QIBA PET Tau Biomarker Committee (BC)

Friday, November 10, 2023, at 9 am CT Call Summary

Notes derived in part from Ms. Matthews' slides

In attendance

Tammie Benzinger, MD, PhD (co-chair) Dawn Matthews, MS, MBA (co-chair) Tobey James Betthauser, PhD, MS Santiago (Santi) Bullich, PhD Charlie Chen, PhD Patricia E. Cole, PhD, MD Rachid Fahmi, MSc, PhD Clara Ferreira Leonardo Iaccarino, PhD Gregory Klein, PhD Lauren Koenig, PhD Adriaan Lammertsma, PhD Antoine Leuzy, PhD Nancy Obuchowski, PhD John Seibyl, MD Jean-Luc Vanderheyden, PhD **RSNA Staff** Julie Lisiecki

Progress since October meeting

- BC members' input will be incorporated into the <u>draft Profile</u> (posted to Dropbox)
- ADNI data analysis as comparator to test-retest literature reviewed and analyzed; additional literature compared
- Dr. Leuzy re-sent letter to <u>Alzheimer's and Dementia journal</u> to explore possible publication
 - \circ $\,$ $\,$ Dr. Leuzy to circulate the paper for group reference

Profile Updates

- Consensus among BC members regarding Profile feedback
- Follow up for open questions may be addressed via email surveys or small group calls
- wCV calculations are in line with ADNI data and are the same for Meta Temporal and Centaur approximations
- No hands-on data for other tracers, though checking continues for similarity at test-retest data points
- Concern expressed regarding lack of tracer data new details may increase the 'N' number for studies or patients
 - $\circ \quad \mbox{Will need to demonstrate impact on quantification}$
- Additional relevant papers were shared for reference:
 - Bollack, A, Pemberton, HG, Collij, LE, et al. Longitudinal amyloid and tau PET imaging in Alzheimer's disease: A systematic review of methodologies and factors affecting quantification. *Alzheimer's Dement*. 2023; 1-21. <u>https://doi.org/10.1002/alz.13158</u>. <u>https://alz-journals.onlinelibrary.wiley.com/doi/10.1002/alz.13158</u>
 - Obuchowski, N, Mozley PD, Matthews D, Bucker A, et al. Statistical Considerations for Planning Clinical Trials with Quantitative Imaging Biomarkers. JNCI: Journal of the National Cancer Institute, Volume 111, Issue 1, January 2019, Pages 19–26, <u>https://doi.org/10.1093/jnci/djy194</u>
- Targeted SME lists to be developed for public comment to include pharma contacts and SNMMI
- Dr. Betthauser to inquire about the 2022 Human Amyloid Imaging (HAI) attendee list, as well as a specialized Neuroimaging committee contact list from the Alzheimer's Association for public comment SMEs
- Dr. Vanderheyden to work on an introductory paragraph to accompany public comment request, explaining briefly what / who QIBA is and why special expertise would be appreciated for Tau Profile review
- If needed, it may be possible to post the document in a publicly accessible Box, though QIBA wiki and Google form will be available before the end of December
- Utilizing some 'coming soon' messaging and posting on LinkedIn were suggested to promote public comment once near ready for deployment

Next Steps

- Refine Profile sections and consolidate input; volunteer input needed
- Complete description of wCV, longitudinal claims and use cases; volunteer input needed
- Cross-sectional claim(s) describe how phantom data would be used
- Resolve questions via email surveys or small group calls
- Prepare technical conformance (clinical feasibility, Stage 3) in parallel
- Profiles can be submitted for QUIC endorsement after December following the process posted on the QIBA Wiki

Meeting of BC members at RSNA 2023

• The <u>109th Scientific Assembly and Annual Meeting for RSNA</u> (Nov. 26-30, 2023) is coming up, and PET Tau BC leaders would like to invite BC members to meet informally if attending either of these meetings.

• A <u>Google form</u> has been prepared to determine interest

Proposed Timeline

- Public comment timelines minimum of 30 days is planned
- November intensive review and BC/CC voting to release
- December public comment
- January address feedback received

Updated Schedule (11.10.2023):

	Au	gust	September	October	November	December
Planning						
Decide on plan forward (Profile by year end)						
Sign up for Profile ingredients						
Claim Development						
Literature review						
Initial wCV calculations based upon literature						
Decision regarding pooling vs. separate wCV per tracer						
Additional data (internal ADNI analysis, other)						
Consensus wCVs						
Bias analysis for cross sectional claim(s)						
Translate to Cases						
Profile Drafting: Other sections (amyloid adaptation/tailoring)						
Internal review						
Public Comment and Incorporate Feedback					30	days
Technical Confirmation (assuming same as amyloid)						
Final Profile Posting						
Manuscript Development						
Literature Review as context for claims						
Profile description						
Group Review and Submit						

References

QIBA PET Amyloid Profile	QIBA FDG-PET/CT Profile			
QIBA SPECT Ioflupane Profile, v2 (example of cross-sectional claim)				
QIBA US SWS Profile (example of cross-sectional claim)				
QIBA LinkedIn page	QIBA Twitter page			
QIBA Videos				
Consensus (Stage 2): Comment Resolution Spreadsheet				
Clinically Feasible (Stage 3): Feedback Resolution Spreadsheet				
http://tinyurl.com/QIBA-Public-Comment-Form				

Next Call: Friday, December 8th at 9 am CT {whole group}

	PET Tau BC
12/08	Q4 NM Coordinating Ctte – 1 pm CT

QI Sessions and Activities at RSNA 2023 (McCormick Place, Chicago)

- Building a Quantitative Imaging Research Study, Tues., Nov. 28, 2023, from 11 am to 12pm CT. Room S405. (available via virtual program, Session Number T4-RCP19)
- 2023 QI Symposium: Sponsored by QIBA: Quantitative Imaging in the Era of Artificial Intelligence: Opportunities and Needs, Wed., Nov. 29, 2023, from 2 to 4 pm CT. Room E253AB.