QIBA PET Tau Biomarker Committee (BC)

Friday, October 14, 2022, at 9 am CT

Call Summary

Additional notes provided by Ms. Matthews

In attendance

Tammie Benzinger, MD, PhD (co-chair)
Dawn Matthews, MS, MBA (co-chair)
Suzanne L. Baker, PhD
Tobey James Betthauser, PhD, MS
Orest Boyko, MD, PhD
Charlie Chen, PhD candidate
Rachid Fahmi, MSc, PhD
Norman Foster, MD
Adriaan Lammertsma, PhD
Satoshi Minoshima, MD, PhD
Nancy Obuchowski, PhD
David Scott, PhD
Sergey Shcherbinin, PhD, DrSc
Anne M. Smith, PhD
Jean-Luc Vanderheyden, PhD
Gudrun Zahlmann, PhD

RSNA Staff

Joe Koudelik
Julie Lisiecki

***Moderator**: Ms. Matthews*

The following topics were discussed:

- Update on NM committee vote – officially a QIBA biomarker committee
- Dropbox reference library
- Response to Focus Area participation questionnaire
- Setting claim objectives
- Literature search with aid from institution librarians
- Systematic approach to developing Profile contents within a target schedule
- Harmonization with C-Path efforts

QIBA Steering Committee Vote Outcome

- The QIBA Steering Committee ballot closed on Wednesday, September 19th, with a majority (**14 votes**) in favor with **0** "no" votes and **0** abstentions. (24 voting members)
- The new biomarker committee (BC) is officially approved.

Primary outcomes of Discussion

- As per an earlier committee meeting, tracers expected to be included are: flortaucipir (Tauvid®), [18F]MK-6240, [18F]PI-2620, [18F]RO-948, [18F]GTP1 given their use in clinical trials. Tracers must have supporting test/retest data. FDA clearance is not a prerequisite for inclusion. [18F]APN-1607 remains a consideration but requires company interest, data, and relevant specificity for AD
- Cross-sectional claim(s) and longitudinal claim(s) are both desirable due to the use of both applications in clinical trials
- Formal librarian search recommended to support test-retest data composition; Dr. Boyko and Dr. Benzinger offered to aid in this effort
- To achieve a reasonable timeline, prioritize the AD applications over others (e.g., PSP)
- Can include a descriptive paragraph for aspects such as other indications that are not addressed in first version
- Applications or aspects not included in a first version can then be addressed in a second version
- Aims of the Profile will include quantifying image acquisition variability and harmonize with various tracers

Committee Next Steps

- Goal to have a QIBA PET Tau Profile draft and ready for public comment completed by September 2023
- Sources of variance and differences between tau and amyloid should be explored
- Estimates of precision and accuracy, along with the tracer detection threshold will be needed
- Explore availability of supporting test/retest data for tracers to be included

- Use case and analysis methods need discussion; de novo analysis was suggested
- Collaboration with Critical Path for Alzheimer's Disease (CPAD), under the Critical Path Institute (C-Path) to harmonize tau PET quantification (several members are involved in both QIBA and CPAD, supporting coordination)
- Task force calls will be scheduled independently by task force champions/leaders, who will have the responsibility of reporting back to the BC; Co-Chairs will follow up with Focus Area volunteers for next steps

Claim details (Dr. Obuchowski)

- QIBA has two types of claims:
    1. A **cross-sectional** claim describes the ability to measure change in the quantitative imaging biomarker (QIB) at one time point
    2. A **longitudinal** claim describes the ability to measure change in the QIB over multiple time points.

- Both a longitudinal and a cross-sectional claim are being considered
- A narrower, clinical use-case claim might be more manageable
- Whether a change is real can be determined via quantitation and a confidence interval for true changes
- Profile helps to determine the performance that can be achieved if recommendations are followed
- For a cross-sectional claim, bias is needed
- For a longitudinal claim, precision would be needed: bias is not needed if constant.
- If the bias is not constant, the slope would be needed
- Examining the PET Amyloid Profile and sources of variance may be helpful

Additional comments

- Dr. Benzinger noted that treatment for Alzheimer's Disease may require use of multiple tracers/drugs

PET Amyloid Publication Update (Dr. Smith)

- The PET Amyloid manuscript has been accepted for publication by the Journal of Nuclear Medicine (JNM)
- A final manuscript will be available soon

Action items (some ongoing):

- Dr. Boyko to check with USC and VA librarians re: literature search (also volunteered to help with claims)
- Charlie to check with WUSTL librarians
- Ms. Matthews to follow up with tracer manufacturers and others re: test-retest data that may be available
- Julie to add new participants to Dropbox, etc. and capture chat notes for leadership
- Dr. Wong to send a paper to Ms. Matthews for inclusion on the Dropbox
- Any feedback may be sent to Dr. Benzinger and Ms. Matthews
- **Link to** task force sign-up sheet (areas of focus for the Profile)

Next Call: Friday, Nov. 11th at 9 am CT

Parties interested in joining the QIBA LinkedIn page for QIBA updates should visit: https://www.linkedin.com/company/rsna-qiba

Reference: Ms. Matthews' slides (07.15.2022)