QIBA Amyloid → Tau Profile Transition: Exploratory Meeting

Friday, July 15, 2022, at 9 am CT

Call Summary

In attendance

Dawn Matthews, MS, MBA [1,2]
Anne Smith, PhD [1]
Satoshi Minoshima, MD, PhD [1]
Tammie Benzinger, MD, PhD *[2]*
Vasily Belov, PhD
Tobey James Betthauser, PhD, MS
Marina Emborg, MD, PhD
Norman Foster, MD
Adriaan Lammertsma, PhD
Peter Ngum, MSc
Nancy Obuchowski, PhD
Jean-Luc Vanderheyden, PhD
Richard Wahl, MD, FACR
Yibao Wu, PhD
Xiaoyou Ying, PhD
Gudrun Zahlmann, PhD
Tamm

RSNA Staff

Joe Koudelik
Susan Stanfa

[1] Amyloid Co-Chair; [2] Tau Co-Chair

***Moderator**: Dawn Matthews*

The following topics were discussed:

- Focus and aim of proposed Tau Profile
- Possible Tau BC Co-Chairs and participants
- Test-retest literature availability and review
- Amyloid Profile translation to Tau Profile
- Approach to Claim development
- Ms. Matthews' slides

Decisions / Action items:

- PET Amyloid BC has achieved Technical Confirmation (Stage 3) and invited PET Amyloid BC members to consider whether a proposed new biomarker committee for PET Tau could be successful
- Dr. Benzinger and Ms. Matthews would step up as Co-Chairs, with Drs. Obuchowski and Smith and other attendees as key contributors to Tau BC efforts
- The Amyloid Profile was deemed translatable to Tau in terms of fundamentals that impact the technical validity of a measurement, e.g., data acquisition, subject motion, etc.
- Off-target binding, kinetic differences, and biological nuances between tracers needs better understanding
- The Amyloid Profile is being used as a template to create an early draft Tau Profile (Stage 0)
- The next step would be further review, focusing on inserting data and variability parameters specific to Tau, editing and augmentation
- Dr. Obuchowski reviewed test-retest literature available on flortaucipir, [18F]MK-6240, and [18F]PI-2620, and there seemed to be sufficient data for Claim feasibility depending upon whether tracers or other study data can be pooled
    - In addition, there is a large portfolio of published work on various tau tracers
    - Dr. Obuchowski's simulated study demonstrated that a test-retest study would require at least 35 subjects (N=35) to constitute a basis for a Claim with a 95% confidence interval
    - Over the five test-retest studies, there were 40 patients and 37 controls, but BC member assessment would be needed re: whether data could be pooled across papers that used various tracers with different characteristics, or whether separate analyses for each tracer would be needed
- NIH funding was recently granted to two large multicenter studies focusing on direct comparisons between Tau PET tracers, but they will not be completed for five years

- There was consensus that another discussion on framework for constructing Claims was merited; attendees were asked to gather additional literature for planning a reasonable approach for Tau Profile Claim development
- Staff to work with Co-chairs to schedule a follow-up call, by which time attendees would have been sent and had the opportunity to review a Profile draft and select areas of interest for Profile-writing assignments
- To move forward with a Tau Profile BC, a New QIBA Biomarker Committee Application would need to be completed
- Amyloid BC members who are not interested in participating in a Tau BC were asked to notify staff at qiba@rsna.org to be removed from the list

Next Call: TBD

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