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Clinical plasma biomarker development for major depressive disorder (MDD)

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Major depressive disorder (MDD), also known as clinical depression, is a mental disorder characterized by at least two weeks of low mood, independent of life experience. It is often accompanied by low self-esteem, loss of interest in normally enjoyable activities, low energy and pain without a clear cause. Major depressive disorder affected approximately 216 million people (3% of the world's population) in 2015 and is the leading cause of disability in the US for ages 15 to 44. MDD affects more than 15 million American adults, or about 6.7 percent of the US population aged 18 and older in a given year. The American Psychiatric Association added "major depressive disorder" to the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) in 1980. The diagnosis of major depressive disorder can be based on the person's reported experiences and a mental status examination. There is currently no laboratory or blood test for major depression. Two of the most common examinations are the CES-D and HAMD-17 scores. While the specificity of these scores can be close to 100%, the sensitivity can be as low as 40%, i.e., when the score diagnoses MDD, it can do so very well, however, more than half of the patients with MDD can be missed. Using metabolomics, HMT, in collaboration with Dr. Noriyuki Kawamura of the Gyokikai Medical Corporation we identified a plasma metabolite, phosphoethanolamine or PEA, that was consistently low in patients with clinically diagnosed MDD. PEA measured by it has over 90% sensitivity and specificity, but in conjunction with a clinical score can achieve close to 100% sensitivity and specificity for MDD. Low levels of PEA distinguish MDD from other forms of mental disorders such as schizophrenia, bipolar disorder or other anxieties. Early studies also suggest successful treatment where MSS, PEA levels are restored to normal. Multi-center large clinical studies in the US, Japan, Europe and in China are currently ongoing to validate the diagnostic utility of PEA for MDD patients. The talk will provide a walk-through the development process of PEA for MDD from early discovery to large scale clinical validation, from CE-MS discovery measurements to a recently released beta version clinical assay kit designed for large scale clinical measurements at independent laboratories.

Biography

Alexander M Buko received his PhD in 1980 from the University of Virginia under Professor Donald F Hunt. He went onto work at the Bureau of Biologics and Biophysics (Today called CBER) for four years then moved to Abbott Labs for 18 years as a distinguished research fellow. From 2002 to 2012, he was Sr. Director of Translational Medicine at Biogen Idec. Currently, he is the Vice President of Business and Product Development for HMT-America (Human Metabolome Technologies).

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