

Global Biomarkers Standardization Consortium (GBSC)

Teleconference Minutes

Tuesday, September 23, 2014

Time: 10:00 am EDT / 9:00 am CDT / 7:00 am PDT / 4:00 pm Europe

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

Facilitator: Jim Hendrix

Attendees	
Tobias Bittner	Les Shaw
Kaj Blennow	Randy Slemmons
Joel Braunstein	Beth Snowden
Maria Carrillo	Holly Soares
Rand Jenkins	Diane Stephenson
Magdalena Koreckab	Gabrielle Strobel
Julia Kuhlmann	Heather Snyder
Max Lamb	Bob Umek
Andy Lockhart	Manu Vandijck
Mark Lowenthal	Tim Veenstra
Rick Margolin	Teresa Waligorskaa
Meredith McNeil	Tim West
John Osth	Moucan Yuan
Mary Savage	Henrik Zetterberg
Guus Scheefhaals	

MINUTES

1. Introduction

After a brief review of the agenda by Jim, Maria welcomed all the participants and noted new members (see agenda). She asked Mark Lowenthal of NIST for a brief introduction about the role of NIST.

2. Presentation: “Probing the Markers of Disease to Diagnose and Treat”, C₂N Diagnostics – Joel Braunstein, Tim West, Tim Veenstra

Tim West opened the presentation with a review of C₂N’s science. The company was established in 2007 by technology licensed from Washington University, St Louis. Their focus is on the detection of metabolites of brain derived proteins in blood. They developed the SILK-Aβ[®] SPOT Diagnostic Test to detect changes in the early stage of AD or MCI. They hope that it might be possible to detect changes in the pre-symptomatic stage. C₂N cited a Harvard School of Public Health survey study from 2011 that evaluated the interest of individuals from Europe and the US to know whether they were going to develop Alzheimer’s disease through a medical test. It appears that the majority of people polled would be highly likely or somewhat likely to get such a test, even if presymptomatic.

The SILK-A β [®] test is performed by injecting a stable (non-radioactive, naturally occurring) isotope, ¹³C₆-leucine. The labeled leucine gets incorporated into the Amyloid Precursor Protein in the brain, which is then metabolized to various forms of A β that can be detected in the blood.

Tim Veenstra then went on to describe C₂N's path to making their test a point-of-care diagnostic. Comparisons of amyloid beta's half-life in blood using the SILK-A β [®] test were compared to the half-life in CSF. C₂N is moving toward a blood test and is changing the administration of the ¹³C₆-leucine to a bolus formulation. They also hope to markedly simplify the test by limiting the number of blood draws to one or two in order to improve patient acceptance and convenience. Efforts are also on-going for full qualification with GMP ¹³C₆-leucine.

Joel added C₂N is looking for reference labs to test for inter-laboratory variation. They will provide limited licenses to centers that wish to collaborate. He reports that the kits are nearly qualified and GMP production of ¹³C₆-leucine is in progress. They are looking for 5-15 centers. They are in touch with the UK Dementia Platform. **Anyone interested in collaborating or recommending a center is invited to contact Joel directly at jbraun@c2ndiagnostics.com.**

3. Discussion on Tau – Henrik Zetterberg

Henrik described early efforts to develop a reference method for Tau. He hopes to utilize the method described by McAvoy. The McAvoy method utilizes the Merck Ab to measure total Tau in CSF. They will attempt both with and without the trypsination step. **Henrik suggested that anyone interested could continue the discussion on-line by contacting him or Kaj directly at henrik.zetterberg@clinchem.gu.se or kaj.blennow@neuro.gu.se**

4. Feedback from JCTLM on the Abeta reference method – Henrik Zetterberg

Feedback is expected in October and will be updated on a future teleconference.

5. Next Meeting: December 2, 2014

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