

QIBA PET Tau Biomarker Committee (BC)

Friday, September 8, 2023, at 9 am CT

Call Summary

Notes derived in part from Ms. Matthews' slides

In attendance

Dawn Matthews, MS, MBA (co-chair)

Tobey James Betthausen, PhD, MS

Santiago (Santi) Bullich, PhD

Charlie Chen, PhD

Rachid Fahmi, MSc, PhD

Clara Ferreira

Michael Haas, BSc

Leonardo Iaccarino, PhD

Gregory Klein, PhD

Lauren Koenig, PhD

Adriaan Lammertsma, PhD

Antoine Leuzy, PhD

Nancy Obuchowski, PhD

Jean-Luc Vanderheyden, PhD

RSNA Staff

Julie Lisiecki

Proposed Timeline

- Public comment timelines – minimum of 30 days is planned
- BC considering ways to reach Stage 2 (Consensus) in parallel
- September and October – claims development / drafting
- November – intensive review
- December – public comment

Task Forces

- Independent Task Forces are working offline on various sections, e.g., connecting ADNI datasets, evaluating what analyses would be most helpful, etc.
- Task Force volunteers still welcome, the sign-up form is still available: <https://forms.gle/XLEcTnEjHzU7EpGF6>

Profile

- Consider adding a disclaimer re: AI because there is not enough time to sufficiently address AI concerns
- While drafting, keep in mind, “how is this useful?” to keep the Profile user-focused
- Internal analysis using ADNI data will be conducted
- Manuscript to include literature review as context for claims, and description of the Profile
- Initial wCV calculations based upon test-retest literature, have been provided by Dr. Obuchowski
- Decisions:
 - Don't pool tracers
 - Use regions of interest for data which are available in literature and for internal analyses.
- Since August call:
 - Profile adaptation from PET Amyloid Profile continued
 - Sections have been posted on Dropbox
 - Analysis of ADNI Tau PET data (Flortaucipir) has been initiated
- ADNI Data Analysis:
 - Goal: Additional supportive data, both cross-sectional and longitudinal, for claims development
 - Data to include:
 - Two-year time interval (primarily)
 - Multiple populations: Am- Cog Normal, Am+ MCI, Am+ AD
 - Multiple target and reference regions for comparison (within a realistic timeframe)

Next Steps

- Provide specifics and content access to team members (Ms. Matthews)
- Complete translation
- Complete internal analyses and claim development
- Edit / augment
- Dr. Klein suggested reaching out to Andrew Stephens for data
- Drs. Chen, Koenig, and Obuchowski to meet offline to discuss what analyses would be most helpful
- BC member welcome to sign up for PET Tau Task Forces: <https://forms.gle/XLEcTnEjHzU7EpGF6>
- BC members are welcome to submit comments or questions to the [Future Direction of QIBA Activities Form](#)

Updated Schedule:

	August	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					
Technical Confirmation (assuming same as amyloid)					30 days
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, October 13th at 9 am CT {whole group}

10/13	PET Tau BC
11/10	PET Tau BC
12/08	PET Tau BC
12/08	Q4 NM Coordinating Ctte – 1 pm CT