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

Planning Committee Biographies

Linda Brady (Co-Chair), PhD, serves as the Director of the Division of Neuroscience and Basic Behavioral Science at the National Institute of Mental Health (NIMH). In this role, she provides scientific, programmatic, and administrative leadership for an extramural research program portfolio in basic neuroscience to support NIMH's mission of transforming the understanding and treatment of mental illnesses. Dr. Brady has directed programs in neuropharmacology, drug discovery, and clinical therapeutics, and organized consortia focused on ways to accelerate the development and clinical application of radiotracers in clinical research. She has provided leadership for the National Cooperative Drug/Device Discovery/Development Groups for the Treatment of Mental Disorders and First in Human and Early Stage Clinical Trials of Novel Investigational Drugs or Devices for Psychiatric Disorders initiatives. Dr. Brady serves as co-chair of the Neuroscience Steering Committee of the Biomarkers Consortium, a public-private research partnership of the Foundation for the National Institutes of Health (FNIH) that focuses on discovery, development, and qualification of biological markers to support drug development, preventive medicine, and medical diagnostics. She serves as co-chair of the Steering Committee for the Accelerating Medicines Partnership®—Schizophrenia, a public-private partnership to generate tools to improve success in developing early stage interventions for patients who are at risk of developing schizophrenia. She is also a member of the National Academies Forum on Drug Discovery, Development, and Translation. Dr. Brady was trained in pharmacology and neuroscience. She completed her PhD at Emory University School of Medicine, followed by post-doctoral work and research positions at the Uniformed Services University of the Health Sciences and the NIMH Intramural Research Program. She is the author of more than 70 peer reviewed scientific publications and is a member of the Society for Neuroscience and a Fellow and President of the American College of Neuropsychopharmacology. Dr. Brady has received NIH Director's Awards and NIH Merit Awards in recognition of her activities in biomarker development and drug development for mental disorders.

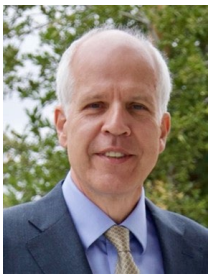
Vikas Sharma (Co-Chair), MD, is the Global Head Medicine CNS, Retinopathies & Emerging Areas at Boehringer Ingelheim. Dr. Sharma is an industry leader with more than 20 years of experience in healthcare and clinical development with a skill mix of clinical acumen, clinical development, research ethics, and patient safety. He has obtained leadership roles in healthcare, contract research organizations, and the pharmaceutical industry, including a corporate leadership role for patient safety and medical research ethics. He has navigated complex research scenarios leading to the success of the business deliverables. In his current role, Dr. Sharma is responsible for the clinical development of novel early and late-stage products, leading global clinical development, medical affairs, and scientific relations teams across multiple therapeutic areas. He has proven success in leading First in Class, Blue Ocean and Beyond the Pill product strategies. Dr. Sharma is an independent Ethics Expert working with European Research Council and is passionate about the cause of children with special needs.

Alan Anticevic, PhD, trained in clinical psychology and cognitive neuroscience at Washington University in St. Louis where he trained with Drs. Deanna Barch and David Van Essen. Following graduate training, Dr. Anticevic completed his internship in clinical neuropsychology at Yale University. After his internship, he joined the Yale University Department of Psychiatry as research faculty while concurrently serving as the Administrative Director for the Center for the Translational Neuroscience of Alcoholism. Subsequently, he was appointed as an Assistant Professor of Psychiatry and Psychology at the Yale University School of Medicine, where he directs a clinical neuroimaging laboratory focused on severe mental illness. Dr. Anticevic is a recipient of the NARSAD Young Investigator Award, the International Congress of Schizophrenia Research Young Investigator Award, the NIH Director's Early Independence Award, the NARSAD Independent Investigator Award, and the Klerman Prize for Exceptional Clinical Research. He currently serves as the Director of the Division of Neurocognition, Neurocomputation, and Neurogenetics (N3) at Yale School of Medicine.

His group's research focus is centered on computational and cognitive neuroscience of mental illness. Specifically, Dr. Anticevic's group is interested in characterizing neural mechanisms involved in higher order cognitive operations, such as working memory, as well as their interaction with neural systems involved in affective processes, with the aim of understanding how these computations may go awry in the context of severe mental illness. Methodologically, his group uses the combination of task-based, resting-state, pharmacological multi-modal neuroimaging, as well as computational modeling approaches to map neural alterations that lead to poor mental health outcomes. The overarching goal of the group is to develop neurobiologically principled and computationally grounded mapping between neural and behavioral levels of analyses in people to inform personalized and rational treatment design for mental health symptoms.

Stuart W. Hoffman, PhD, is the Senior Health Science Officer for TBI for the Office of Research and Devleopment. Dr. Hoffman is responsible for providing overall direction, program planning, development and implementation for ORD TBI research; coordinating with ORD leads and Federal partners in other high priority nationwide efforts in TBI and brain health; promoting data sharing in TBI research; and to expand the clinical trials network nationally to improve TBI treatments and diagnostics for Veterans. Dr. Hoffman received his Ph.D. in behavioral and molecular neuroscience at Rutgers University in 1995 and completed his postdoctoral training in pharmacology at Virginia Commonwealth University in 1997. Dr. Hoffman was a full-time Emory University faculty member from 1998-2006. Immediately prior to joining the VA in 2010, Dr. Hoffman was the Research Director for the Defense and Veterans Brain Injury Center in Johnstown, Pennsylvania. Dr. Hoffman has over 50 peer-reviewed publications and more than 35 years of translational neuroscience research experience that focused on TBI therapeutics.

Samantha Hutten, PhD, is the Director of Discovery and Translational Research at the Michael J. Fox Foundation for Parkinson's Research (MFJJ). In this role, Dr. Hutten oversees the MJFF's biomarker strategy. Since its inception, MJFF has prioritized biomarker research, supporting around $85M to date. There remains an urgent unmet need for robust, reliable Parkinson's disease biomarkers to aid in diagnosis, enable patient selection for trials, and monitor disease progression. Dr. Hutten graduated with honors from Vassar College and then went on to complete her PhD at Albert Einstein, where she studied the role of dysfunctional autophagy in Parkinson's Disease. She has been with MJFF for almost 9 years, where she has worn many different hats. Over the years, these have included a focus on molecular based bioassays, oversight of MJFF's Biosample Resources Programs, scientific liaison for MJFF's Research Cohorts, and lead of the Foundation's Women's Employee Resource Group. In addition to being responsible for the Foundation's biomarker strategy as a whole, Dr. Hutten manages a diverse translational research portfolio, including digital health and physiologic biomarker efforts, molecular bioassays for high priority targets, and pre-clinical symptomology therapeutics.



Hartmuth Kolb, PhD, received his PhD in Organic Chemistry in 1991 at Imperial College of Science, Technology and Medicine, London. He joined Ciba-Geigy in 1993 and in 1997 started collaborating with K. Barry Sharpless (2001 Chemistry Nobel Laureate) to pioneer Click Chemistry (Sharpless received the 2022 Nobel prize for Click Chemistry). He then became head of Siemens Biomarker Research, where he and his team developed PET tracers using Click Chemistry. The PHF-Tau PET tracer [18F]-T807 (aka "Flortaucipir", "Tauvid") was recently approved by the FDA to image a distinctive characteristic of Alzheimer's disease in the brain called tau pathology. Dr. Kolb joined Janssen in January 2014. His research interests include the development of PET tracers for all

therapeutic areas, and the development of precision medicine approaches in neuroscience. His lab developed a p217Tau blood test that detects the presence of Alzheimer's pathology in patients. Dr. Kolb serves as co-chair of the Neuroscience Steering Committee of the Foundation of NIH Biomarkers consortium. He has over 180 peer reviewed scientific papers and over 100 patents.

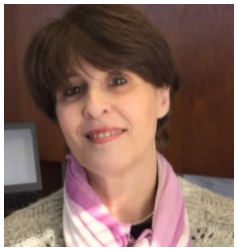
Valentina Mantua, PhD, Valentina Mantua is medical doctor and psychiatrist with a PhD in neurobiology. She has over ten years of working experience in regulatory science. She served in high-level positions within the European Medicines Agency (EMA) for 7 years and obtained relevant experience of the US regulatory environment in the last 3 years at the FDA, where is currently serving as a clinical team leader in the Division of Psychiatry. While at EMA (January 2013-October 2019), she served as Italian delegate to several committees and working parties including the Scientific Advice Working Party, and the Central Nervous System Working Party and the European (EU) Innovation Network. Her main roles and responsibilities included review of marketing authorization applications (MAAs) for psychiatry, scientific advice related to centralized marketing submission in the EU, qualification of biomarkers, outcomes, and novel methodologies for use in drug development. In her policy roles, Dr. Mantua worked towards establishing new regulatory frameworks for the regulation of innovative products and particularly digital tools for use in drug development.

Dr. Mantua represents the FDA at external committees and working groups, including scientific societies and other government organizations, such as NIH and FINH. She is also a member of the program committee of the American Society of Clinical Psychopharmacology (ASCP); member of the editorial board of Nature Digital Medicine; and holds a temporary professorship at the University of Modena and Reggio Emilia in Italy, where she teaches “Clinical Research Methods in Neuropsychopharmacology” to residents and PhD students in Neuroscience.

Adriana Di Martino, MD, is an internationally recognized autism researcher and the founding research director for the Autism Center at the Child Mind Institute. Dr. Di Martino has a long-standing research interest in autism spectrum disorder and how to best understand its neurobiology using brain imaging and a range of other clinical and cognitive approaches. Her study places a particular emphasis on detecting autism-related differences in brain connectivity that emerge in early childhood, with the goal of identifying objective biological markers that can one day be used to improve early intervention efforts and the selection of treatments. In order to accelerate the pace of autism research, Dr. Di Martino established and directs the Autism Brain Imaging Data Exchange (ABIDE), which aggregates and shares functional and structural brain imaging data from laboratories around the world. The datasets made available to the scientific community by ABIDE have attracted a broad

range of researchers to the study of autism, with expertise ranging from neuroscience and psychology to statistics, mathematics, and engineering. New insights are emerging through the studies of ABIDE at a rate of more than a publication per month. Dr. Di Martino is also a leader in efforts to recognize and understand overlaps in the neural bases of other neurodevelopmental conditions that commonly co-occur with autism, such as attention-deficit hyperactivity disorder. Insights from this work are helping to provide a better understanding of differences in the clinical presentation of autism among individuals, as well as variations in the responses of treatment. Dr. Di Martino is one of our nation's most prolific researchers in the neuroimaging of autism, with publications in the most scientifically respected journals in the field of psychiatry, including the JAMA-Psychiatry, American Journal of Psychiatry, Biological Psychiatry and Molecular Psychiatry. She has also received honors and funding support from the National Institute of Mental Health (NIMH) and the Simons Foundation and has been invited to lecture at multiple national and international scientific conferences.

Alessandra Rovescalli, PhD, MD, is a Program Director in the Clinical Interventions and



Diagnostics Branch of the Division of Neuroscience at the National Institute on Aging. Dr. Rovescalli oversees a research portfolio that includes the discovery of biomarkers of cellular processes and physiological functions leading to or precipitating neurodegeneration, as well as the discovery, development, and dissemination of new or emerging imaging (PET/SPECT) biomarkers for AD/ADRD research. Dr. Rovescalli received her MS in Pharmaceutical Chemistry and Technology, her doctoral degree in Experimental Endocrinology, and a PhD in Pharmacology and Toxicology from the University of Milan in Milan, Italy. She completed her research training at the Institute of Pharmacological Science, University of Milan, Italy, and in the laboratory of Nobel Laureate Marshall Nirenberg at the National Institutes of Health, Bethesda, MD, where she remained as staff scientist for 12 more years.

In 2014, she joined the NIH Center for Scientific Review, where she was the Scientific Review Officer for the Clinical Neuroscience and Neurodegeneration study section, as well as multiple other special emphasis panels within the Brain Disorders and Clinical Neuroscience Integrated Review Groups. Throughout her career, Dr. Rovescalli conducted and published research in multiple fields of neuroscience, including neuropharmacology (e.g., characterization and mechanisms of action of antidepressants and antipsychotics), neuroendocrinology (effects of drugs and neurotransmitters on the hypothalamus-pituitary-gonad axis), chronobiology (interactions between drugs, drugs receptors and circadian rhythms), and developmental neurobiology (transcriptional regulation of the development of the embryonic nervous system).

Carol Taylor-Burds, PhD, is a Program Director in the Division of Translational Research for the National Institute of Neurological Disorders and Stroke (NINDS) Biomarker Program where she oversees a biomarker portfolio of development and clinical validation studies. She also serves as a Scientific Project Manager for the NIH's Blueprint Neurotherapeutics Network (BPN) for Small Molecules. Previously, she was a Health Program Specialist at NINDS where she supported the neurotrauma portfolios, including programmatic management of the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system for data sharing. Dr. Taylor-Burds received her neuroscience training at Regis University, with a BS in Neuroscience, her PhD in Biology from the University of Vermont, and completed her postdoctoral training at the NINDS Division of Intramural Research.

Alessio Travaglia, PhD, is the Director of Neuroscience at the Foundation for the National Institutes of Health (FNIH). In his role, he leads the Neuroscience Research Partnership programs, facilitate the advancement and execution of innovative neuroscience research and biomarker development, engages international participation from government, industry, academia, patient-advocacy and private sector organizations. Dr. Travaglia is a neuroscientist with over 15 years of experience in basic and translational neuroscience, in academia, non-profit, management consulting, and venture philanthropy. Prior to joining the FNIH, he was the Associate Director of Scientific Affairs at the Alzheimer's Drug Discovery Foundation (ADDF), where he executed strategic plans and scientific due diligence to develop and manage the ADDF's therapeutic portfolio.

Charisse Winston, PhD, earned her B.S. in Biochemistry from the University of Virginia (UVA) in 2006. After working for a year as a lab tech at UVA, Dr. Winston matriculated to the DC area where she obtained a M.S. in Biochemistry (2009) and a PhD in Neuroscience from Georgetown University. In 2015, Dr. Winston began her postdoctoral training at UC San Diego (UCSD) where she characterized blood-based extracellular vesicle (EV) cargo as diagnostic biomarkers for Alzheimer's Disease. Presently, Dr. Winston is an Assistant Project Scientist at UCSD, where she has extended her research to focus on the cellular mechanisms of EV trafficking and understanding the pathogenic potential of blood-based EV cargo in vivo and in vitro. Dr. Winston is a MOSAIC K99/R00 (2021-2026) awardee where she proposes to examine the ethno-

racial impact on the biomarker potential of EVs in AD. Dr. Winston's overall research goal is to improve diagnostics for early AD identification and to address brain health inequities that exist amongst minority patients' groups, while increasing the translational capacity of race-specific biomarkers in AD. In addition to her research, Dr. Winston has served as an adjunct biology and neuroscience professor for over 5 years. Dr. Winston is a proud member of Alpha Kappa Alpha Sorority, Inc. and numerous other professional organizations including the International Society for Extracellular Vesicles, Society for Neuroscience, and Alzheimer's Associational International Society to Advance Alzheimer's Research and Treatment.

National Academy of Medicine Fellow

Julianne Sees, DO, MBA, FAOAO, FAOA, FAAOS, is a pediatric/neuro-orthopaedic surgeon with dual fellowship training in pediatric orthopaedic surgery and neuro-orthopaedic surgery, having expertise in care for children and young adults with neuroorthopaedic disorders. Dr. Sees serves on the American Osteopathic Association Board of Trustees, American Osteopathic Academy of Orthopedics Board of Directors, American Osteopathic Foundation Board of Directors, as Delaware State Osteopathic Medical Society President, American Academy for Cerebral Palsy and Developmental Medicine Webmaster and National Academy of Medicine Fellow. Dr. Sees has authored over 75 peer-reviewed publications/chapters and made over 190 national and international conference presentations/instructional courses including healthcare delivery, neuroscience, and international strategy. Her research includes best practices within physician professional development, neuro-orthopaedics, complex motor conditions, gait abnormalities, pediatric subspecialty care, clinician well-being and emerging leadership in health, education, and medicine.