

Global Biomarkers Standardization Consortium

Friday, May 10, 2019

9 a.m. Central / 10 a.m. Eastern / 3 p.m. BST

Summary

- Update on SABB-blood pre-analytical variable workgroup - Charlotte Teunissen
 - Charlotte asked the companies if they will be willing to share their pre-analytical protocols. There were ~ 19 factors under discussion, such as time of day for collection, fasting, needle size and location of plastic tubing,
 - For preparation, variables were tube inversion, time from collection to centrifugation, centrifugation procedures, etc.
 - For storage, temperature was one variable.
 - Only a few labs had actually tested pre-analytical factors. Testing all 19 factors is not doable for this work group.
 - In companies, 40% of studies studied time of day, 56% in cohort studies.
 - There was no difference in tube inversion, each tube was inverted up to 10 times.
 - The conclusion of the workgroup was that it is too early to define a unified consensus SOP for now but the WG has identified the most important factors.
 - The next steps are to rank importance of variables and build study proposal to assess variables. Analytes under discussion include A β , tau and NfL.
 - Mass spectrometry, immunoassays and nucleic acid platforms are still under consideration.
 - The workgroup wants to analyze factors with 1 set of samples that can be distributed to participants.
 - Timeline for sample collection and recommendations: Want to make a simple plan with minimum variables to start experiments. The workgroup will start in a few months and finalize in 6 months to a year. What is crucial is time from collection to centrifugation. The WG need fresh samples and waiting approval.

- Update on tau reference method projects - Johan Gobom
 - Communicability study- 40 clinical samples analyzed and 3 candidate CRMs, they are using calibrators.
 - Collaborated with Les Shaw and a lab in Paris.
 - Starting Round robin with CSF pools to test variations in mass spectrometry and will test the use of master calibrators.

- Progress report on the CSF pre-analytical manuscript – Sandra Rutz
 - The Consortium has been working on creating a CSF pre-analytical protocol for the past 2 years and now are towards the end of acquiring data and finalizing the protocol. Phase 1 experiments for Roche was conducting internal investigations and phase 2 was collaborating with Oskar and Kaj's lab on handling with A β and measuring several variables.
 - The focus is mainly on fresh CSF but have also conducted experiments on frozen CSF. Roche plans to conduct phase 3 experiments to determine the clinical cut off for fresh CSF, will start this by middle of this year.
 - There is a variation in A β concentrations if the sample is transported in horizontal vs upright position. Roche wants to increase the filing volume.
 - For pTau and tTau results were more robust.
 - Next steps: Communication of the final pre-analytical protocol and preparation of manuscript with the Consortium

- Potential to submit a late-breaking submission to AAIC.
- Discuss agenda for GBSC AAIC Meeting, Sat. July 13th
 - Re-standardization of the A β 42 assays vs CRMs; the group would like a Round Robin and would like to see the data.
 - Kaj conducted a Round Robin on plasma A β 42/40
 - Add SABB working group on the agenda