Critical Path for Alzheimer's Disease 2018 Annual Meeting and Regulatory Science Workshop

November 13, 2018

Overview and Objectives:

The Critical Path for Alzheimer's Disease (CPAD) is a public-private partnership aimed at creating new tools and methods that can be applied to increase the efficiency of the development process leading to treatments for neurodegenerative diseases that progress to dementia with the shared characteristics of Alzheimer disease (AD), the most common and devastating form of dementia globally. In August 2018, CPAD (rebranded in January 2018) celebrated the 10th Anniversary of the original formation of the Coalition Against Major Diseases (CAMD), the name of the founding consortium.

CPAD has the following areas of pre-competitive focus: (1) regulatory qualification of biomarkers [fluid, imaging, and digital/biosensor observational- and performance-based], (2) creation of integrated databases for observational and clinical trial data, (3) development of CDISC data standards for AD endpoint assessments, and (4) development of quantitative model-based tools for drug development.

Over the last year there have been a number of key developments in the field of AD and dementias highlighting the heterogenous nature of dementias that we believe warrant realigning our focus.

The objectives of the meeting are to:

- Review this year's accomplishments, current working group status, and latest developments in this space
- Obtain community commitment for precompetitive structured sharing across the AD scientific community of rigorously-collected standardized data as a crucial component of this research to understand the AD continuum. Targeted studies will:
    1. Inform an understanding of disease progression in pre-dementia stages of AD and be useful for designing primary prevention studies;
    2. Contain primary and secondary endpoints, imaging and fluid biomarkers, genetic information, and detailed patient selection criteria; and
    3. Have the potential for supporting regulatory-accepted Drug Development Tools developed by CPAD for use in future clinical studies that would accelerate the delivery of innovative AD treatments.
- Celebrate CPAD's 10th Anniversary by sharing prior accomplishments of the consortium.

Meeting Notes

Annual Meeting Agenda

8:15 – 9:00 am	**Continental Breakfast**

9:00 – 9:20 am	**Welcoming Remarks & CPAD Impact** *Stephen Arneri? (C-Path, CPAD Executive Director)*
SESSION I: Building Alignment & Vision for the Future ***Moderator: Martha Brumfield (C-Path, President & Chief Executive Officer)***	
9:20 – 11:35 am	**Vision for the Future: Strengthening Communication Across the AD Drug Development Community** *Samantha Budd-Haeberlein (Biogen, Vice-President and Head of Alzheimer's Disease), and Billy Dunn (FDA, Director, Division of Neurology Products)*
	CPAD – Realizing the Potential *Speakers and Moderator* • **Examples of C-Path Consortia Achievements** *Martha Brumfield (C-Path, President & Chief Executive Officer)* • **Meeting the Challenges** *Klaus Romero (C-Path, Director, Clinical Pharmacology & Quantitative Medicine)* • **Highlights of C-Path Data Sharing Metrics** *Richard Liwski (C-Path, Chief Technology Officer)* • **Outline of C-Path's Capabilities** *Klaus Romero (C-Path, Director, Clinical Pharmacology & Quantitative Medicine)*
11:35 – 11:50 am	**Evolving and Sustaining our EMA Support/Engagement/Collaboration** *Maria Tome – **remote** (EMA, Pharmaceutical Medicine Physician, Senior Scientific Officer)*
11:50 – 12:05 pm	**Break**
SESSION II: **10 Years of Consortium Successes & a View Towards the Future** ***Moderator: Diane Stephenson (C-Path, CPP Executive Director; former CAMD Executive Director)***	

12:10 – 12:17 pm	**Building the Foundational Vision** *Raymond Woosley (Founder of C-Path)*
12:17 – 12:31 pm	**Evolving and Sustaining our FDA Support/Engagement/Collaboration** *Janet Woodcock (FDA, Director, Center for Drug Evaluation and Research)*
12:31 – 12:38 pm	**Critical Path Institute** *Martha Brumfield (C-Path, President & Chief Executive Officer)*
12:38 – 13:35 pm	**Lunch**
SESSION III: **CPAD's Regulatory Science Milestones** ***Moderator: Vikram Sinha (Merck, Vice President & Head, Quantitative Pharmacology & Pharmacometrics)***	
1:35 – 1:55 pm	**Updates to the mild-to-moderate AD Clinical Trial Simulator** *Klaus Romero (C-Path, Director, Clinical Pharmacology & Quantitative Medicine)*
1:55 – 2:25 pm	**Clinical Trial Simulator for Pre-Dementia and the Role of Hippocampal Volume Neuroimaging** *Daniela Conrado (C-Path, Associate Director, Quantitative Medicine)*
2:25 – 2:50 pm	**How the FNIH has Achieved Impact: Multiple Paths to Success** *Joseph Menetski (FNIH, Associate Vice President Research Partnerships)*
2:50 – 3:10 pm	**Break**
SESSION IV: **Solving Industry Needs Through Data Sharing: From Prevention to Treatment of Dementia** ***Moderators: Stephen P. Arneri? (C-Path, CPAD Executive Director), Martha Brumfield (C-Path, President & Chief Executive Officer), Klaus Romero (C-Path, Director, Clinical Pharmacology & Quantitative Medicine), Samantha Budd-Haeberlein (Biogen, Vice-President and Head of Alzheimer's Disease), and Billy Dunn (FDA, Director, Division of Neurology Products)***	

3:20 – 4:15 pm	**Working Roundtable Discussion** *All*