QIBA PET Amyloid Biomarker Committee (BC) Call
11 August 2017 at 9:00 AM CT
Call Summary

In attendance:

<table>
<thead>
<tr>
<th>Name</th>
<th>Tammie Benzinger, MD, PhD</th>
<th>Adriaan Lamertsma, PhD</th>
<th>Joe Koudelik</th>
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<tbody>
<tr>
<td>Dawn Matthews, MS, MBA (Co-Chair)</td>
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<td>Anne Smith, PhD (Co-Chair)</td>
<td>Eshan Dahal, MS</td>
<td>Nancy Obuchowski, PhD</td>
<td>Julie Lisiecki</td>
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<td>Anne Smith, PhD (Co-Chair)</td>
<td>Rachid Fahmi, PhD</td>
<td>Richard Wahl, MD, FACR</td>
<td>Julie Lisiecki</td>
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<td>RSNA</td>
<td>Adriaan Lamertsma, PhD</td>
<td>Joe Koudelik</td>
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Moderator: Dr. Smith

New Co-Chair Announcement:
- Dr. Smith and other members of the PET Amyloid BC welcomed Ms. Matthews as the new BC co-chair
- BC leadership composition is well-rounded:
  - Dr. Smith (Equipment/Industry)
  - Dr. Minoshima (Academia)
  - Ms. Matthews (CRO/Pharma)

Key takeaway from the Alzheimer’s Conference:
- There is a lack of education about binding potential and its effect on quantification
- Most analyses uses SUVR for both tau and amyloid
- Substantial press coverage for the Imaging Dementia-Evidence for Amyloid Scanning Study (IDEAS Study)
  - Very positive update
  - >60% change in diagnosis
  - Large portion of the cohort was diagnosed as having mild cognitive impairment (MCI) rather than Alzheimer’s / Dementia (AD)
  - Follow up with attendees who were at the face-to-face meeting will be needed to review the test-retest details and standard patient datasets
    - Attendees included: Drs. Wahl, Kinahan, Sunderland, and Subramaniam

Pharma Contacts Needed: (Ms. Matthews to provide individual contact info)

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<thead>
<tr>
<th>Company</th>
<th>Drug</th>
<th>Action</th>
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<tbody>
<tr>
<td>Amgen/Novartis</td>
<td>AMG 520</td>
<td>BACE inhibitor</td>
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<tr>
<td>Archer Pharmaceuticals/NILVAD Consortium</td>
<td>ARC-029 (nilvadipine)</td>
<td>Amyloid beta inhibitor</td>
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<td>AZ Therapies</td>
<td>ALZT OP1</td>
<td>Amyloid beta inhibitor</td>
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<td>Biogen/Neurimmune</td>
<td>Aducanumab</td>
<td>Amyloid beta inhibitor</td>
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<td>Biogen/Esai</td>
<td>E2609</td>
<td>BACE inhibitor</td>
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<td>Eli Lilly/Astra Zeneca</td>
<td>Lanabecestat</td>
<td>BACE inhibitor</td>
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<tr>
<td>Genentech</td>
<td>Crenzumab</td>
<td>Amyloid beta inhibitor</td>
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<td>Genentech</td>
<td>Gantenerumab</td>
<td>Amyloid beta inhibitor</td>
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<td>Janssen</td>
<td>JNJ-54861911</td>
<td>BACE inhibitor</td>
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<td>Novartis</td>
<td>CAD106</td>
<td>Amyloid beta-targeting immunotherapy (vaccine)</td>
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<td>vTv Therapeutics</td>
<td>Azeliragon (TTP488)</td>
<td>RAGE inhibitor</td>
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<tr>
<td>Merck</td>
<td>?</td>
<td>BACE modulator</td>
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Profile Public Comment Update:

- The Profile was released for public comment on June 1st; four comments have been received to-date
- Public Comment ends on September 15th
- Committee members intend to follow up personally with colleagues in order to solicit targeted feedback
- Volunteer contacts for sister organizations are as follows:
  - Alzheimer’s Association (Dr. Minoshima)
  - ADNI (Dr. Minoshima)
  - GAAIN (Dr. Minoshima)
  - FNIH (Drs. Wahl and Benzinger)
  - NIA (Drs. Wahl and Minoshima to contact Peter H. and others)
  - European and Japanese Initiatives (Dr. Boellaard)
  - Human Amyloid Imaging Group (Dr. Subramaniam and Ms. Matthews)
  - SNMMI Brain Council (already have Profile)
  - AMYPAD European Consortium, will collect 6k scans/ 4 years (Dr. Lammerstma)
  - International Committee for MR and PET imagers (Dr. Benzinger)
  - Centiloid Working Group (Dr. Benzinger)

- Boilerplate text regarding the value of the Amyloid Profile is needed when reaching out to sister organizations, to include:
  - Brief background with purpose and intended audience/use of the profile
  - What types of comments are requested, and suggested method for providing (e.g. the Excel spreadsheet)
- A strategy to triage and address comments is under development; co-chairs will review comment resolution spreadsheets from FDG-PET, SPECT, and MR Profiles and incorporate feedback

Open Issues requiring resolution include:

- Claim context and tolerance
- Conformance methodology (draft plan)
  - Region segmentation requirements
- Conformance testing (draft plan)
- Reference section

Next Steps for the Current Profile:

- Completion of the DRO, which is important to move the Profile forward (Drs. Kinahan, Pierce, and team at UW Seattle)
  - Volunteers are needed to drive this effort and perform feasibility tests

Reference region / segmentation project:

- Once the DRO is stable, group to determine what is needed for imaging analysis work station (IAW) conformance
- A volunteer Amyloid BC Task Group will develop an analysis protocol (similar to the one for the FDG DRO)

Sources for data may include:

- Dr. Boellaard: Hoffman Brain phantom data from different PET/CT models and vendors
- Dr. Lammertsma: data from his study utilizing a coffee break protocol with 2 amyloid agents
- Dr. Koepppe and the Alzheimer’s Association: test-retest data

DRO Testing / Analysis Protocol:

- A standard set of patient data will be used to test the variability of different analysis packages
• Results will be kept confidential and feedback will be provided to participating IAW vendors
• Results will be reviewed and Profile modifications made for the DRO and conformance sections
  o Reports will be generated on the variability of region statistics and SUVRs
  o Data are needed from 3 different PET amyloid tracers
  o Assistance will be requested from: Drs. Obuchowski and Koepppe and Ms. Matthews, as well as representatives from the Alzheimer’s Disease Neuroimaging Initiative (ADNI)

• Image analysis vendors to be involved including the following known vendors and others, TBD:
  o CorTech Labs (?)
  o GE Healthcare (CortexID)
  o MIM Software (MIMNeuro)
  o Mirada Medical (NeuroQ)
  o Segami (Neurogam?)
  o Siemens Healthineers (Scenium)

• The following labs will be asked to help with standard datasets and advise on the project protocol:
  o Bill Jagust at UC Berkeley
  o Cliff Jack at Mayo Clinic
  o Reisa Sperling at Brigham and Women’s

• Funding may be needed to complete the test-retest studies; agencies to be contacted include:
  o National Institute on Aging (NIA)
  o Alzheimer’s Association

**Action Items:**
• All: volunteer liaisons to solicit feedback for the Profile be submitted by the September 15th deadline
• Dr. Smith to send example request text for soliciting Profile feedback to Dr. Benzinger and others who are soliciting feedback
• Dr. Smith and Ms. Matthews to work on approach to resolve profile claim
• Drs. Kinahan, Pierce and team to complete DRO at UW, Seattle, and develop an evaluation protocol for testing and feedback
• Ms. Matthews to provide contact names for pharma groups (see notes above)
• Exploration of potential synergies with two on-going projects:
  o AA is starting a test-retest study looking at scanner model variability (Dr. Bob Koepppe at UM is the lead)
  o Dr. Lammertsma and his team have test-retest data for both BP and SUVR for one of the tracers that can be shared once the study is published
• Formation of a task group to develop standard patient datasets to aid with conformance testing in the Profile
  o A funding application will need to be submitted in the near future
  o Co-Chairs to contact Dr. Knopp and the Imaging and Radiation Oncology Core (IROC) to discuss cancer-centric options

**NM WebEx Schedule**

<table>
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<tr>
<th>Date</th>
<th>Meeting</th>
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<tr>
<td>8/18</td>
<td>SPECT BC</td>
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<td>8/25</td>
<td>NM Leadership (TBD)</td>
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<tr>
<td>9/1</td>
<td>FDG-PET BC</td>
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<tr>
<td>9/8</td>
<td>PET-Amyloid BC</td>
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<td>9/15</td>
<td>SPECT BC</td>
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<td>9/22</td>
<td>NM Leadership (TBD)</td>
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<td>9/29</td>
<td>NM Coordinating Ctte</td>
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**SPECT Task Forces**

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<th>Date</th>
<th>Task Force</th>
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<tr>
<td>9/5</td>
<td>I-123 Profile Comment Resolution</td>
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<tr>
<td>9/12</td>
<td>TC 99m Profile Development</td>
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SAVE-THE-DATE:

QIBA Working Meeting at RSNA 2017 | Wednesday, November 29, 2:30-5 pm – Lakeside Center