlmann, PhD

### RSNA

Joe Koudelik

Julie Lisiecki

**Moderator:** Dr. Smith

### DRO Progress:

- Dr. Pierce and Mr. Byrd are finalizing the DRO, and it will soon be in a usable form for conformance testing
- Mr. Byrd to create noise instances and Dr. Pierce to transform these into DICOM files, more applicable to modern PET scanners
- The head orientation within the digital DRO has been corrected so automated registration for PET amyloid will work seamlessly with it
- Once these files are available, Dr. Fahmi will test the latest DRO

### Profile 2.0 Discussion:

- Because the FDA has fast-tracked the Biogen anti-amyloid submission (tauvid tracer), the time may be right to develop a Tau Profile, using the PET Amyloid Profile as a template, particularly sections on prep and basic format
- The purpose of this test is to evaluate, not diagnose, if there is Tau buildup in the brain
- Typical amyloid diagnosis involves binary evaluation, e.g., yes, or no, though the QIBA Profile has more detail
- Writing a Tau Profile would rely on published data to create the Profile and standard; it is not necessarily the team's charge to do the research
- Not certain if SUVR would remain the measurand
- Dr. Foster noted the difficulty with visual Tau interpretation and stressed the need for a quantitative approach, as this would also help the FDA approval process
- Suggested that rather than focusing on "how strong is the signal," it would be important to consider distribution for quantitation and measures being used for plasma and cerebrospinal fluid (CSF)
- This research is just beginning, though no increase in staging of pathology has been shown
- It was agreed that CSF and PET provide different information
- Dr. Benzinger mentioned that while PET amyloid and CSF match closely, there is more discrepancy with Tau, which likely reflects different stages of the biology; a clinical cut point for clinical trials is critical
- Dr. Lammertsma suggested that a coffee-break study might be helpful to obtain data
- Dr. Vanderheyden noted that there could be significant clearance differences if binding to soluble Tau as compared to solid mass, which could impact background.
- Another reference point or a clearance point may need to be added, or at least a beginning correlation with soluble tau in fluid
- Dr. Fahmi asked about target references, as it is not clear how to report the burden or quantify Tau
- More Tau experts will be needed if it is agreed that a Tau-specific Profile will be pursued, though Dr. Smith suggested that the team focus on finalizing the PET Amyloid Profile by the end of 2020 and consider a focus on Tau in 2021

### Publishing the PET Amyloid Profile:

- Dr. Wahl recommended publishing a peer-reviewed article about the Profile to promote QIBA and use of the Profile in *Radiology* or *the Journal of Nuclear Medicine*
- Dr. Sunderland noted that a fair amount of the [FDG paper published in Radiology](#) by Dr. Kinahan included details about the QIBA Process
- The FDG-PET article will be referenced for the QIBA Process and the article itself will serve as a template
- Dr. Sullivan promised to bring up the idea of having a standardized QIBA template for future publications with the Process Committee and EC

- Drs. Fahmi and Obuchowski volunteered to help with authoring a PET Amyloid Profile article for *Radiology* or another suitable journal
- A copy of the manuscript for FDG will be shared only with the group on this call; a Word version may be available from Dr. Sunderland or Wahl

**Chat and Discussion Forums:**

- Dr. Sullivan noticed that many comments were added in the chat window for this call and mentioned that this was popular at the QIBA Annual Meeting also
- He is working with RSNA Staff to create a discussion forum for QIBA, which he hopes may help to move action items along between monthly calls
- All active participants would be added to these forums, and would likely receive emails with a daily digest or be able to search the forum via a Table of Contents or key words

**Next meeting topics:**

- Finish up with the PET Amyloid Profile and related manuscript
- Set the stage for a Tau Profile

**Action items**

- Dr. Fahmi to test the new DRO to make certain that the noise levels are correct
- Ms. Matthews to follow up with Dr. Pierce and Mr. Byrd
- Dr. Smith or Ms. Matthews to add a note in the Profile indicating that the data are simulated to ensure that no questions are raised pertaining to HIPAA regulations
- Ms. Matthews to reformat the Profile checklist from Excel to Word for ease of use
- Publish Profile special report in a suitable journal

**Next Steps (ongoing)**

- Ms. Matthews to get in touch with Drs. Minoshima and Wahl regarding site testing
  - Actor-specific checklists to be distributed to participating sites
  - Ms. Matthews may also contact Drs. Sunderland and Subramaniam
- The group is considering proposal of a new BC on Tau, or an extension of the existing PET Amyloid BC
  - More specialized expertise would be needed for a Tau working group
  - Leadership to consider possible experts to invite, if agreed

**QIBA Nuclear Medicine Schedule:**

<b>11/18</b>	NM Coordinating Ctte @ 1 pm CT
<b>11/13</b>	PET Amyloid BC @ 9 am CT
<b>12/11</b>	PET Amyloid BC @ 9 am CT