Harnessing Mobile Technology to Predict, Diagnose, Monitor, and Develop Treatments for Nervous System Disorders—A Workshop

June 5-6, 2018
Keck Center of the National Academies
500 Fifth Street, NW | Washington, DC

Background:

Despite the prevalence of central nervous system (CNS) disorders worldwide, there is limited understanding of natural disease course, patients' own experiences of the illness, the manifestation of its symptoms, and responses to treatment. Assessment of function for many disorders—including Parkinson's disease, Alzheimer's disease, mood disorders, and schizophrenia—typically is based on subjective or self-report tests during clinical visits. These provide only snapshots in time, and patients may use extra effort in a doctor's office, which obscures usual function. The miniaturization and proliferation of devices and mobile technology has led to an explosion of interest in developing tools that provide reliable, high quality, continuous data collection from large patient populations in their natural settings and activities.

The use of devices to advance research and treatment for CNS disorders holds tremendous promise, including enabling major advances in identifying prodromal and subclinical states, but also raises important technological, methodological, ethical, privacy, security, and regulatory issues. For example, there are challenging questions regarding validation of data obtained using device and mobile health technologies. Other important methodological considerations arise with novel approaches for data collection and treatment delivery, such as open source platforms for obtaining and distributing digital biomarker data, behavioral and digital phenotyping, data-driven learning engines, and the use of real-world evidence. There are also questions about who bears responsibility for supporting the cost and infrastructure for data storage and analysis, and how to integrate these data with clinical records. Additionally, while the use of mobile technology for treatment may increase access to care, it also raises ethical issues related to the "digital divide," informing people about prodromal and sub-clinical states, as well as data-ownership and release.

To help advance the appropriate use of devices and mobile technology to predict, diagnose, monitor, assess adherence, and develop treatments for CNS disorders, the National Academies of Sciences, Engineering, and Medicine's Forum on Neuroscience and Nervous System Disorders will host a public workshop.

Workshop Objectives:

The workshop will bring together experts and key stakeholders from academia, government research and regulatory agencies, the technology and pharmaceutical sectors, and non-profit organizations to explore current opportunities afforded by developments in device and mobile health technology to advance research and treatment of CNS disorders. Invited presentations and discussions will:

- Explore innovative approaches to using device and mobile health technology to predict, diagnose, monitor, assess adherence, and develop treatments for CNS disorders, including discussion of methodology, analytical techniques, and the evidence needed to validate the data for use in research and the clinic.
- Share approaches and lessons across efforts to apply device and mobile health technology in different CNS disorders, and identify opportunities for collaboration.
- Discuss regulatory, privacy, ethical, security, and practical issues that specifically arise when using devices for CNS disorders, such as collection, analysis, storage, and use of behavioral information and assuring parity in access to these technologies.

DAY ONE: June 5, 2018

1:30pm   **Welcome**
> HUSSEINI MANJI, Janssen Research and Development, *Co-Chair*
> JP ONNELA, Harvard School of Public Health, *Co-Chair*

Session 1: Current Measurement Gaps and Opportunities Afforded by Mobile Technology

Session Objectives:
- Provide an overview of current measurement challenges and gaps in predicting, diagnosing, monitoring, and assessing treatment effects for central nervous system disorders.
- Discuss how mobile technology could address these gaps, illustrated with use cases from different domains, such as neurodegenerative, neuropsychiatric, and substance use disorders.
- Highlight which technologies are viable now and outline a vision for future digital technologies that could be useful in this domain.

1:40pm   **Introductory Remarks**
> STEVEN HYMAN, Stanley Center for Psychiatric Research, Broad Institute of Harvard and MIT, *Moderator*

1:50pm   **Speakers**
> WILLIAM MARKS, Verily
> HUSSEINI MANJI, Janssen Research and Development
> JP ONNELA, Harvard School of Public Health

2:25pm   Discussion

2:50pm   Break

Session 2: Making Sense of Mobile Technology Data, Data Standards, Validation, and Reproducibility

Session Objectives:
- Explore challenges in making sense of raw smartphone sensor and log data for the purposes of predicting, diagnosing, monitoring, and developing treatments for nervous system disorders.
- Examine how data standards and validation requirements differ according to intended purpose—such as basic research, use in therapeutic development, clinical decision making, and patient self-management—with a focus on challenges specific to CNS disorders.
- Discuss data analytic approaches that could help address these challenges and enhance interoperability, validity, and reproducibility.

3:20pm	**Session Overview**
	JP ONNELA, Harvard School of Public Health, *Moderator*

3:30pm	**Speakers**
	DANIELA BRUNNER, Early Signal Foundation
	TANZEEM CHOUDHURY, Cornell University
	MUNMUN DE CHOUDHURY, Georgia Institute of Technology
	CHRISTIAN GOSSENS, Roche

4:30pm	**Discussion**

5:30pm	Adjourn session

DAY TWO: June 6, 2018

8:30am	**Overview of the Second Day**
	HUSSEINI MANJI, Janssen Research and Development, *Co-Chair*
	JP ONNELA, Harvard School of Public Health, *Co-Chair*

Session 3: Regulatory Considerations and Pathways

Session Objectives:
- Provide an overview of current regulatory pathways that involve digital technologies, including any specific policies or considerations for nervous system disorders.
- Explore challenges, such as the need to balance data required for regulatory purposes with the speed at which this field is moving.
- Discuss standards and metrics of quality and strength of evidence, beyond safety considerations, and how these standards and metrics can be developed.
- Examine how to "future proof" research through the evolving Common Rule, and consider key HIPAA compliance issues in research and development of wearables.

8:40am	**Session Overview**
	VAIBHAV NARAYAN, Janssen Research and Development, *Moderator*

8:50am	**Speakers**
	CARLOS PEÑA, Center for Devices and Radiological Health, FDA
	JACQUELINE CORRIGAN-CURAY, Center for Drug Evaluation and Research, FDA
	STEPHEN ARNERIĆ, Critical Path Institute
	KRISTEN ROSATI, Coppersmith Brockelman; past president, American Health Lawyers Association

9:50am	**Discussion**

10:45am	Break

Session 4: Designing with the Users
Part 1: Integrating Mobile Technology into Clinical Practice

Session Objectives:
- Discuss potential benefits of integrating mobile technology into clinical practice, e.g., for use as decision-making tools and for forecasting.
- Explore how to better engage physicians as a key stakeholder and user of mobile technologies to predict, diagnose, and monitor nervous system disorders.
- Consider incidental findings related to brain disorders, especially with regard to predicting and diagnosing prodromal and subclinical states, and discuss how approaches in other fields (e.g., radiology) could inform policies in this domain.

11:00am   **Session Overview**
                   LINDA BRADY, National Institutes of Mental Health, *Moderator*

11:10am   **Speakers**
                   DROR BEN-ZEEV, University of Washington
                   LARA MANGRAVITE, Sage Bionetworks

11:40am   **Discussion**

12:00pm   Lunch

Session 4: Designing with the Users
Part 2: Patient Attitudes and Preferences

Session Objectives:
- Describe user/consumer attitudes and ideas related to mobile technologies—both universal themes across different populations of people with health conditions, as well as preferences and considerations are specific to patients with CNS disorders.
- Explore potential benefits to patients; innovative digital technologies that enable implementation of patient preferences on data ownership, access, and privacy; and use of digital technologies in patient self-management.

1:00pm   **Session Overview**
                   MAGALI HAAS, Cohen Veterans Bioscience, *Moderator*

1:10pm   **Speakers**
                   SARA LOUD, COO, Accelerated Cures Project for Multiple Sclerosis
                   JEFFREY KAYE, Oregon Health & Science University

1:40pm   **Discussion**

2:15pm   Break

Session 5: Moving Forward through Building Partnerships

Session Objectives:
- Synthesize key highlights from the workshop presentations and discussions, including identifying next steps and promising areas for future action and research.
- Explore the "ecosystem of partnerships" needed to drive the field forward, and discuss mutually beneficial models that could help overcome differences in business models and incentives used by the various stakeholders in this space, including tech companies, app developers, therapeutics developers, foundations, and electronic health records companies.

2:30pm   **Session Overview**
         HUSSEINI MANJI, Janssen Research and Development, *Co-Chair*
         JP ONNELA, Harvard School of Public Health, *Co-Chair*

2:45pm   **Panel Discussion**
         KATIE KOPIL, Michael J. Fox Foundation for Parkinson's Research
         IAIN SIMPSON, IXICO
         PAUL DAGUM, Mindstrong
         PETER PEUMANS, IMEC
         ARDY ARIANPOUR, Seqster
         JOHN TOROUS, Beth Israel Deaconess Medical Center

3:45pm   **General Discussion**

4:50pm   **Closing Remarks from the Co-Chairs**

5:00 p.m.   Adjourn Workshop

Workshop Planning Committee

Husseini Manji, Janssen Research and Development, *co-chair*
JP Onnela, Harvard School of Public Health, *co-chair*
Linda Brady, National Institute of Mental Health
Ray Dorsey, University of Rochester
Deborah Estrin, Cornell University
Magali Haas, Cohen Veterans Bioscience
Daniel Karlin, Pfizer
Story Landis, Vice Chair, Forum on Neuroscience and Nervous System Disorders
Robert McBurney, Accelerated Cures Project for Multiple Sclerosis
Vaibhav Narayan, Janssen Research and Development
Louis Pasquale, Harvard Medical School
Nora Volkow, National Institute on Drug Abuse