

# Clinical Trial Design & Optimization Working Group Biofluid/Tissue Biomarker Symposium

Monday, January 25, 2020 12:00-4:00 PM EST via web-conference

# **SPEAKER BIOS**

#### **MODERATORS**

# David Irwin MD, University of Pennsylvania

Dr. David Irwin is the primary investigator (PI) of the Penn Digital Neuropathology Lab and co-PI of the Lewy Body Dementia Association Research Center of Excellence at the University of Pennsylvania. He is a cognitive neurologist, and his research focuses on integrating human brain histopathology and imaging methods to develop and validate tissue-sensitive biomarkers, with the overall goal of improving diagnosis and clinical trials for emerging therapies for Lewy body disorders and associated neurodegenerative diseases.

# Joseph Quinn, MD, Oregon Health & Science University

Dr. Joseph Quinn is the Wayne and Sandra Erickson Endowed Professor of Neurodegeneration Research at Oregon Health and Science University (OHSU). He is the Director of the OHSU Parkinson's Center and the Portland VA Medical Center PADRECC and Biomarker Core Leader for the Oregon Alzheimer's Disease Center. He is engaged in translational research in Parkinson's disease, Alzheimer's disease, and Lewy body dementia, including biomarker research.

#### **PRESENTERS**

#### **SESSION 1:**

# Prof. Henrik Zetterberg University of Gothenburg, Sweden

Henrik Zetterberg is a Professor of Neurochemistry at the University of Gothenburg, Sweden, and University College London, UK, and a Clinical Chemist at Sahlgrenska University Hospital in Gothenburg, Sweden. He is Head of the Department of Psychiatry and Neurochemistry at the University of Gothenburg and leads the UK DRI Fluid Biomarker Laboratory at UCL. His main research focus and clinical interest are fluid biomarkers for brain diseases, neurodegenerative dementias in particular. He has published more than 1300 scientific articles and received numerous awards.

# Prof. Charlotte Teunissen, VU University Medical Center, Amsterdam, Netherlands

Charlotte Teunissen is a full professor in Neurochemistry at the VU University Medical Center. She is responsible for the Alzheimer Center Amsterdam body fluid biobank and has strong expertise with assay development on state of the art technologies, such as ultrasensitive and array-based technologies. She leads several international biomarker networks, such as the Society for Neurochemistry and routine CSF analysis and the Alzheimer Association-Global Biomarker Standardization consortium. She is the coordinator of the Marie Curie MIRIADE project, aiming to train 15 novel researchers into accelerate dementia biomarker development. She aims to improve care of patients with neurological diseases by developing body fluid biomarkers for diagnosis, stratification, prognosis and monitoring treatment responses.

# Evelien Lemstra, MD, PhD, VU University Medical Center, Amsterdam, Netherlands

A.W. Lemstra, MD PhD is a senior staff neurologist at the Alzheimer center of the Amsterdam University Medical Centres. Dr Lemstra is specialized in dementia syndromes with movement disorders especially dementia with Lewy Bodies. She is PI of various research projects involving dementia with Lewy bodies. She started the DEVELOP project in 2016, a longitudinal DLB cohort study focusing on prognostic markers and clinical heterogeneity in DLB. Dr. Lemstra is member of the steering committee of the European DLB Consortium.

# Leslie Shaw, PhD, University of Pennsylvania

Leslie M Shaw, PhD, Professor, Directs the Biomarker Research Laboratory and Directs the Toxicology Laboratory, in Clinical Chemistry, at the Perelman School of Medicine, University of Pennsylvania, in the Department of Pathology and Laboratory Medicine. He is PI and co-director of the ADNI Biomarker Core laboratory and co-leads the Biomarker Core of the UPenn ADCC. He has published more than 280 scientific papers and reviews in the peer-reviewed literature. Dr Shaw's interests include assessment and validation of pre-analytical steps involved in analyses of biofluids, development and validation of methods for quantification of CSF AD biomarkers including A $\beta$ 42 and related A $\beta$  peptides, t-tau and p-tau181 and new promising biomarkers in CSF and plasma for early disease detection, and pursuit of methods for using these for detection of AD prediction of disease progression.

## **SESSION 2:**

#### Thomas Beach, MD, PhD, Banner Sun Health Research Institute

Thomas Beach, MD, PhD, FRCPC, is Neuroscience Director and Director of the Arizona Study of Aging and Neurodegenerative Disorders and Brain and Body Donation Program, located at Banner Sun Health Research Institute (BSHRI) in Sun City, Arizona. A Canadian board-certified neuropathologist, Dr. Beach has been the recipient of multiple grants and awards from agencies including the National Institutes of Health and the Michael J. Fox Foundation for Parkinson's Research. Additionally, he has served industry as a consultant and as a neuropathology core leader for several imaging-to-autopsy FDA-licensing clinical trials. His research is focused on elucidating early neuropathological stages and biomarkers of normal human aging, Parkinson's disease, Alzheimer's disease and other neurodegenerative diseases.

#### Christopher Gibbons, MD, Harvard Medical School

Christopher Gibbons is an Associate Professor of Neurology at Harvard Medical School and on staff at Beth Israel Deaconess Medical Center and Joslin Diabetes Center in Boston, Massachusetts. Dr. Gibbons is the director of the Joslin Diabetes Center neuropathy clinic and is director of the neurocutaneous skin biopsy lab at Beth Israel Deaconess Medical Center. He is former Chair for the Autonomic Section of the American Academy of Neurology and Past-President of the American Autonomic Society. Dr. Gibbons current serves as Chair of the International Diabetes Neuropathy Consortium. Dr. Gibbons is actively engaged in clinical/translational research and has published extensively on peripheral and autonomic neuropathies.

#### Russ Lebovitz, MD, PhD, Amprion

Dr. Lebovitz is CEO and Co-Founder of Amprion, where he oversees an extremely talented team focused on accurate and early diagnosis of Alzheimer's, Parkinson's and related neurodegenerative diseases. Prior to founding Amprion, he worked for 15 years as a successful senior scientist and research physician in of academia before transitioning to a second career focused on financial, operational and executive management of emerging technology companies. He has managed global projects in operations, marketing and finance for a number of Fortune 100 technology including Royal Dutch Shell, Enron, ABB, SprintNextel, AT&T Wireless, Johnson & Johnson, Merck, Compaq/HP, King Pharmaceuticals, and JPMorganChase. Since 2003, Dr. Lebovitz has been a serial entrepreneur and active investor in life sciences projects involving protein diagnostics, imaging technology & image analysis, machine learning, drug development and medical devices.

# Anumantha Kanthasamy, PhD, Iowa State University

Dr. Anumantha Kanthasamy is Distinguished Professor and Eugene and Linda Lloyd Endowed Chair and Eminent Scholar in the Department of Biomedical Sciences at Iowa State University. He is also a director of Iowa Center for Advanced Neurotoxicology, and he previously served as department chair. Dr. Kanthasamy's research focuses on the cellular-molecular and epigenetic mechanisms and protein misfolding underlying chronic exposure to environmental neurotoxicants as it relates etiopathogenesis of chronic neurodegenerative diseases such as Parkinson's and other related neurological diseases. He has published over 190 peer-reviewed papers and book chapters, has been continuously supported by multiple NIH grants for over 20 years, and currently includes both NIH- and DoD-funded research program applying modern cellular, molecular, metabolomic, and genomic approaches to understand disease mechanisms and to identify biomarkers for chronic neurodegenerative disorders like Parkinson's Disease and other related neurological diseases.

#### **INVITED DISCUSSANTS**

#### Victor Abler, MD

Executive Director, Medical Affairs ACADIA Pharmaceuticals

#### Debra Babcock, MD, PhD

Program Director, Division of Neuroscience
National Institute of Neurological Disorders and
Stroke
National Institutes of Health

#### Kevin Biglan, MD, MPH

Medical Fellow – Neuroscience Research Eli Lilly

# Bradley F. Boeve, MD

Professor of Neurology Chair, Enterprise Division of Behavioral Neurology, Department of Neurology Mayo Clinic College of Medicine and Science

## Douglas R. Galasko, MD

Professor in Residence, Neurosciences University of California, San Diego

#### James E. Galvin, MD, MPH

Professor of Neurology
Director of the Comprehensive Center for Brain
Health
University of Miami Miller School of Medicine

#### Stephen N. Gomperts, MD, PhD

Assistant Professor of Neurology Director, Lewy Body Dementia Unit Massachusetts General Hospital Harvard Medical School

## Michael Irizarry, MD, MPH

Vice President, Clinical Research Neurology Business Group Eisai Pharmaceuticals

#### James B. Leverenz, MD

Principal Investigator, US Dementia with Lewy Bodies Consortium Director, Cleveland Alzheimer's Disease Research Center Neurological Institute, Cleveland Clinic

## Codrin Lungu, MD

Program Director, Division of Clinical Research National Institute of Neurological Disorders and Stroke

National Institutes of Health

# Eliezer Masliah, MD

Director, Division of Neuroscience National Institute on Aging National Institutes of Health

#### Ian McKeith, MD, FMedSci

Professor of Old Age Psychiatry Newcastle University Translational and Clinical Research Institute, UK

#### Charbel Moussa, MBBS, PhD

Associate Professor of Neurology
Director, Translational Neurotherapeutics
Program

## Lisa Opanashuk, PhD

Program Director, Division of Neuroscience National Institute on Aging National Institutes of Health

# Fernando Pagan, MD

Associate Professor of Neurology Chairman of the Movement Disorders Department,

Vice Chairman of the Neurology Department Georgetown University School of Medicine

## Henry Paulson, MD

Lucile Groff Professor of Neurology Director of the Michigan Alzheimer's Disease Research Center University of Michigan

## Kathleen Poston, MD, MS

Associate Director of Neurology Co-Director, Pacific Udall Center Stanford University

# Laurie Ryan, PhD

Chief of the Clinical Interventions and Diagnostics Branch National Institute on Aging National Institutes of Health

#### Marwan Sabbagh, MD, FAAN, CCRI

Director, Lou Ruvo Center for Brain Health Cleveland Clinic Las Vegas

## Andrew Siderowf, MD

Hurtig-Stern Professor of Neurology
Director, Parkinson's Disease and Movement
Disorder Center
University of Pennsylvania

## Nina Silverberg, PhD

Director, Alzheimer's Disease Centers Program Division of Neuroscience National Institute on Aging National Institutes of Health

## **Christine Swanson-Fischer, PhD**

Scientific Project Manager, Division of Neuroscience National Institute of Neurological Disorders and Stroke National Institutes of Health