

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

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| 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?</i> (Critical Path Institute) |
| 8:30 – 9:25 am | <u>The Potential of BMDs in Assessing Real-World Function</u> <i>Jeffrey Kaye</i> (Oregon Health Sciences University) |
| 9:25 – 9:45 am | <u>Voice of the Patient-Advocate</u> <i>David Levine</i> |
| 9:45 – 10:00 am | Questions |

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| 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

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