

QIBA PET Amyloid Biomarker Committee (BC) Call

11 August 2017 at 9:00 AM CT

Call Summary

In attendance:			RSNA
<i>Dawn Matthews, MS, MBA (Co-Chair)</i>	Tammie Benzinger, MD, PhD	Adriaan Lammertsma, PhD	Joe Koudelik
<i>Anne Smith, PhD (Co-Chair)</i>	Eshan Dahal, MS	Nancy Obuchowski, PhD	Julie Lisiecki
	Rachid Fahmi, PhD	Richard Wahl, MD, FACR	

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 takeaways 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)

Company	Drug	Action
Amgen/Novartis	AMG 520	BACE inhibitor
Archer Pharmaceuticals/NILVAD Consortium	ARC-029 (nilvadipine)	Amyloid beta inhibitor
AZ Therapies	ALZT OP1	Amyloid beta inhibitor
Biogen/Neurimmune	Aducanumab	Amyloid beta inhibitor
Biogen/Esai	E2609	BACE inhibitor
Eli Lilly/Astra Zeneca	Lanabecestat	BACE inhibitor
Genentech	Crenezumab	Amyloid beta inhibitor
Genentech	Gantenerumab	Amyloid beta inhibitor
Janssen	JNJ-54861911	BACE inhibitor
Novartis	CAD106	Amyloid beta-targeting immunotherapy (vaccine)
vTv Therapeutics	Azeliragon (TTP488)	RAGE inhibitor
Merck	?	BACE modulator

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)
 - FNIIH (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. Koeppe 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
 - Reports will be generated on the variability of region statistics and SUVRS
 - Data are needed from 3 different PET amyloid tracers
 - Assistance will be requested from: Drs. Obuchowski and Koeppe 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:
 - CorTech Labs (?)
 - GE Healthcare (CortexID)
 - MIM Software (MIMNeuro)
 - Mirada Medical (NeuroQ)
 - Segami (Neurogam?)
 - Siemens Healthineers (Scenium)
 - The following labs will be asked to help with standard datasets and advise on the project protocol:
 - Bill Jagust at UC Berkeley
 - Cliff Jack at Mayo Clinic
 - Reisa Sperling at Brigham and Women’s
 - Funding may be needed to complete the test-retest studies; agencies to be contacted include:
 - National Institute on Aging ([NIA](#))
 - 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:
 - AA is starting a test-retest study looking at scanner model variability (Dr. Bob Koeppe at UM is the lead)
 - 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
 - A funding application will need to be submitted in the near future
 - Co-Chairs to contact Dr. Knopp and the *Imaging and Radiation Oncology Core* ([IROC](#)) to discuss cancer-centric options

NM WebEx Schedule

8/18	SPECT BC
8/25	NM Leadership (TBD)
9/1	FDG-PET BC
9/8	PET-Amyloid BC
9/15	SPECT BC
9/22	NM Leadership (TBD)
9/29	NM Coordinating Ctte

SPECT Task Forces	
9/5	I-123 Profile Comment Resolution
9/12	TC 99m Profile Development

SAVE-THE-DATE:



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