# Coalition Against Major Diseases and FDA 2015 Annual Scientific Workshop

## October 15, 2015

## 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.

Click here for the 2015 Annual Meeting Minutes.

# Agenda

| | |
|---|---|
| 7:30-8:30 am | **Continental Breakfast** |
| 8:30-9:00 am | **Welcoming Remarks**<br><br>*Martha Brumfield*, CEO (Critical Path Institute)<br>*Janet Woodcock*, Director (Center for Drug Evaluation and Research, FDA)<br>*Diane Stephenson & Stephen Arneric*, Executive Co-Directors (CAMD) |
| 9:00-9:20 am | **Keynote Address**<br><br>*Manuel Haas* (EMA)<br>Coalition Against Major Diseases and FDA 2015 Annual Scientific Workshop |

| | |
|---|---|
| 9:20-9:40 am | **Regulatory Perspectives**<br><br>*ShaAvrée Buckman-Garner* (FDA)<br>FDA Biomarker Learnings and the Future |
| 9:40-9:55 am | **BREAK** |
| **SESSION I: Exciting Developments in CAMD Working Groups**<br>*Mark Gordon*, Chair | |
| 9:55-10:10 am | **Meeting the Needs of the Parkinson's Community**<br>*Steve Ford* (Parkinson's UK) |
| 10:10-10:25 am | **Computational Modeling for AD**<br>*Julie Stone* (Merck) & *Klaus Romero* (C-Path)<br>Where has CAMD come and where do we need to go?<br>How can we achieve better understanding of disease progression and efficient clinical t<br>populations? |
| 10:25-10:40 am | **AD Hippocampal Volume Team**<br>*Derek Hill* (Ixico) |
| 10:40-10:55 am | **AD CSF Biomarkers Team**<br>*Robert Dean* (Lilly) |
| 10:55-11:40 am | **Regulatory Panel Discussion: Regulatory Innovation Now and in the Future**<br>Moderator: *Richard MeibachJim Kaiser (FDA), Eric Bastings (FDA), Keiju Motohashi*<br>*(FDA), Sandra Kweder (FDA), Maria Isaac (EMA), Vikrma Sinha (FDA), Chris Lepta* |
| 11:40-12:25 pm | **LUNCH & AWARDS** |
| **SESSION II:**<br>**Strategies for Successful Implementation of Biomarkers in Clinical Trials**<br>**CAMD Data Sharing and Integration…Looking to the Future**<br>*Peter Loupos*, Chair (Sanofi) | |
| 12:25-12:40 pm | **Data Sharing…What Can Be Learned from ALS?**<br>*Melanie Leitner* (Biogen) |
| 12:40-12:55 pm | **PPMI Paving the Way for Defining Prodromal PD**<br>*Ken Marek* (MNI) |
| 12:55-1:10 pm | **Data sharing…Success Story from Multiple Sclerosis (MSOAC)**<br>*Jesse Cedarbaum* (Biogen) |
| 1:10-1:25 pm | **Panel Discussion on Prospective Directions for CAMD…Focus on Data**<br>*Melanie Leitner, Jesse Cedarbaum, Ken Marek, Paul Maruff* (Cogstate, AIBL) |
| 1:25-1:35 pm | **BREAK** |
| 1:35-1:50 pm | **Transforming Alzheimer's Disease Therapies Through Collaboration**<br>*James Hendrix* (Alzheimer's Association) |

| **Integrated Focus Sessions** | |
|---|---|
| 1:50-2:30 pm | **Session III: Modeling**<br><br>How can we achieve better understanding of disease progression and efficient clinical t populations?<br><br>*Vikram Sinha* (FDA Co-chair) *& Klaus Romero* (CAMD Co-chair) |
| 2:30-3:10 pm | **Session IV: Biomarkers**<br><br>*Chris Leptak* (FDA Co-chair) *& Richard Meibach* (CAMD Co-chair) |
| 3:10-3:50 pm | **Session V: Digital Biomarker Technologies**<br><br>Medical Device Regulatory Decision Points<br><br>Defining Context of Use and Challenges to Deploying Wearables and Digitial Technol<br>*Peter Como* (FDA Co-chair) & *Jesse Cedarbaum* (CAMD Co-chair) |
| 3:50-4:05 pm | **BREAK** |
| 4:05-4:35 pm | **KEY RECOMMENDATIONS: SESSIONS III-V** |
| 4:35-4:45 pm | **Wrap-up and Looking Ahead**<br>Diane Stephenson & Stephen Arneric |