NATIONAL ACADEMIES Sciences Engineering Medicine

Forum on NEUROSCIENCE and NERVOUS SYSTEM DISORDERS

Multimodal Biomarkers for Central Nervous System Disorders: Development, Integration, and Clinical Utility – A Workshop

March 13–14, 2023

Workshop Speaker Biographies

Marc Aafjes, MSM, MSc, is the CEO of Deliberate AI, a startup that applies multimodal machine

learning to enable data-driven diagnostics, biomarker discovery, and phenotyping in psychiatry and neurology. He is an international executive and entrepreneur with over 22 years of experience leading new businesses and corporate strategy & development at high-growth and large technology companies across the US, Europe, Asia, and MENA. Deliberate's integrated multimodal biomarker discovery and validation platform, Multitude™, has been used to develop the world's first Artificial Intelligence generated Clinical Outcome Assessments (AI-COAsTM) for Depression and Anxiety that can significantly increase power in clinical trials. Deliberate's work has received several industry awards, including Boehringer Ingelheim's Annual Innovation Prize, the Distinguished Poster Award at the 18th Annual Scientific Meeting of the International Society for CNS Clinical Trials & Methodology (ISCTM), and Mount Sinai School of Medicine's annual innovation award (awarded by Dean Dennis S. Charney, M.D.) After founding his first startup in high school, Marc started his career as a management consultant with Gemini Consulting, advising blue-chip companies in multiple industries on corporate strategy and innovation. He subsequently led Vodafone Group's worldwide entry into Managed Services and led Corporate Strategy and Business Transformation at Ooredoo Group. He has been involved with data science startups over the past decade. Marc received his MSM from Stanford's Graduate School of Business, and his MSc in Monetary Economics & Finance at the Vrije Universiteit Amsterdam.

Visar Berisha, PhD, is an Associate Professor at Arizona State University (ASU), with a joint

appointment in the College of Engineering and the College of Health Solutions. He was previously Fulton Entrepreneurial Professor at ASU and Research Fellow at Mayo Clinic. Dr. Berisha's main research interests include clinical speech analytics and machine learning for healthcare. With a focus on speech, his lab has developed and validated on a large-scale new machine learning and statistical signal processing tools for remote assessment of clinically-relevant changes in speech. This has led to global adoption of these tools by pharmaceutical companies and healthcare providers to track patient outcomes. Dr. Berisha's research is primarily funded by the National Institutes of

Health, the Department of Defense, and the National Science Foundation. This work has led to many academic publications, several patents, and a VC-backed company. Dr. Berisha's work has also been featured in the New York Times, on ESPN, National Public Radio, the Wall Street Journal, and several other international media outlets.

María L. De León, MD, is a patient council member at the Michael J. Fox Foundation for Parkinson's Research. Dr. De Leon is a trained movement disorder specialist with 3 decades experience caring for patients and families with neurodegenerative disease. She is an avid patient and research advocate. As a patient herself she realizes importance of early diagnosis and treatment. Over the last decade, Maria has spent most of it her time championing women's issues and setting ground for understanding of gender differences in neurological diseases particularly that of Parkinson's disease (PD); while attempting to decrease the disparity in healthcare treatment among minorities through her work as part of PAIR (Parkinson's Advocates in Research) program. She served as a member of PPAC (People with Parkinson's Advisory Committee) for 4 years for Parkinson's Disease Foundation (now known as Parkinson's Foundation) and has been instrumental in developing the 'Women & PD initiative.' As such she wrote the first book for women with PD addressing the gender differences. She has also authored 2 other books and several other publications– "Viviendo mas alla…" (Living beyond…) takes into account the cultural barriers that exist for Hispanics to obtain diagnosis and treatment for PD along with the obstacles that preclude them from participating in clinical research. This has led to an extensive collaboration with the Hispanic Outreach program through MACP (Muhammad Ali Center of Parkinson's). She currently serves as a public policy advocate for Michael J Fox Foundation working closely with the DOD in helping secure grant money for Parkinson's research.

Emily Dennis, PhD, is an Assistant Professor of Neurology at the University of Utah. She completed her Neuroscience PhD at the University of California, Los Angeles in 2013 focusing on structural connectivity across development with Dr. Paul Thompson. She completed postdocs at the University of Southern California and Brigham & Women's Hospital. Her work focuses on the effects of traumatic brain injury on brain structure and function and aims to better understand sources of variability in post-injury outcome. Along with Drs. Tate and Wilde, Dr. Dennis is a co-PI of the Brain Injury working group of the ENIGMA consortium (Enhancing NeuroImaging Genetics through Meta-Analysis). ENIGMA is a worldwide collaboration including 2000+ researchers seeking greater sample sizes to identify genetic influences on the brain and how numerous psychiatric and neurological disorders affect the brain. The ENIGMA Brain Injury working group

currently has over 220 researchers from 96 institutions across 16 countries involved across 10 different subgroups. The subgroups are either focused on specific patient populations (military, sports, pediatric, moderate/severe TBI, acute mild TBI, intimate partner violence) or methods development (resting state fMRI, magnetic resonance spectroscopy, clinical endpoints, arterial spin labeling). She is the co-PI of the Imaging Biomarker Core for CARE4Kids, a member of the LIMBIC-CENC project, and the director of ENIGMA-U.

Rebecca Edelmayer, PhD, is the Senior Director of Scientific Engagement for the Alzheimer's

Association. Dr. Edelmayer leads efforts to accelerate the organization's scientific agenda through the creation and delivery of ongoing research education. She manages national and international initiatives in dementia science uniting researchers and clinicians on topics related to biomarker testing, drug discovery and therapeutic development. She has over 20 years of experience as a scientist and educator, spending more than six years as a pharmacologist in the Neuroscience and Immunology Divisions at Abbott and AbbVie. She has lectured, published, and led collaborations in areas of neurodegenerative disease, neurophysiology, and pain neurobiology. She completed her PhD and postdoctoral training in medical pharmacology with a focus on neuropharmacology at the University of Arizona College of Medicine. She holds a bachelor's degree in neuroscience from the University of Pittsburgh, where she also completed a NIMH research fellowship.

Amit Etkin, MD, PhD, is the Founder and CEO of Alto Neuroscience. He is a trained psychiatrist,

neuroscientist and joined the faculty at Stanford University in 2010. As a tenured Professor, he became an international leader in the neuroscience of psychiatric disorders and their treatments. In recognition of the influence of his ideas and work, Amit received the Director's Pioneer Award; the most competitive and prestigious NIH grant and the first one given in clinical psychiatry. The success of his work at Stanford led him to leave his professorship to found Alto, which builds on this work in order to advance precision psychiatry with respect to actionable, real-world, clinical and commercial outcomes. Amit brings broad-based scientific and programmatic leadership and a compelling vision for connecting scientific discoveries to pragmatic clinical and business goals. He has a proven track record of success, with publications in high-impact journals, raising extensive public and private funding, and managing a large and diverse team of scientists, clinicians, and engineers towards a shared scientific vision.

Adam Ferguson, MS, PhD, is Director of Data Science in the Brain and Spinal Injury at the Zuckerberg San Francisco General Hospital, Professor of Neurological Surgery in the Weill Institute for Neurosciences at UCSF, and Principal Investigator in the San Francisco VA Healthcare System. His research interests span from mechanistic neuroscience in model organisms to large-scale clinical data science and precision medicine research. He directs a diverse team of researchers performing a hybrid of bench neuroscience and translational data science, supported by grants from the NIH, VA, DoD, DARPA and non-profits. He currently serves as Vice President and President-elect of the National Neurotrauma Society. He is a founder and Co-director of international data sharing efforts through the Open Data Commons for SCI (odc-sci.org) and TBI (odc-tbi.org), federally-supported data management ecosystems that enable FAIR data sharing, data publication, and citation. He and his team have a history of harnessing advanced AI/ML tools to drive multi-modal biomarker discovery, bench-to-bedside translation, and support precision therapeutics using pooled multicenter data. He has authored 190+ peer-reviewed papers across bench science, data science, and clinical neurotrauma research.

Ellen Grant, MD, is the Käthe Beutler Harvard Professor of Pediatrics and Professor of Radiology at Harvard Medical School. She is a practicing neuroradiologist, the Director of Faculty Affairs in the Department of Radiology, the Director of Research for the Maternal Fetal Care Center and the founding Director of the Fetal Neonatal Neuroimaging and Developmental Science Center (FNNDSC) in the Departments of Medicine and Radiology. The FNNDSC currently has over 70 members with 17 faculty and 5 postdoctoral students. Dr. Grant is a Senior Fellow of the International Society of Magnetic Resonance in Medicine (ISMRM) and sits on the Board of Scientific Counselors for National Institute of Child Health and Human Development (NICHD). In 2021 she received the Outstanding Contributions in Research Award from the American Society of Neuroradiology and in 2022 she received the Gold Medal Award from the American Society of Pediatric Neuroradiology. She is currently PI/MPI of 7 NIH grants.

Clifford Jack, MD, is Professor of Radiology and the Alexander Family Professor of Alzheimer's Disease Research at Mayo Clinic in Rochester, MN. His Aging and Dementia Imaging Research (ADIR) Lab is engaged in brain imaging research in cognitive aging and Alzheimer's disease and related disorders. Specific goals are to understand how various imaging measures relate to neuropathology, fluid biomarkers, genetics, psychometric, and cognitive/ behavioral phenotypes. All modern brain imaging modalities are used including amyloid PET, FDG PET, tau

PET, anatomic MRI, diffusion imaging, perfusion imaging, task free functional MRI, and quantitative susceptibility mapping. The ADIR Lab also serves as the MR center for large multi-site observational and interventional studies including ADNI, DIAN, the ACTC consortium (e.g. A4, AHEAD 3-45, TRC-DS), ARIC, Jackson Heart Study, ALLFTD, US Pointer, LEADS, ABC-DS, Discovery, and SCAN.

Martien Kas, PhD, is Professor of Behavioral Neuroscience at the Groningen Institute for Evolutionary Life Sciences at the University of Groningen in the Netherlands. The research of his group focuses on determinants of behavior, especially of behavioral strategies and of biological processes that are essential across species and that are affected in various neuropsychiatric disorders (e.g., social interaction and sensory information processing). By means of cross-species genetic analysis of neurobehavioral traits (of mice and men), they aim to identify genotype-phenotype relationships relevant to the development and treatment of autism spectrum disorders, Alzheimer's Disease, eating disorders, and schizophrenia. These studies will lead to the understanding of conserved gene function in regulating essential behavioral strategies and will ultimately improve therapeutic and preventive strategies to contribute to healthy aging. In addition, he is the President of the European College of NeuroPsychopharmacology (ECNP), Editorial board member of Mammalian Genome, and project coordinator of the PRISM1 and PRISM2 projects, two large EU Innovative Medicine Initiative (IMI) projects that aims to unpick the biological reasons underlying social withdrawal, which is a common early symptom of Schizophrenia, Alzheimer's disease and Major Depressive Disorder.

Carlos Larrauri, MSN, serves on the National Alliance on Mental Illness (NAMI) Board of Directors and as co-chair for the Accelerating Medicines Partnership® program – Schizophrenia (AMP® SCZ). Diagnosed with schizophrenia at 23 years of age, access to affordable health care, community-based treatments, and early intervention afforded him the best opportunity for recovery. Mr. Larrauri is board certified as a family nurse practitioner and psychiatric mental health nurse practitioner and formerly lectured at the University of Miami and Miami Dade College. Mr. Larrauri is pursuing a law degree and concurrent master's in public administration at the University of Michigan Law School and the Harvard Kennedy School as a Zuckerman Fellow. He aspires to interface advocacy, health policy, and research to reduce health inequities for people with mental illness. To this end, he has worked on projects with the BROAD Institute, the Foundation for the National Institutes of Health, the National Academies of Sciences, Engineering, and Medicine, the American Psychiatric Association, One Mind, and the Healthy Global

Brains Initiative. His work has focused on patient burden and engagement, outreach, ethics, and incorporating lived experience into scientific research.

Chris Leptak, MD, PhD, is Executive Vice President of Drug and Biological Products at Greenleaf Health. He specializes in the regulatory use of novel clinical endpoints, including surrogates for both traditional and accelerated marketing approval. While at the FDA, Chris began as a medical officer in the gastroenterology division. With his immunology expertise, his primary focus was on immunomodulator drug and biologic product development. After joining OND's Guidance and Policy team, he became OND's first biomarker and companion diagnostic lead, responsible for developing guidance and evidence requirements to support regulatory acceptance. As CDER's lead for implementation of the 21st Century Cures legislation for Section 3011 Drug Development Tools, he supervised staff responsible for Clinical Outcomes Assessments, biomarkers, and innovative drug development tools and approaches. As part of OND's modernization effort, he led the creation of ODES, served on OND's Senior Management Council, and supervised groups responsible for safety analytics as well as regulatory research in addition to the qualification programs. Chris served as the Chair of CDER's Drug Development Tools Committee, the group of senior staff responsible for advice for novel surrogate endpoints and acceptance of DDT qualification submissions. He worked closely with all OND offices and divisions as well as CDER, CBER, and CDRH and founded and chaired an FDA-wide biomarker working group. Chris is frequently invited to speak and serve as a panelist at scientific conferences. Chris completed a combined B.S./M.S. in Molecular Biophysics and Biochemistry from Yale University in 1990. His graduate work included an M.D. and Ph.D. in Microbiology/Immunology at the University of California, San Francisco in 1999. He completed his residency in Emergency Medicine at Harvard's Brigham and Women's Hospital and Massachusetts General Hospital in 2003.

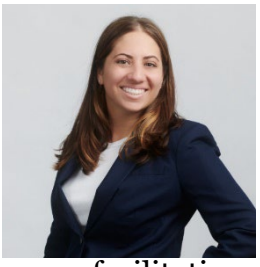
Bill Martin, PhD, is the Global Therapeutic Area Head of Neuroscience for Janssen Research & Development. Dr. Martin brings a diverse background and more than 20 years of demonstrated success in neuroscience R&D leadership to the scientific community. His experience spans drug discovery and development, scientific and business strategy, as well as company formation and growth. At Janssen, Bill has end-to-end responsibility for the neuroscience R&D portfolio from discovery, translational medicine, biomarkers and to clinical development. Prior to Janssen, Bill co-founded Blackthorn Therapeutics where he held positions of increasing responsibility, from Chief Scientific Officer and Head of R&D to President and CEO. He began his career at Merck and later joined Theravance Biopharma where he held multiple leadership positions across all aspects of Neuroscience

R&D. Bill has served on numerous Boards of Directors and Advisory Councils, including those of BlackThorn Therapeutics, the Alliance for Artificial Intelligence in Healthcare, the Coalition for the Life Sciences and Brown University's Carney Institute for Brain Science. He has held leadership positions in the Society for Neuroscience, the American Physiological Society and the International Brain Research Organization and has published extensively, with more than 75 publications in scientific journals. He graduated from Swarthmore College, earned a Ph.D. from Brown University, and conducted postdoctoral research at the Keck Center for Integrative Neuroscience at the University of California, San Francisco.

Terina Martinez, PhD, is the Executive Director of Critical Path for Rare Neurodegenerative Diseases (CP-RND) and leads the Huntington's Disease Regulatory Science Consortium (HD-RSC) and Critical Path to Therapeutics for the Ataxias (CPTA) at The Critical Path Institute (C-Path). Terina is a highly motivated neuroscientist with experience in science communication, research program leadership, biomarker and drug development in neurodegenerative diseases across diverse sectors including academia, industry, nonprofit foundations, and patient advocacy groups. Prior to joining C-Path, Terina was at The Michael J. Fox Foundation for Parkinson's Research in New York City, where she led the Foundation's programs for preclinical tools and animal models, emerging targets, and inflammation. Thereafter, Terina was a field application and collaboration scientist with Taconic Biosciences based out of Cambridge, MA, where she provided expert technical and scientific consultation across all research sectors for preclinical model selection, application, translational and IND-enabling study design, encompassing diverse disease and therapeutic areas. Terina received her undergraduate degree in Biology from the University of Dallas and earned a Ph.D. in Integrative Biology from the University of Texas Southwestern Medical Center at Dallas, where she studied cellular and molecular neuroscience. She completed her postdoctoral training at The University of Pittsburgh. Terina is passionate about improving the lives of people living with devastating neurodegenerative disease and is thrilled to lead the HD-RSC and CPTA Consortia in executing C-Path's mission to develop drug development tools to advance therapeutic innovation and regulatory science for rare neurodegenerative diseases.

Jukka-Pekka "JP" Onnela, PhD, is an Associate Professor of Biostatistics in the Department of Biostatistics at the Harvard T.H. Chan School of Public Health of Harvard University. He is also the Co-Director of the Master's Program in Health Data Science, one of the three data science programs at the university. After completing his doctorate in network science in Finland, he completed a junior research fellowship in the Department of Physics at the University of Oxford, was a Fulbright scholar at Harvard, and a postdoctoral fellow at Harvard Medical School. His main interest is in developing quantitative methods in two areas: statistical network science and digital phenotyping. He received a 2013 NIH Director's New Innovator Award for his digital phenotyping research.

Luca Pani, MD, is a Professor of Pharmacology at the University of Modena and Reggio Emilia in Italy and of Clinical Psychiatry at the University of Miami, USA. As the former Director-General of the Italian Medicines Agency (AIFA, 2011-2016) and a former member of the Board of Directors of the Committee for Human Medicines (CHMP) and the Scientific Advice Working Party (SAWP) for the European Medicines Agency (EMA) in London (2010-2017), where he was elected Chair of the EU Telematics Committee (2013-2016) overlooking the EMA databases transition plan. Luca is currently the coordinator of FACILITATE (FrAmework for ClinIcaL triaL particIpants' daTA reutilization for a fully Transparent and Ethical ecosystem), the last IMI-2 project funded by the European Commission (Jan 2022- Dec 2025). This project is built on patient-centered, data-driven technological platforms to develop a new ethical, legal, and regulatory framework enabling the return of clinical trial data to study participants and other healthcare professionals involved in their care within a GDPR-compliant and approved ethical framework. Luca is the Author of over 200 peer-reviewed scientific publications and a recognized expert in basic and clinical pharmacology and regulatory science, emphasizing health technology assessments linked with large web-based clinical datasets to guide novel approval and negotiation strategies. During his tenure as AIFA's Director-General, he implemented the first advanced Managed Entry Agreements linked to regulatory validated registries for real-life data follow-up and further evaluations based on bioinformatics.



Jillian Papa, MPH, is a professional program evaluator and the Board President of Emotions Matter, a nonprofit organization with a mission to support, educate, and advocate for people impacted by borderline personality disorder (BPD). Jillian was diagnosed with BPD in 2012. As a result of DBT and medication management, she was able to achieve recovery. During her recovery journey, she discovered Emotions Matter and was inspired by the mission. Over the last 6 years, she has supported Emotions Matter in varying capacities, including online peer support group facilitation and chairing the Program Evaluation Committee. Jillian is a Monitoring, Evaluation, Research and Learning (MERL) Advisor for Save the Children US. She has spent the last decade of her professional career evaluating nonprofit and government children's health programs. She received her Master's degree in Epidemiology from Emory University Rollins School of Public Health.

Jane Paulsen, PhD, is a neuropsychologist, research methodologist, and professor University of Wisconsin School of Medicine and Public Health. Dr. Paulsen applies her knowledge to improve methods and practices to improve rigor for clinical trials. Dr. Paulsen has been continuously funded as a PI on NIH-funded grants for 28 years, having been awarded over $115 million funding from various sources, and also serving as site PI on numerous clinical trials and worldwide observational studies as well as membership on clinical trial Executive Committees and Safety Monitoring Boards. She consults for the Food and Drug Association, The Movement Disorder Society, the American Psychiatric Association, the NIH and several pharmaceutical companies on clinical trial design/methods, biomarkers and clinical outcome assessments. Dr. Paulsen recently completed a 5-year term on the NIH Center for Scientific Review's Clinical Neuroscience and Neurodegeneration Study Section and continues to serve on the Biorepository Research Advisory Committee for the NINDS. Dr. Paulsen conducted one of the first multi-site studies to recruit and follow healthy persons at increased genetic risk for brain disease. Using the rare disease, Huntington's disease, she developed the 12-year, 33-site NIH-sponsored study of prodromal HD (i.e. PREDICT-HD). Her original study followed nearly 1500 persons with the gene mutation for HD up to 12 years and documented imaging, biomarker, motor, cognitive, psychiatric, functional and patient-reported outcomes as persons progressed from healthy to prodromal and symptomatic to having manifest diagnosed disease. She continues to examine biological and refined clinical markers to improve disease models of the natural progression of disease from health to death. Dr. Paulsen recently received funding to develop a USA CADASIL Consortium to examine vascular cognitive decline and dementia using the most heritable vascular dementia, cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy. Using this rare genetic disease as a model for more prevalent kinds of vascular cognitive decline and dementia, she hopes to begin to develop natural history models of early vascular dementia.

Diego Pizzagalli, PhD, received his MA (1995) and PhD (1998) from the University of Zurich, Switzerland and did post-doctoral work at University of Wisconsin, Madison. In 2010, he was recruited to McLean Hospital to serve as the Founding Director of the newly established Center for Depression, Anxiety and Stress Research (CDASR), as well as the Director of the McLean Imaging Center (MIC). Since September 2015, he also serves as the Director of Research for the Division of Depression and Anxiety. He is currently a Professor of Psychiatry at Harvard Medical School, and the Center Director for a Silvio O. Conte Center for Basic Translational Mental Health Research focused on the neurobiology of and novel treatment targets for depression and anxiety disorders. The main goals of his research are to improve our understanding of the psychological, environmental, and neurobiological factors associated with mood disorders, particularly major depression. To this end, he integrates behavioral, electrophysiological, neuroimaging, and, more recently, pharmacological approaches to investigate three putative endophenotypes of depression: anhedonia (loss of pleasure), increased stress sensitivity, and executive function deficits. Dr. Pizzagalli has published over 340 papers and chapters and serves on the editorial board of 13 journals. He is the Editor-In-Chief for the journal Cognitive, Affective and Behavioral Neuroscience, as well as the Principal Editor for Psychopharmacology (Human Psychopharmacology: Experimental).

Arthur Simen, MD, PhD, is the Executive Medical Director at Takeda Development Center Americas. He received his MD degree as well as a PhD in neurobiology from the University of Chicago where his thesis in the laboratory of Richard Miller was focused on protein structural and biophysical features of presynaptic calcium channels that mediate presynaptic inhibition in neurons, and also studied statistical genetics. Arthur then completed a residency program in Psychiatry at Yale University as a part of an NIH-funded Neuroscience Research Training Program which combined clinical training with laboratory investigations in neuroscience and genetics. After graduation, Arthur ran a research lab in the Department of Psychiatry Divisions of Molecular Psychiatry, Aging Research, and Human Genetics. Arthur subsequently moved to pharma, initially as a part of Merck's GCDRA leadership development program in North Wales PA where he had opportunities to work across drug development from experimental medicine to late-phase clinical development in neuroscience. Arthur then moved to Pfizer's Neuroscience Research Unit in Cambridge MA where he led multiple clinical development programs for neurodegenerative disorders and other CNS conditions, and led a broad quantitative Alzheimer's analysis and modelling team focused on endpoint selection, optimization, and development for internal Alzheimer's trials. Arthur

then moved to Takeda in Cambridge MA where he is currently Executive Medical Director and leads clinical development for neurodegenerative disorders including Alzheimer's disease, frontotemporal dementia, Parkinson's disease and related disorders, and leads Takeda's Neurodegenerative Disorders Unit (NDU), a cross-functional effort to organize the company's drug development efforts in neurodegeneration, including integrated development from concept to clinical trial execution and alignment with Takeda Neuroscience strategy.

Elias Sotirchos, MD, is an Assistant Professor of Neurology at the Johns Hopkins University School of Medicine. He earned his medical degree from the National and Kapodistrian University of Athens and subsequently completed his internship and neurology residency training at The Johns Hopkins Hospital. He then pursued advanced clinical and research training in neuroimmunology at Johns Hopkins as a National MS Society Sylvia Lawry Fellow. His research focuses on developing and validating novel imaging and blood-based biomarkers of neuroimmunological disorders affecting the central nervous system. Furthermore, he studies the effects of treatments in these conditions on clinical outcomes and disease biomarkers, both in the context of observational studies and clinical trials.

Kirsten Taylor, PhD, is an Expert Scientist and Group Leader of Neurocognitive and Digital Biomarkers in the Biomarkers and Translational Technologies section of the Neuroscience and Rare Disease Department of F. Hoffmann-La Roche, Ltd. Pharma Research and Early Development (pRED) organization in Basel, Switzerland. Kirsten studied bioengineering and psychology at the University of California, San Diego (UCSD) and obtained a PhD in neuropsychology at the University of Zurich and a Dr. habil. at the Department of Psychology in Basel, Switzerland. She trained as a psychometrist at UCSD's Veteran's Administration Hospital and Alzheimer's Disease Research Center, as a clinical neuropsychologist at the University Hospital Zurich Neurology Clinic, and as a cognitive neuroscientist at the University of Zurich and Department of Experimental Psychology at the University of Cambridge, U.K. Kirsten's academic work at the Universities of Zurich, Cambridge and later University Hospital Basel focused on understanding the functional neuroanatomy of visual object processing, semantic and episodic memory, and applying this knowledge to develop novel tools to detect preclinical Alzheimer's disease. At Roche, Kirsten is part of a team responsible for developing biomarker strategies for drug programs, and novel neurocognitive and digital health technology biomarkers, focusing mainly in Parkinson's disease and Alzheimer's disease.

Mary Thanh Hai, MD, is currently the Deputy Director for Clinical in the Office of New Drugs Immediate Office at the U.S. Food and Drug Administration (FDA). In this role, she works directly with the Super Office Director overseeing the development programs of drugs and biologics regulated by the Center of Drug and Evaluation and Research across 27 review divisions. She also oversees the Office of Drug Evaluation Science including the Biomarker and Clinical Outcome Assessments Qualification Programs, the Biomedical Informatics Team, the OND Research Program, and the Drug Trials Snapshot Program. Dr. Thanh Hai is an internist/endocrinologist receiving her medical degree from Georgetown University. Prior to joining the FDA in 1998, she had an interest in disorders of water metabolism and the role of vasopressin receptor antagonism in the treatment of hyponatremic states. Over the past 24 years, she has held several leadership roles at the FDA including Director of the Division of Metabolism and Endocrine Products (DMEP) from 2006-2013, which oversaw development programs for dyslipidemia, diabetes, obesity, growth and metabolism, and general endocrinology diseases. From 2013-2018 she was the Deputy Office Director for the Office of Drug Evaluation 2 overseeing three review divisions: DMEP, Division of Pulmonary, Allergy, and Rheumatology Products (DPARP), and Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), and was the acting Office Director of ODE 2 before moving into her current role. Dr. Thanh Hai has served on several internal and external committees, served as the rapporteur for the development of ICH E19 Guideline, and participated in PDUFA and BSUFA negotiation meetings between FDA and industry.

Leanne Williams, PhD, is the inaugural Vincent V.C. Woo Professor of Psychiatry and Behavioral Sciences and Associate Chair of Translational Neuroscience at Stanford University School of Medicine. She is founding director of the Stanford Center for Precision Mental Health and Wellness and of the Stanford PanLab for Precision Psychiatry and Translational Neuroscience. She holds a joint appointment as Director of the Precision Medicine Core at the Palo Alto VA Mental Illness Research, Education and Clinical Center. Prior to joining the Stanford community, Dr. Williams was the Professor of Cognitive Neuropsychiatry and Director of the Brain Dynamics Center at Sydney Medical School. Her PhD was completed with a British Council Scholarship for study at Oxford University. She has developed a the first-of-its-kind technology to identify neuroscience-based biotypes of depression and anxiety. Her biotype approach integrates advanced neuroimaging and data sciences. Her treatment studies use biotypes to personalize to tailor interventions and promote wellness. Biotypes are applied in studies of pharmacotherapies, behavioral interventions, novel selective medicines, neuromodulation, and exploratory therapeutics. Dr. Williams' research programs are supported by funding from the National Institutes of Health and foundations. She has published the first book on Precision Psychiatry and contributed over 360 scientific papers to the field.

Hao Zhu, MD, is the director of the Division of Pharmacometrics in the Office of Clinical Pharmacology and Office of Translational Science in the Center of Drug Evaluation and Research at the U.S. Food and Drug Administration. Dr. Zhu received his Ph.D. in pharmaceutical sciences and Master in statistics from the University of Florida. He started his career in modeling and simulation teams in Johnson & Johnson and Bristol-Myers-Squibb. He joined FDA as a pharmacometrics reviewer more than 16 years ago. Dr. Zhu has been a clinical pharmacology team leader for more than 6 years and a QT-IRT scientific lead for 2 years. Then he became the deputy director at the Division of Pharmacometrics. His division reviews the pharmacometrics related submissions and supports pharmacometrics-related policy development.