Coalition Against Major Diseases and FDA 2014 Annual Scientific Workshop

October 20, 2014

FDA White Oak Campus

CO-SPONSORED BY:
Critical Path Institute
U.S. Food and Drug Administration

Overview and Objectives

The Coalition Against Major Diseases (CAMD) is a public-private-partnership aimed at creating new tools and methods that can be applied to increase the efficiency of the development process of new treatments for Alzheimer's disease (AD) and Parkinson's disease (PD). The annual meeting brings together members from the pharmaceutical industry, academic key opinion leaders, NIA, FDA, EMA and advocacy groups. The objectives of the meeting are: understand accomplishments of CAMD scientific projects, discuss how these tools are currently or will be applied in drug development, obtain commitment for sharing information/data to begin quantifying benefits of these tools, and facilitate robust and open discussion among all parties of drug development in Alzheimer's and Parkinson's diseases. Experts in the fields of Alzheimer's disease and Parkinson's disease, and leaders of the patient stakeholder community will deliver keynote presentations and regulatory science will be prominently featured throughout the meeting.

Agenda

7:30-8:30 am	**Continental Breakfast**
8:30-8:50 am	**Welcome Remarks** *Diane Stephenson,* Executive Director, CAMD *Martha Brumfield,* CEO, Critical Path Institute *Janet Woodcock,* Director, FDA,
8:50-9:40 am	**Keynote Address Speakers** *Eric Reiman:* Enabling the Path to Prevention of Alzheimer's disease *Caroline Tanner:* Unmet needs for Parkinson's disease therapeutics *Richard Mohs:* Beyond ADAS-Cog: Lessons Learned and Looking Ahead

9:40-10:00 am	*Carl Ames:* Vision and Views from a Patient's Perspective *Walter Koroshetz, NINDS:* NINDS PD Recommendations: Filling Gaps for PD Drug D
SESSION I: Mark Gordon (Chair) Exciting Developments in CAMD Working Grou	
10:00-10:15 am	*Klaus Romero and Tim Nicholas*: Modeling and Simulation for Parkinson's Disease
10:15-10:30 am	*Les Shaw*: AD CSF Biomarkers Team
10:30-10:45 am	*Derek Hill*: AD HV MRI Biomarkers Team
10:45-11:00 am	*Johan Luthman/Michael Ropacki*: Predementia Clinical Outcome Assessment Team
11:00-11:15 am	**BREAK**
SESSION II: Richard Meibach (Chair) Strategies for Successful Implementation of Biomarkers in Clinical Trials What is on the Horizon for Biomarkers in CAMD?	
11:15-11:30 am	*Peter Loupos (Sanofi)*: Why Data Standards?
11:30-11:50 am	*Issam Zineh (FDA)*: A Regulatory Perspective on Strategies for Implementation of Bio
11:50-12:10 pm	*Ken Marek (Institute of Neurodegenerative Diseases)*: Learnings from Parkinson's dise Biomarkers In successful drug development
12:10-12:20 pm	*Jim Hendrix (Alzheimer's Association)*: Progress and Needs in Biomarker Standardizat AD
12:20-12:40 pm	*Billy Dunn (FDA) and Dave G. Podskalny (FDA):* Panel Discussion on Prospective Di Qualification of Biomarkers by CAMD
12:40-1:10 pm	**LUNCH & AWARDS**
SESSION III: Eric Reiman (Chair); Eric Karran (Co-chair) Successful Data Sharing in the Current Landscape and in the future	
1:10-1:30 pm	*Eric Karran (Alzheimer's Research UK)*: Clinical Data Sharing Today: Where Are We Be? Learnings from amyloid trials to date
1:30-1:45 pm	*George Vradenburg (USAgainstAlzheimer's)*: Overcoming Challenges

1:45-2:50 pm	PANEL Discussion: Current Therapeutic Trials in Pre-dementia AD: Focus on Biomar **SESSION SPEAKERS** *Johan Luthman (Eisai), Mike Egan (Merck), Bob Dean (Lilly), Robert Alexander (AZ),* *Steve Brannan (Takeda), J. Michael Ryan (Novartis), Vlad Coric (BMS), Mark Gordon* *Jesse Cedarbaum (Biogen Idec)*
2:50-3:05 pm	**BREAK**
	SESSION IV: Jesse Cedarbaum (Chair) **Improved Clinical Outcome Measures**
3:05-3:20 pm	*Billy Dunn (FDA)*: Delivering on the FDA's Draft Guidance: Drug Development for Ea
3:20-3:40 pm	*Keiju Motohashi (Expert advisor, PMDA office of new drugs)*: PMDA Considerations f
3:40-4:00 pm	PANEL Discussion on COA Qualification **SESSION SPEAKERS** *Ashley Slagle (FDA), Johan Luthman (Eisai), Michael Ropacki (Janssen R&D), Nick K*
4:15-4:30 pm	*Diane Stephenson and Mark Gordon*: Wrap Up and Looking Ahead