Coalition Against Major Diseases 2016 Annual Regulatory Science Workshop

October 12, 2016

College Park Marriott Hotel and Conference Center, Hyattsville, Maryland

SPONSORED BY: Critical Path Institute

MEETING MINUTES [PDF]
(Presentations are linked in the agenda, below.)

Overview and Objectives

The Coalition Against Major Diseases (CAMD) is a public-private partnership aimed at developing creating Drug Development Tools that can be applied to increase the efficiency of the development process of new treatments for Alzheimer's disease (AD) and related dementias. The annual meeting, which is open to the public, brings together members from the pharmaceutical industry, academic key opinion leaders, NIA, FDA, EMA and advocacy groups. The objectives of the meeting are:

- To understand accomplishments of CAMD's scientific project teams;
- To discuss how these tools are currently, or will be applied in drug development;
- To obtain commitment for sharing information/data to begin quantifying benefits of these tools;
- To facilitate robust and open discussion among all parties of drug development for the treatment of dementias.

Experts in the fields of Alzheimer's disease and other neurodegenerative diseases and leaders of the patient stakeholder community will deliver keynote presentations and regulatory science will be prominently featured throughout the meeting.

Annual Meeting Agenda

	Continental Breakfast

8:15 – 8:30 am	**Welcoming Remarks** *Martha Brumfield* (Critical Path Institute) *Stephen P. Arneri?* (Critical Path Institute)
8:30 – 9:00 am	**The Voice of the Alzheimer's Disease Patient** *Brian Van Buren* (National Early-Stage Advisor)
9:00 – 9:30 am	**Informed Consent – Making Patient Data Count!** *Penny Dacks* (Alzheimer's Drug Discovery Foundation) *Monica Moreno* (Alzheimer's Association) *James Hendrix* (Alzheimer's Association)
9:30 – 10:00 am	**FDA Priorities and Initiatives** *ShaAvhrée Buckman-Garner* (FDA) – 30 minutes
10:00 – 10:15 am	**Break**
	SESSION I: Johan Luthman (Eisai, Chair) ***Smart Standardized Data: Objective Measures of Patient 'Signs'***
10:15 – 10:35 am	**Integration of Models in Biomarker Qualifications** *Klaus Romero* (Critical Path Institute) *Brian Corrigan* (Pfizer)
10:35 – 10:55 am	**Digital Drug Development Tools Team – Building a Regulatory Roadmap** *Dan Karlin* (Pfizer)
10:55 – 11:10 am	**Data Standards for Mobile Devices** *Sam Hume* (Clinical Data Interchange Standards Consortium)
11:10 – 12:00 am	**Gaps & Opportunities for Mobile Devices in Clinical Trials** FDA Participants: *Eric Bastings, Billy Dunn, Sean Khozin* EMA Participant: *Maria Isaac* PMDA Participant: *Yoshiko Komuro*
12:00-1:00 pm	**Lunch**
	SESSION II: Richard Meibach (Novartis, Chair) ***Progress in the Qualification of Biomarkers***

1:00 – 1:20 pm	**AD Hippocampal Volume Team – Steps Enabling a Qualification Package** *Derek Hill* (IXICO)
1:20 – 1:40 pm	**The IDEAS Study – PET Imaging Update** *James Hendrix* (Alzheimer's Association)
1:40 – 2:00 pm	**CSF Biomarker Team – Refocusing on Low Hanging Fruit** *Mary Savage* (Merck)
2:00 – 2:30 pm	**Panel Discussion: Biomarker Qualifications – Where should AD focus?** *Shashi Amur* (FDA) *James Hendrix* (Alzheimer's Association) *Mary Savage* (Merck) *Derek Hill* (IXICO)
2:30 – 3:00 pm	**Break**
	SESSION III: Dan Karlin (Pfizer, Chair) ***Working Across Eco-Systems: Lessons Learned***
3:00 – 3:20 pm	**Wearable Devices in Parkinson's Disease Research** *Lauren Bataille* (Michael J. Fox Foundation)
3:20 – 3:40 pm	**Challenges to GCP Compliant Deployment of Biosensors in Cognitively Impaired** *Derek Hill* (IXICO)
3:40 – 4:00 pm	**Deep Phenotyping of AD patients – Modeling Real World Evidence** *John Gallacher* (Oxford-ROADMAP)
4:00 – 4:20 pm	**CTTI's Mobile in Clinical Trials Program: Opportunities for Transforming the C through the Appropriate Use of Mobile Technology** *Jennifer Goldsack* (CTTI)

4:20 – 4:45 pm	**Panel Discussion on Global Synergies** *Lauren Bataille* (Michael J. Fox Foundation) *Derek Hill* (IXICO) *John Gallacher* (Oxford-ROADMAP) *Jennifer Goldsack* (CTTI)
4:45 – 5:00 pm	**Wrap Up, Looking Ahead & Adjournment** *Stephen P. Arneri?* (Critical Path Institute)