Global Biomarkers Standardization Consortium (GBSC) Methods Subgroup Teleconference Agenda September 27, 2013

ATTENDEES

Kaj BlennowMary LameAdam SimonTrevor BrownJohn LawsonHeather SnyderMaria CarrilloMichael MarlattHolly SoaresRobert DeanRobert MartoneBob Umek

Andreas Jeromin Meredith McNeil Henrik Zetterberg June Kaplow Mary Savage Christie Weiss

Julia Kuhlmann - IRMM Les Shaw

Maria reminded everyone regarding the GBSC website that holds the agendas, minutes, and presentations of the GBSC discussions. We will resend the website in follow up to this webinar - http://www.alz.org/research/funding/global_biomarker_csf docs.asp

1. Update of progress each lab has made in the development of the 'substitute' or 'surrogate' matrix

a. Rat plasma based

Mary Lame from the Chambers laboratory provided a brief update. The lab chose to mimic all of the other core lab matrices including their own. They have noticed background when using rat plasma, and have moved to an emphasis on screening multiple lots of plasma or alternatively adding BSA. This was done for discovery purposes. To date, preference is same vendor and a pool of multiple lots.

b. hCSF based

Henrik Zetterberg shared an update that they are working with Ingrid from IRMM to test different pilot materials based on these studies. IRMM has started to calibrate materials and once characterized will be able to distribute.

- c. BSA & HSA based Rand Jenkins was unable to join.
- d. BSA based surrogate and analytical measures Les Shaw provided update on their work with the BSA based surrogate and analytic methods. They are continuing to validate and have nearly completed validation protocol. On next call, they will be in a position to discuss in greater detail.

2. Update on the Alz Association CSF QC program

Kaj Blennow presented an update from the Alzheimer's Association CSF QC program. For participating labs, they are required to provide data in return. If this does not happen, then these laboratories should be dropped from the program. In 2013, the AA QC CSF program completed round 12 (56 labs). The data is available but not as easy to find clear explanation – perhaps could be due to individual differences; may be small tweaks made by individual laboratories; etc. Discussion around results from the QC program and how have sources of variation been identified. JPND invested in biomarker standardization for Europe and supported a smaller sub-study with 10 centers. (SEE SLIDES)

3. Update on the GBSC Round Robin program

Les Shaw provided update on the progress to date for the GBSC Round Robin program. How standards are prepared, including dilutions is important in the discussion. There are four collaborating centers in this program with different mass spec and HPLC platforms, and initially multiple surrogate matrices. Sample preparation is a key component. Example of the 12 CSF pooled samples for this study. There is a range of reproducibility from 7% to 19.7% in one sample. Mean within center is 4.8% and between centers is 12.2% reproducibility. The group felt there is reasonable reproducibility for a large protein or technique. This is one of the highest levels of reproducibility seen to date. IFCC encouraged additional method development.

4. Update on the IFCC workgroup

Henrik Zetterberg focused on reference material for AB42. Companies are free to have their secondary calibrators. Not creating reference materials for QC right now – focused on calibrators. The workgroup is responsible for the oversight of work being done and will report back at the end of this year on progress.

 NEXT MEETING: December 19, 2013 at 9:30 AM central/ 10:30 AM eastern/ 7:30 AM pacific/ 4:30 PM Sweden