Global Biomarkers Standardization Consortium
March 18, 2020
10 a.m. Central / 11 a.m. Eastern / 3 p.m. GMT / 4 p.m. CET

Meeting Summary

Attendees (Names taken from webinar attendee information if a name was listed. This is not a complete list of attendees. There were ~85 attendees):

Results from the BioFINDER study indicate that p-Tau 181 in blood was fairly specific for AD dementia, when compared to non-AD dementia. p-Tau 181 in blood was closely correlated to Tau PET data and p-Tau in blood was indicative of tau PET positivity. Similar results observed in autopsy samples. Results were similar to those observed in a UCSF study. p-Tau 181 in blood was also a good p-Tau 181 was able to predict patients that would go on to develop AD (AD converters).

Collaborations with Fujirebio and Kaj Blennow and Henrik Zetterberg using multiple platforms and different cohorts show assays correlate with similar results across platforms.

Further optimization and study is needed, but plasma pTau has promising clinical utility.

Update on the biorepository on mistreated samples for development on preanalytical protocol for blood (Inge Verberk)

The focus of this study is to gain a consensus on preanalytical effects on blood biomarkers to develop a uniform blood handling SOP that will apply to all platforms. Preanalytical phases covers everything from the sample collection to storage, including collection tube type, standing time between collection and centrifugation, temperature of standing time, centrifugation temperature, aliquot size, storage temperature and freeze/thaw cycles.

Blood samples from 90 individuals have been collected at Amsterdam UMC Hospital. Blood was mistreated according to study design with 10 sample sets per protocol, 6 aliquots each. One aliquot for Amsterdam UMC and the others for external lab analysis.

Early results indicate that amyloid levels are impacted by collection tube type, when samples are standing for 24hr at RT (not when kept at 4°C), and when stored at 4°C for 2 weeks. Overall NfL and GFAP were stable with additional analysis needed.

Next steps are to send samples to other labs for analysis in a wide variety of markers and platforms.

Update on reference material commutability and harmonization of methods using the CRM (Britta Brix)

Previously, Euroimmun, Fujirebio and Roche formed a group to test and calibrate -42 assays. Results led to all companies recalibrating asssays.

Next Euroimmun and Fujirebio aim to compare neat CSF samples in re-calibrate tests using 25 frozen samples with some variable results (possibly due to sample handling, materials, assays). Last year companies decided to continue to work together to identify second study to compare neat CSF samples in side by side study.

In the Commercial Ring trial (INSTAND) samples are analyzed twice a year to measure amyloid, tau, p-tau 181. Results from October 2019 show alignment

between calibrated Fujirebio and Euroimmun groups, and will continue to next round.

In the future, all companies must do more validation studies and samples are needed, though difficult to obtain. How can we (academia and companies) work together to create a pool of samples for validation purposes?

Association can take lead on forming a workgroup through GBSC to address this need. Company representatives can regroup to determine what exactly is needed in terms of sample type.