Exploring the Adoption of Implantable Brain Stimulation into Standard of Care for Central Nervous System Disorders: A Workshop

Committee

Timothy Denison

Co-Chair

Tim Denison, MD, MS, holds a joint appointment in Engineering Science and Clinical Neurosciences at Oxford, where he explores the fundamentals of physiologic closed-loop systems in collaboration with the MRC Brain Network Dynamics Unit. Tim also serves as an advisor to several governments and industry boards on the field of translational medical devices; in particular, helping define strategies for mapping scientific discovery to product development roadmaps within the regulatory and economic constraints of medical systems. He is currently the Chief Engineer at Amber Therapeutics which recently acquired Bioinduction Limited and its Picostim DyNeuMo neuromodulation therapy platform. Prior to Oxford, Tim was a Technical Fellow at Medtronic PLC and Vice President of Research & Core Technology for the Restorative Therapies Group, where he helped oversee the design of next generation neural interface and algorithm technologies for the treatment of chronic neurological disease. In 2015, he was elected to the College of Fellows for the American Institute of Medical and Biological Engineering (AIMBE). He has an MS and PhD from MIT in electrical engineering, and an AB in Physics and MBA from the University of Chicago.

Helen S. Mayberg

Co-Chair

Helen Mayberg, MD, a neurologist, is Professor of Neurology, Neurosurgery, Psychiatry and Neuroscience, and the Mount Sinai Professor in Neurotherapeutics at the Icahn School of Medicine where she serves as Founding Director of the Nash Family Center for Advanced Circuit Therapeutics. Recognized for her neuroimaging studies of brain circuits in depression and their translation to the development of deep brain stimulation as a novel therapeutic for treatment resistant patients, she now leads a patient-focused transdisciplinary research team with the shared mission to advance precision surgical treatments for complex neuropsychiatric disorders. Active studies focus on refinement of deep brain stimulation for treatment resistant depression utilizing a range of mechanism-of-action and predictive biomarker strategies including collaborations involving animal models. Complementary strategies using chronic intracranial monitoring, computer vision and machine learning approaches are being developed to detect more subtle changes in core depression-relevant behaviors relevant to further DBS optimization. She serves on the scientific advisory boards for Blackrock Neuro, Cogwear, and NextSense and as a consultant to Abbott Labs. Dr. Mayberg is a member of the U.S. National Academy of Sciences, the National Academy of Medicine, the National Academy of Inventors and the American Academy of Arts and Sciences and participates in a wide variety of advisory and scientific activities across multiple fields in neuroscience.

Nita Farahany

Member

Nita Farahany, JD, PhD, is a leading authority on law, ethics, and emerging technology, and serves as a distinguished professor of law and philosophy and founding director of Duke University's Science & Society initiative. Dr. Farahany also serves on the Blackrock Neurotech Ethics Advisory Board. In her book, The Battle for Your Brain, she champions cognitive liberty in the digital era. Her insights, shared from TED stages to global policy forums, guide responsible advancements in science and technology.

Sarah H. Lisanby

Member

Sarah Hollingsworth "Holly" Lisanby, MD, DLFAPA, an internationally renowned innovator of neuromodulation technologies, is Director of the Division of Translational Research at the National Institute of Mental Health (NIMH), which funds research supporting the discovery of preventions, treatments, and cures for mental illness across the lifespan. She founded and directs the Noninvasive Neuromodulation Unit in the NIMH Intramural Research Program, a pioneering translational research program specializing in the use of brain stimulation tools to measure and modulate neuroplasticity to improve mental health. Currently, she is Professor Emeritus at Duke University Department of Psychiatry and Behavioral Sciences. Previously, she was the first woman to serve as Chair of the Duke University Department of Psychiatry. She founded and directed both the Duke University and the Columbia University Divisions of Brain Stimulation, where she built interdisciplinary research programs specializing in the convergence of Psychiatry, Neuroscience and Engineering. She co-led the NIH BRAIN Initiative Team focused on largescale neural recording and modulation devices. Dr. Lisanby's laboratory has been continuously federally funded for over 20 years. She has been principal investigator on a series of NIH and DARPA funded studies on the development of novel neuromodulation technologies, including studies on the rational design of magnetic and electrical seizure therapies. Her team pioneered magnetic seizure therapy (MST) as a novel depression treatment from the stages of animal testing, first-in-human, and now international trials. A prolific author with over 290 scientific publications, she has received national and international recognition, including the Distinguished Investigator Award from the National Alliance for Research on Schizophrenia and Depression (NARSAD), the Max Hamilton Memorial Prize of the Collegium Internationale Neuro-Psychopharmacologicum (CINP), the Gerald Klerman Award from the National Depression and Manic Depression Association (NDMDA), and the Eva King Killam Research Award from the American College of Neuropsychopharmacology (ACNP). Dr. Lisanby serves on the FDA Neurological Devices Advisory Panel and has held key leadership positions in professional organizations including serving as President of the International Society for ECT and Neurostimulation and Chair of the American Psychiatric Association Task Force to Revise the Practice on Electroconvulsive Therapy (ECT). A Board-Certified Psychiatrist and Distinguished Life Fellow of the American Psychiatric Association (DLFAPA), Dr. Lisanby received her dual BS in Mathematics and Psychology and her MD at Duke University as an Angier Biddle Duke Scholar.

Brian Litt

Member

Brian Litt, MD, is the Perelman Professor of Neurology, Neurosurgery and Bioengineering at the University of Pennsylvania. He divides his time equally between the Schools of Medicine and Engineering, as the founding director of both Penn's Center for Neuroengineering and Therapeutics and a cross-campus medical technology initiative, Penn's Center for Health, Technology and Devices (Penn Health-Tech). He has served on the faculty at Johns Hopkins University, Emory University and the Georgia Institute of Technology, in addition to Penn. Dr. Litt is a neurologist who treats patients with epilepsy. His research focuses on NeuroEngineering: materials, hardware, imaging, algorithms, data science, machine learning, and high-speed computing for neural interfaces and devices. His laboratory translates basic science into new diagnostic and therapeutic technologies, with a focus Epilepsy and other brain network disorders. Dr. Litt also works on international collaboration for data sharing and integration at scale, and training underrepresented groups in STEM and neuro-related fields. He specializes in translating health technologies to industry, and its interface with academia. Dr. Litt holds a substantial portfolio of patents, advises, contributes to and has co-founded a number of device companies including Neuropace, MC10, Blackfynn, Hyperfine, Butterfly Systems, and Jonathan Rothberg's 4Catalyzer companies. Dr. Litt has trained over 80 PhD students, Postdocs, and many more clinical trainees. He has won a number of awards for his research and mentoring, most recently an NIH Pioneer Award, and the NINDS Landis Award for mentoring.

Laura Lubbers

Member

Laura Lubbers, PhD, MS, brings more than 25 years of research experience to her position of Chief Scientific Officer at CURE Epilepsy, the largest non-governmental funder of epilepsy research. She is responsible for developing the organization's research strategy, and developing and overseeing all research programs which collectively seek to cure epilepsy, not just treat the symptoms. Dr. Lubbers also contributes to educational and federal advocacy activities to increase awareness of epilepsy and federal investment in epilepsy research. Prior to joining CURE Epilepsy, she spent 15 years in a large pharmaceutical company as a drug discovery scientist. Importantly, Dr. Lubbers' sister suffered from intractable epilepsy from an early age and her mother was diagnosed later in life. The impact of epilepsy on her family has fueled her passion to find better healthcare solutions for people with epilepsy. Dr. Lubbers holds a Bachelor of Science in Physiology, as well as a Master of Science and a PhD from the University of Illinois, Urbana.

David McMullen

Member

David McMullen, MD, is the Director of the Office of Neurological & Physical Medicine Devices (OHT5) within the FDA's Center for Devices and Radiological Health. OHT5 is responsible for the total product lifecycle review of neurosurgical, neurointerventional, neurodiagnostic, neuromodulation, and rehabilitation devices. Dr. McMullen was previously the Program Chief of the Neuromodulation and Neurostimulation Program at the National Institute of Mental Health (NIMH) and co-leader of the NIH BRAIN Initiative team focused on the development of non-invasive brain stimulation. Dr. McMullen is a neuroscientist and medical doctor whose program of research focuses on sensorimotor neuroscience and improving brain-computer interfaces (BCIs) by incorporating novel technology, such as augmented reality interfaces and intelligent robotics.

Jim McNasby

Member

Jim McNasby, JD, is the General Counsel of the Michael J Fox Foundation for Parkinson's Research (MJFF). Before joining MJFF, Jim served as Managing Director, Global Sales (2017-2020) and General Counsel (2007-2017), for Marsh LLC, the world's leading insurance broker and risk advisor. Prior to Marsh, Jim held various in-house legal positions at Kraft Foods (2004-2007) and Altria (1998-2004) in the US and abroad. He began private practice in New York at Davis Polk & Wardwell (1995-1998), after serving as a law clerk to the Chief Judge of the US District Court in Providence, RI. Jim attended the University of Virginia ('91) and Harvard Law School ('94). He is currently a Director of The Billy Rose Foundation. He formerly served as a director of United Biscuits Group Investments, PLC, in the UK (2004-2006). Jim was diagnosed with Parkinson's disease in 2000 and had deep brain surgery in 2019 and 2022.

Martha Morrell

Member

Martha Morrell, MD, FAAN is Chief Medical Officer of NeuroPace, Inc. and a Clinical Professor of Neurology at Stanford University. Previous positions include the Caitlin Tynan Doyle Professor of Clinical Neurology at Columbia University and Director of the Columbia Comprehensive Epilepsy Center at New York Presbyterian Hospital in New York City, and earlier, Director of the Stanford Comprehensive Epilepsy Center. Dr. Morrell has been actively involved in helping to bring new therapies to patients. Her responsibilities at NeuroPace include all clinical and pre-clinical research for a novel responsive neurostimulator for the treatment of medically uncontrolled epilepsy. She has also been actively involved in investigational trials of new epilepsy therapies as an academic investigator. She is the principal investigator of an NIH funded UH3 grant to study responsive cortical and thalamic stimulation for treatment of Lennox-Gastaut Syndrome, a devastating epilepsy.

Yagna Pathak

Member

Yagna Pathak, PhD, is currently focused on improving the application of neuromodulation therapies in a patient-centric manner as a Medical Science Manager at Abbott Neuromodulation. She leads the efforts on novel digital solutions for expanding the application of Neuromodulation therapies and has contributed to several high-impact products, including the award-winning Neurosphere™ Virtual Clinic, a unique telemedicine platform. She is passionate about innovating with a purpose and holds several patents in the neuromodulation space aimed at improving healthcare inclusivity. Prior to joining Abbott Neuromodulation, Yagna received her bachelor's degree in biomedical engineering from Illinois Institute of Technology and her master's from Cornell University. To further pursue her research interests, she received her PhD in Biomedical Engineering under the guidance of Dr. Chris Butson (Marquette University) and completed a postdoctoral fellowship in Neurosurgery with Dr. Sameer Sheth (Columbia University), both focused on the application of neuromodulation therapies for neurological and psychiatric disorders.

Sarah Perides

Member

Sarah Perides, MSc, is a Pediatric Advanced Nurse Practitioner working with the Complex Motor Disorder Service at the Evelina London Children's Hospital, one of the largest pediatric deep brain stimulation (DBS) centers internationally. She has over 13 years' experience working with deep brain stimulation and other motor disorder management and treatment strategies including intrathecal baclofen and polypharmacy. Within pediatric movement disorders her specialty is dystonia covering genetic, acquired, idiopathic and neurodegenerative etiologies, she has experience in DBS programming, troubleshooting, assessment, and selection of all subgroups. Her current interests include transitioning young people with movement disorders to adult services and the positive impact that deep brain stimulation can have on painful dystonia. She believes wholly in multi-disciplinary care and the importance of lifelong support.

Rita Valentino

Member

Rita Valentino, PhD, is the Director of the Division of Neuroscience and Behavior at the National Institute on Drug Abuse. She received a B.S. in Pharmacy from the University of Rhode Island and a Ph.D. in Pharmacology from the University of Michigan. She went on to postdoctoral fellowships at the University of North Carolina and the Salk Institute. Dr. Valentino has held faculty positions in the Department of Pharmacology at George Washington University, the Department of Mental Health Sciences at Hahnemann University and Department of Anesthesiology at the University of Pennsylvania. She directed the Stress Neurobiology Division within the Department of Anesthesiology at The Children's Hospital of Philadelphia. Dr. Valentino is particularly recognized for her research on the effects of stress on brain function and behavior and the impact of sex, age and coping style in stress vulnerability. Her laboratory was the first to demonstrate sex differences in receptor signaling and intracellular trafficking. Her laboratory's research demonstrating sex differences in signaling and trafficking of corticotropin-releasing factor receptors provided a molecular basis for increased sensitivity of females to stressors. She is a Fellow and Secretary-Elect of the American College of Neuropsychopharmacology, a Fellow of the American Society for Pharmacology and Experimental Therapeutics and a member of the Scientific Advisory Board of the Brain Behavior Foundation. She is also the Editor-in-Chief of Neurobiology of Stress.

Alik Widge

Member

Alik Widge, MD, PhD, is a brain stimulation psychiatrist and biomedical engineer. He is an Associate Professor of Psychiatry at the University of Minnesota, where he directs the Translational NeuroEngineering Lab. Dr. Widge completed his MD at the University of Pittsburgh, his PhD in Robotics at Carnegie Mellon University, psychiatry residency at the University of Washington, and fellowships at Massachusetts General Hospital and the Massachusetts Institute of Technology. His research focuses on brain stimulation for severe and treatment-resistant mental illness, with particular emphasis on deep brain stimulation and related implantable technologies. Dr. Widge's recent work has demonstrated new algorithms for closed-loop brain stimulation, stimulation methods for modifying connectivity in the distributed circuits of mental illness, and hardware solutions for embodying those insights. His laboratory studies both rodent models for prototyping these new technologies and human participants to identify biomarkers and targets for future intervention. Dr. Widge serves as a consultant to Abbott on clinical trial design.