Mass General Brigham

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Implantable Brain-Computer Interface Collaborative Community (iBCI-CC) to Drive Innovation in Neurotechnology

BOSTON – (March 11, 2024) Mass General Brigham is establishing the Implantable Brain-Computer Interface Collaborative Community (iBCI-CC). This is the first Collaborative Community in the clinical neurosciences that has participation from the U.S. Food and Drug Administration (FDA).

BCIs are devices that interface with the nervous system and use software to interpret neural activity. Commonly, they are designed for improved access to communication or other technologies for people with physical disability. Implantable BCIs are investigational devices that hold the promise of unlocking new frontiers in restorative neurotechnology, offering potential breakthroughs in neurorehabilitation and in restoring function for people living with neurologic disease or injury.

The iBCI-CC (https://www.ibci-cc.org/) is a groundbreaking initiative aimed at fostering collaboration among diverse stakeholders to accelerate the development, safety and accessibility of iBCI technologies. The iBCI-CC brings together researchers, clinicians, medical device manufacturers, patient advocacy groups and individuals with lived experience of neurological conditions. This collaborative effort aims to propel the field of iBCIs forward by employing harmonized approaches that drive continuous innovation and ensure equitable access to these transformative technologies.

One of the first milestones for the iBCI-CC was to engage the participation of the FDA. “Brain-computer interfaces have the potential to restore lost function for patients suffering from a variety of neurological conditions. However, there are clinical, regulatory, coverage and payment questions that remain, which may impede patient access to this novel technology,” said David McMullen, M.D., Director of the Office of Neurological and Physical Medicine Devices in the FDA’s Center for Devices and Radiological Health (CDRH), and FDA member of the iBCI-CC. “The IBCI-CC will serve as an open venue to identify, discuss and develop approaches for overcoming these hurdles.”

The iBCI-CC will hold regular meetings open both to its members and the public to ensure inclusivity and transparency. Mass General Brigham will serve as the convener of the iBCI-CC, providing administrative support and ensuring alignment with the community’s objectives.

Over the past year, the iBCI-CC was organized by the interdisciplinary collaboration of leaders including Leigh Hochberg, MD, PhD, an internationally respected leader in BCI development and clinical testing and director of the Center for Neurotechnology and Neurorecovery at Massachusetts General Hospital;

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Jennifer French, MBA, executive director of the Neurotech Network and a Paralympic silver medalist; and Joe Lennerz, MD, PhD, a regulatory science expert and director of the Pathology Innovation Collaborative Community. These three organizers lead a distinguished group of Charter Signatories representing a diverse range of expertise and organizations.

“As a neurointensive care physician, I know how many patients with neurologic disorders could benefit from these devices,” said Dr. Hochberg. “Increasing discoveries in academia and the launch of multiple iBCI and related neurotech companies means that the time is right to identify common goals and metrics so that iBCIs are not only safe and effective, but also have thoroughly considered the design and function preferences of the people who hope to use them”.
Jennifer French, said, “Bringing diverse perspectives together, including those with lived experience, is a critical component to help address complex issues facing this field.” French has decades of experience working in the neurotech and patient advocacy fields. Living with a spinal cord injury, she also uses an implanted neurotech device for daily functions. “This ecosystem of neuroscience is on the cusp to collectively move the field forward by addressing access to the latest groundbreaking technology, in an equitable and ethical way. We can’t wait to engage and recruit the broader BCI community.”

Joe Lennerz, MD, PhD, emphasized, "Engaging in pre-competitive initiatives offers an often-overlooked avenue to drive meaningful progress. The collaboration of numerous thought leaders plays a pivotal role, with a crucial emphasis on regulatory engagement to unlock benefits for patients."

The iBCI-CC is supported by key stakeholders within the Mass General Brigham system. Merit Cudkowicz, MD, MSc, chair of the Neurology Department, director of the Sean M. Healey and AMG Center for ALS at Massachusetts General Hospital, and Julianne Dorn Professor of Neurology at Harvard Medical School, said, “There is tremendous excitement in the ALS [amyotrophic lateral sclerosis, or Lou Gehrig’s disease] community for new devices that could ease and improve the ability of people with advanced ALS to communicate with their family, friends, and care partners. This important collaborative community will help to speed the development of a new class of neurologic devices to help our patients.”

Bailey McGuire, program manager of strategy and operations at Mass General Brigham’s Data Science Office, said, “We are thrilled to convene the iBCI-CC at Mass General Brigham’s DSO. By providing an administrative infrastructure, we want to help the iBCI-CC advance regulatory science and accelerate the availability of iBCI solutions that incorporate novel hardware and software that can benefit individuals with neurological conditions. We’re excited to help in this incredible space.

For more information about the iBCI-CC, please visit https://www.ibci-cc.org/.

About Mass General Brigham
Mass General Brigham is an integrated academic health care system, uniting great minds to solve the hardest problems in medicine for our communities and the world. Mass General Brigham connects a full continuum of care across a system of academic medical centers, community and specialty hospitals, a health insurance plan, physician networks, community health centers, home care, and long-term care services. Mass General Brigham is a nonprofit organization committed to patient care, research, teaching, and service to the community. In addition, Mass General Brigham is one of the nation’s leading

biomedical research organizations with several Harvard Medical School teaching hospitals. For more information, please visit massgeneralbrigham.org.

About the iBCI-CC Organizers:
Leigh Hochberg, MD, PhD is a neurointensivist at Massachusetts General Hospital's Department of Neurology, where he directs the MGH Center for Neurotechnology and Neurorecovery. He is also the IDE Sponsor-Investigator and Director of the **BrainGate** clinical trials, conducted by a consortium of scientists and clinicians at Brown, Emory, MGH, VA Providence, Stanford, and UC-Davis; the *L. Herbert Ballou University Professor of Engineering and Professor of Brain Science* at Brown University; *Senior Lecturer on Neurology* at Harvard Medical School; and *Director,* VA RR&D Center for Neurorestoration and Neurotechnology in Providence.

Jennifer French, MBA, is the Executive Director of Neurotech Network, a nonprofit organization that focuses on education and advocacy of neurotechnologies. She serves on several Boards including the IEEE Neuroethics Initiative, Institute of Neuroethics, OpenMind platform, BRAIN Initiative Multi-Council and Neuroethics Working Groups, and the American Brain Coalition. She is the author of *On My Feet Again* (Neurotech Press, 2013) and is co-author of *Bionic Pioneers* (Neurotech Press, 2014). French lives with tetraplegia due to a spinal cord injury. She is an early user of an experimental implanted neural prosthesis for paralysis and is the Past-President and Founding member of the North American SCI Consortium.

Joe Lennerz, MD PhD, serves as the Chief Scientific Officer at BostonGene, an AI analytics and genomics startup based in Boston. Dr. Lennerz obtained a PhD in neurosciences, specializing in electrophysiology. He works on biomarker development and migraine research. Additionally, he is the co-founder and leader of the Pathology Innovation Collaborative Community, a regulatory science initiative focusing on diagnostics and software as a medical device (SaMD), convened by the Medical Device Innovation Consortium. He also serves as the co-chair of the federal Clinical Laboratory Fee Schedule (CLFS) advisory panel to the Centers for Medicare & Medicaid Services (CMS).