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Global Biomarkers Standardization Consortium (GBSC)

Webinar Agenda

December 2, 2014

Time: 10:30 am ET/9:30 am CT/7:30 am PT/4:30 pm Sweden/Germany

Co-Chairs: Holly Soares, Henrik Zetterberg, Kaj Blennow, Piotr Lewczuk

Facilitator: Jim Hendrix, Alzheimer's Association

Attendees	
Corinth Auld	Rick Margolin
Tobais Bittner	Meredith McNeil
Alex Buko	John Osth
Maria Carrillo	Josef Pannee
Erin Chambers	Mary Savage
Vicki Clements	Les Shaw
Rand Jenkins	Holly Soares
Kendall Van Keuren-Jensen	Heather Snyder
June Kaplow	Bob Umek
Sam Kongsamut	Manu Vandijck
Magdalena Koreckab	Tim Veenstra
Julia Kuhlmann	Tim West
Andy Lockhart	Ingrid Zegers
Mark Lowenthal	Henrik Zetterberg

MINUTES

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1. **Introduction -** Jim Hendrix welcomed all participants to the meeting and reviewed the agenda. There was a last minute change to the agenda as Jamie Eberling of the MJFF had to cancel his to presentation on recent efforts around alpha-synuclein due to a scheduling conflict. We will try to reschedule this presentation for a future meeting.

2. **Update on the Abeta standard with IRMM – Henrik Zetterberg & Ingrid Zegers -** Ingrid reviewed the efforts to develop certified reference material for CSF $A\beta_{42}$. Different sources of raw materials have been considered. Optimization is on-going with a focus on finding a commutable material. These efforts include work to standardize collection methods and storage details. Manufacturing details are also being worked out. There are two main uses envisioned for the material; instrument calibration and for quality control. The material will be CSF-like with high concentrations of $A\beta_{42}$ so that end users can dilute the material as needed for their specific needs. The practical details and process testing is in progress. A final material will be processed early in 2015 and will begin a 1 year stability study. Early in 2016 the team should be able to have concrete discussions around the use and distribution

of the material. As each vendor may want to look at different disease stages (i.e. pre-clinical, MCI, AD), the cut points will be different. The details of the mass spec analysis are still being worked out. This reference material is the same material used in the Round Robin study.

3. **Update on the Round Robin Study – Josef Panee –** Josef provided an update on the Round Robin Study. The results of the first study were submitted for publication in Alzheimer's & Dementia in April but were delayed and are still under review. The second study is in progress. There have been issues with the common protocol that are separate from the reference material. As such, PPD reported that they have not yet run the samples. The four participating labs agreed to discuss the protocol issues together in December. Further analyses will wait until after the protocol issues have been discussed.

   Henrik also informed the group that we are still waiting for feedback from JCTLM on the Aβ reference method. This is a long-term process and the delays are a normal and to be expected. Assay developers should move forward and should not be held up by this process.

4. **BMS avagacestat samples – Holly Soares –** Holly informed the group that BMS has CSF samples in storage from the recent avagacestat trial that could be provided to CAMD and the broader research community conditional upon final legal review of the final protocol and global ICFs. The protocol states samples are to be tested for Aβ, Tau and p-Tau and a pre-specified list of analytes. It is proposed that CAMD will host storage in collaboration with U. of Penn in the ADNI core labs of Les Shaw. Some portion of the CSF and data is intended to be used to support CAMD qualification activities (subject to sample and data release, available funding and GBSC technical review). Presumably, the remaining samples will be available for *in vitro* diagnostic test development by interested developers. It is further proposed that the GBSC will assemble a sub-group of impartial academic experts to confidentially assess the technical quality of any proposed research requests for use of the samples. It was further proposed that all data generated from the use of these samples should be open access at some point (it can occur after approval of test) in order to provide maximum benefit to the field.

   There are 1 to 0.5 mL aliquots and 3-4 aliquots per time point. BMS may require that the data be anonymized in which case an independent database will have to be generated and release of samples and associated clinical data may be delayed. Holly is working out these details with BMS. The GBSC is strongly supportive of these efforts and is ready to work with Holly, BMS and CAMD to work out the details so that these valuable samples can be made available to the scientific community for maximum benefit.

Next Meeting: TBD

The Next Face to Face Meeting will be organized around AAIC, July 18-23, 2015 in Washington, D.C. Please save the date.