
Mobile Devices in Clinical Trials for Neurological Diseases: CDISC Standards Development

March 10, 2017

Pointe Hilton Tapatio Cliffs Resort | Phoenix, AZ

Overview and Objectives

The Coalition Against Major Diseases (CAMD), a consortium within the Critical Path Institute, is focused on accelerating the regulatory sciences required to advance innovative treatments for Alzheimer Disease and related neurodegenerative diseases with impaired cognition and function.

In collaboration with The Clinical Data Interchange Standards Consortium (CDISC), CAMD will sponsor a workshop to advance the understanding of the data standards required to integrate data across clinical drug trials using mobile device technologies.

The objectives of the meeting are:

- Review the existing standards that apply to mobile devices that could be implemented in clinical drug trials and longitudinal disease progression studies;
- Identify/prioritize existing gaps;
- Develop a plan to accelerate the creation/implementation of CDISC standards required for future registration studies that assess mobility, sleep and cognitive performance;

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

Meeting Agenda

Continental Breakfast	
8:00 – 8:15 am	Advancing CDISC Standards for BMD Use in Clinical Development of Neurological Diseases <i>Stephen P. Arneri?</i> (Critical Path Institute)
8:15 – 8:30 am	CDISC Standards & Digital Health <i>Michael Ibara</i> (CDISC)

8:30 – 9:00 am	<u>Data Flow: From COIs to Data Archiving</u> <i>Barrie Nelson (CDISC)</i>
9:00 – 9:15 am	<u>Representing Device Data Using CDISC Standards</u> <i>Jon Neville (Critical Path Institute)</i>
9:15 – 9:35 am	Break
SESSION I: Sleep	
9:35 – 10:05 am	BMDs for Sleep <u>Rebecca Spencer (University of Massachusetts)</u> – 20 min. <u>Derek Hill (IXICO)</u> – 10 min.
10:05 – 11:15 am	Capturing Key COIs & Data Flow <i>Barrie Nelson & Rebecca Spencer</i>
11:15 – Noon	Lunch
SESSION II: Mobility	
Noon – 12:30 pm	BMDs for Mobility/Frailty <i>Ray Dorsey (University of Rochester)</i> – 20 min. <u>Jane Mohler (University of Arizona)</u> – 10 min.
12:30 – 1:30 pm	Capturing Key COIs & Data Flow <i>Barrie Nelson & Lynn Hudson</i>
SESSION III: Cognition	
1:30 – 2:10 pm	BMDs for Cognition <i>Lee Ryan (University of Arizona)</i> – 30 min. <u>Jenny Barnett (Cambridge Cognition)</u> – 10 min.
2:10 – 3:30 pm	Key COIs & Data Flow <i>Barrie Nelson & Lee Ryan</i>

3:30 – 3:50 pm	Break
3:50 – 4:50 pm	Summary and Next Steps <i>Barrie Nelson, Jon Neville, Stephen Arneri?</i>