CRITICAL PATH INSTITUTE

Critical Path for Alzheimer's Disease 2020 Annual Meeting and Regulatory Science Workshop – Virtual

October 27, 2020
9:30 a.m. – 1:00 p.m. (US Eastern Time)

The Critical Path for Alzheimer's Disease (CPAD) is a Critical Path Institute public-private partnership aimed at generating actionable solutions and knowledge towards advancing drug development across the AD continuum.

The key objectives of the meeting are:

- Scientific dialogue to guide the strategic development of comprehensive disease progression models spanning the AD continuum by utilizing advanced quantitative modeling methodology, such as nonlinear mixed effects approaches, artificial intelligence, and machine learning.
- Achieve consensus on gaining actionable information from fluid and imaging biomarker data for use in quantitative analysis and disease progression modeling, for the purpose of developing regulatory-endorsed modelinformed quantitative Drug Development Tools in Alzheimer's Disease.

Agenda

	Welcome
9:30 – 9:40 am	**Welcome Remarks** ***Klaus Romero*** *(Chief Science Officer, C-Path)*
9:40 – 9:50 am	**Welcome and Consortium Overview** ***Sudhir Sivakumaran*** *(Executive Director, CPAD, C-Path)*
9:50 – 10:10 am	**CPAD Industry Co-Director Remarks** ***Nusrat Rabbee*** *(NBG Head of Statistical Methodologies & Data Science, Eisai Co., Ltd.)*
10:10 – 10:15 am	**Data Sharing Pioneer Award**

10:15 – 10:35 am	**Keynote 1: Model-Informed Drug Development (MIDD) in Alzheimer's disease: From Data Sharing to Actionable Solutions** ***Jackson Burton*** *(Executive Director, Quantitative Medicine, C-Path)*
10:35 – 10:50 am	**Keynote 2: Integration of Biomarkers and Quantitative Modeling – CSF** ***Kaj Blennow*** *(Professor, University of Gothenburg)*
10:50 – 11:05 am	**Keynote 3: Integration of Biomarkers and Quantitative Modeling – Plasma** ***Henrik Zetterberg*** *(Professor, University of Gothenburg & University College London)*
11:05 – 11:20 am	**Keynote 4: Integration of Biomarkers and Quantitative Modeling – Imaging** ***Brian Gordon*** *(Asst. Professor, Washington University School of Medicine in St. Louis)*
11:20 – 11:35 am	**Keynote 5: Integration of Biomarkers and Quantitative Modeling – Analytical Validation and Standardization of Fluid Biomarkers** ***Charlotte Teunissen*** *(Professor, VU University Medical Center)*
11:35 – 11:45 am	**BREAK**
11:45 am – 12:55 pm	**Expert Panel: Challenges and Opportunities for the Integration of Biomarkers and Models *(Moderators – Jackson Burton and Sudhir Sivakumaran)*** • ***Billy Dunn*** *(Director, Office of Neuroscience (ON), CDER, FDA)* • ***Eric Bastings*** *(Deputy Director (ON) and Director (Acting) (DNI), CDER, FDA)* • ***Kevin Krudys*** *(Senior Clinical Analyst for Quantitative Analysis and Modeling, ON, CDER, FDA)* • ***Nusrat Rabbee*** *(NBG Head of Statistical Methodologies, Eisai Co., Ltd.)* • ***Adam Schwarz*** *(Senior Director, Takeda Pharmaceutical Company Ltd)* • ***Duygu-Tosun Turgut*** *(Assoc. Professor, University of California, San Francisco)* • ***Oskar Hansson*** *(PI, BioFINDER; Professor, Lund University; Consultant Neurologist, Skåne University Hospital)* • ***Keynote Speakers***
12:55 – 1:00 pm	**Closing Remarks** ***Sudhir Sivakumaran*** *(Executive Director, CPAD, C-Path)*