

Advancing CDISC Standards for Biosensors Assessments in Clinical Drug Trials: 2017 Biometric Monitoring Device Workshop

May 9-10, 2017

**Bethesda North Marriott Hotel and Conference Center
Bethesda, MD**

Meeting Overview/Objectives:

- Review contemporary use cases for mobile biosensor assessments of three domains of function that are impacted by Neurological Disorders (mobility/sleep/cognitive performance).
- Review & address key regulatory considerations for various Contexts-of-Use.
- Convene CDISC Standard experts to advance a plan that enables data aggregation across technology platforms to define disease progression in terms of these 3 key domains, and to potentially understand the impact of treatment intervention during clinical drug trials.

[Notes and action items from this meeting](#)

Meeting Agenda

May 9

7:30 – 8:00 am	Continental Breakfast
8:00 – 8:30 am	<u>Welcoming Remarks & Overarching Objectives for Concepts-of-Interest</u> <i>Stephen Arneri? (Critical Path Institute)</i>
8:30 – 9:25 am	<u>The Potential of BMDs in Assessing Real-World Function</u> <i>Jeffrey Kaye (Oregon Health Sciences University)</i>
9:25 – 9:45 am	<u>Voice of the Patient-Advocate</u> <i>David Levine</i>
9:45 – 10:00 am	Questions

10:00 – 10:30 am	Break
SESSION I: Mobility/Frailty	
10:30 – 10:50 am	<u>Luxembourg Centre For Systems Biomedicine (LCSB)</u> <i>Venkata Satagopam</i>
10:50 – 11:10 am	<u>Michael J. Fox Foundation</u> <i>Lauren Bataille</i>
11:10 – 11:30 am	<u>Evidation Health</u> <i>Luca Foschini</i>
11:30 – 11:50 am	<u>APDM Wearable Technologies</u> <i>Matthew Johnson</i>
12:00 – 1:00 pm	Lunch
SESSION II: Sleep	
1:00 – 1:30 pm	<u>Device Comparisons to Polysomnography</u> <i>Rebecca Spence (University of Massachusetts)</i>
1:30 – 2:00 pm	<u>IXICO</u> <i>Derek Hill</i>
2:00 – 2:20 pm	Break
SESSION III: Cognition	
2:20 – 2:40 pm	<u>Cerebral Assessment Systems, Inc., Cognivue®</u> <i>Charles J. Duffy</i>
2:40 – 3:00 pm	<u>ImPACT® Applications, Inc.</u> <i>James Gyurke</i>
3:00 – 3:20 pm	<u>Cambridge Cognition</u> <i>Krystyna Zaluski</i>
3:20 – 3:40 pm	<u>Akili</u> <i>Ashley Mateus</i>
3:40 – 4:00 pm	Break
4:00 – 5:15 pm	<u>Panel Discussion:</u> <i>Michael Davis (FDA, CDER), Jay Gupta (FDA, CDRH), Sean Khozin (FDA, CDER), I</i>
5:15 – 5:25 pm	<u>Summary and Closing Remarks</u> <i>Stephen Arneri? (Critical Path Institute)</i>

May 10

7:30 – 8:00 am	Continental Breakfast
----------------	------------------------------

8:00 – 8:10 am	Welcoming Remarks <i>Stephen Arneri?</i> (Critical Path Institute)
8:10 – 10:00 am	Discussion of Key Themes and Messages from May 9 <i>All</i>
10:00 – 10:30 am	Break
Key Metadata and Concept Maps	
10:30 – noon	Where do we need to focus? Next Steps... <i>All</i>
12:00 – 1:00 pm	Lunch
1:00 pm	Adjourn