



NIH BRAIN INITIATIVE WORKSHOP: INDUSTRY PARTNERSHIPS TO FACILITATE EARLY ACCESS TO NEUROMODULATION AND RECORDING DEVICES FOR HUMAN CLINICAL STUDIES

June 3-4, 2015
Neuroscience Center
6001 Executive Boulevard, Rockville MD
Conference Rooms C/D

NIH intends to initiate a program of collaborative partnerships between clinical/academic researchers and corporate manufacturers of devices for human brain modulation and recording, to address the compelling need for a streamlined path for developing and integrating innovative new technologies for human brain research. The purpose of this workshop is to:

- Bring together stakeholders and interested parties to disseminate information on opportunities for research using latest-generation devices for CNS neuromodulation and interfacing with the brain in humans.
- Describe the proposed NIH framework for facilitating and lowering the cost of new studies using these devices.
- Discuss regulatory and intellectual property considerations.
- Solicit recommendations for data coordination and access.

Wednesday, June 3, 2015 (Day 1)

7:30 a.m. Registration and Check-In

8:00 a.m. Welcome

Edmund Talley, Ph.D., Kip Ludwig, Ph.D. (National Institutes of Health, National Institute of Neurological Disorders and Stroke)

8:10 a.m. Public-Private Partnerships through the BRAIN Initiative

Tom Kalil, Ph.D. (White House Office of Science and Technology Policy)

8:20 a.m. Overview of Workshop Goals

Tom Insel, M.D. (NIH, National Institute of Mental Health)

8:30 a.m. Navigating the FDA Approval Process

John Doucet, Ph.D. (FDA), Dawn Bardot, Ph.D. (Medical Device Innovation Consortium)

Dr. Doucet will present FDA requirements for research using invasive devices in the brain, and how existing safety data can be leveraged as part of this process. Dr. Bardot will describe the MDIC Clinical Trial Innovation and Reform effort, and in particular the development of best practice guidelines for early feasibility first-in-human studies.

9:15 a.m. Development and Commercialization of the Network Neuroprosthesis

Megan Moynahan, M.S. (Institute for Functional Restoration)

Ms. Moynahan will describe the Institute for Functional Restoration's novel non-profit business model to create sustainable manufacture of neuromodulation therapies for small market indications, in particular the Network Neuroprosthetic platform, which has recently received an Investigational Device Exemption through the FDA's new Early Feasibility Study Program.



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9:30 a.m. Latest Generation Devices for CNS Modulation and Recording – Capabilities and Potential for Partnerships Part 1

Florian Solzbacher, Ph.D. (Blackrock Microsystems), Steve Carcieri, Ph.D. (Boston Scientific), Satinderpall Pannu, Ph.D. (Lawrence Livermore National Laboratory)

Manufacturers will present information on implantable device capabilities with existing non-clinical and/or clinical safety and efficacy data that can be leveraged to enable new exploratory clinical research studies, without the need for significant additional pre-clinical data for necessary IRB and/or FDA approvals.

10:15 a.m. Break

10:30 a.m. Latest Generation Devices for CNS Modulation and Recording – Capabilities and Potential for Partnerships Part 2

Tim Denison, Ph.D. (Medtronic), Daryl Kipke, Ph.D. (NeuroNexus), Martha Morrell, M.D. (NeuroPace), Shane Guillory, Ph.D. (Ripple), Arup Roy, Ph.D. (Second Sight)

11:40 a.m. DARPA-Sponsored Research Programs

Emily Caporello, Ph.D. (DARPA), Justin Sanchez, Ph.D. (DARPA)

Dr. Caporello will discuss the DARPA HAPTIX Program for sensorimotor neural prosthetics development. Dr. Sanchez will discuss the RAM Program for overcoming memory deficits in traumatic brain injury, and the SUBNETS Program for modeling and treating neuropsychiatric illnesses. They will outline the goals of these DARPA Programs, and share 'lessons learned' for facilitating public-private partnerships.

12:20 p.m. Lunch

1:10 p.m. Opportunities and Challenges for Clinical Neuroscience Research using Invasive Devices

Speakers will describe the different types of clinical settings where one can conduct clinical neuroscience research utilizing latest generation invasive devices, and will discuss the unique opportunities and barriers for each setting.

Research in Acute/Sub-Chronic Surgical Settings

Kendall Lee, M.D., Ph.D. (Mayo Clinic), Gyorgy Buzsaki, M.D., Ph.D. (NYU), Warren Grill, Ph.D. (Duke), Nathan Crone, M.D. (Johns Hopkins)

Research using Chronic Implantation

Andrew Schwartz, Ph.D. (Pittsburgh), Helen Mayberg, M.D. (Emory), Susan Harkema, Ph.D. (Louisville)

3:30 p.m. Break



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3:45 p.m.

Panel Discussion

Nathan Crone, M.D. (Moderator), Kendall Lee, M.D., Ph.D., Gyorgy Buzsaki, M.D., Ph.D., Warren Grill, Ph.D., Andrew Schwartz, Ph.D., Helen Mayberg, M.D., Susan Harkema, Ph.D.

4:15 p.m.

Partnerships with Lawrence Livermore National Laboratory

Satinderpall Pannu, Ph.D. (Lawrence Livermore National Laboratory)

Dr. Pannu will describe a novel partnership structure and processes for collaborations with the Center for Bioengineering at Lawrence Livermore National Laboratory (LLNL). As a national laboratory, LLNL provides unique capabilities for investigators to enable new exploratory clinical research studies using a novel implantable neural device with hundreds of electrodes under development for human use.

4:30 p.m.

Break and Poster Setup

5:00 p.m.

Poster Session (Bethesda North Marriott Hotel)

We will have unstructured time to view poster presentations and foster collaborations. Refreshments will be available for purchase.

Thursday, June 4, 2015 (Day 2)

8:00 a.m.

Expectations for Intellectual Property and Data Access

Dan Tagle, Ph.D. (NIH, National Center for Advancing Translational Science), Kip Ludwig, Ph.D.

Dr. Tagle will describe previous NIH experience developing partnerships with companies from the pharmaceutical industry through the NCATS Drug Repurposing Initiative, which has served as a model for developing the BRAIN Public-Private Partnerships Program. Dr. Ludwig will describe the envisioned process and expectations for the BRAIN Public-Private Partnerships.

8:45 a.m.

NIH Partnership Program: Feedback on Process, Ideas for Improvements

Panel Discussion

Kip Ludwig, Ph.D. (Moderator), Sarah Lisanby, M.D. (Duke), Shane Guillory, Ph.D., Martha Morrell, M.D., Joseph Fins, M.D. (Cornell), Kimberly Hanke, B.S. (Mayo Clinic)

9:45 a.m.

Break

10:00 a.m.

Ethical Considerations for Exploratory Clinical Research

Joseph Fins, M.D.

Dr. Fins will describe some of the fundamental motivations and end-goals that can serve as guiding principles for the proposed partnerships, and will discuss ethical considerations for conducting exploratory studies in human patients.



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10:20 a.m.

Panel Discussion

Walter Koroshetz, M.D. (NINDS, Moderator), Joseph Fins, M.D., Christine Grady, Ph.D. (NIH), Scott Kim, M.D., Ph.D. (NIH), Paul Ford, Ph.D. (Cleveland Clinic), Helen Mayberg, M.D.

10:45 a.m.

Data Coordination and Access

The goal of this session is to leverage the combined expertise of workshop participants to identify opportunities, barriers, and key existing resources for obtaining, annotating, storing, and hosting electrophysiological and associated data, and providing access to the wider research community for mining.

Considerations for Annotating, Storing, and Hosting

Brian Litt, M.D. (University of Pennsylvania), Greg Farber, Ph.D. (NIMH)

Drs. Litt and Farber will discuss, from the perspective of two different data resources, considerations for annotating, storing, and hosting electrophysiological and associated data from human clinical research.

Mining and Analyzing Human Research Data

Cameron McIntyre, Ph.D. (Case Western)

Dr. McIntyre will discuss the kinds of information that can be mined from electrophysiology and associated data (e.g., fMRI/DTI) obtained in clinical research settings, and the potential impact of reducing barriers to accessing/analyzing such data.

Existing Research Data and Supplemental Research Opportunities

Tim Denison, Ph.D., Florian Solzbacher, Ph.D.

Drs. Denison and Solzbacher will describe opportunities and barriers to data aggregation and access from their global Industry perspectives.

12:05 p.m.

Panel Discussion

Greg Farber, Ph.D. (Moderator), Brian Litt, M.D., Cameron McIntyre, Ph.D., Tim Denison, Ph.D., Florian Solzbacher, Ph.D., Patrick Bellgowan, Ph.D. (NINDS)

12:35 p.m.

Working Lunch: Brainstorming Potential Future Industry Partnership Efforts

1:20 p.m.

Closing Remarks – Wrap Up

Kip Ludwig, Ph.D.