2019 Annual Meeting and Regulatory Science Workshop

October 29, 2019 Crystal Gateway Marriott | Arlington, VA

The key objectives of the meeting are:

- To discuss the proposed strategy for CPAD of developing comprehensive solutions for AD drug development, based on a quantitative understanding of disease progression across the entire AD continuum
- To review and define a path to advance the progress of acquiring datasets which will inform the expansion of the CPAD patient-level database, intended to support the generation of the proposed quantitative models of disease progression across the AD continuum

Agenda

7:15 – 8:00 am	**Continental Breakfast**
8:00 – 8:10 am	**Welcome and CPAD Impact in 2019** *Joseph Scheeren (C-Path, President & Chief Executive Officer)*
8:10 – 8:20 am	**Welcome Remarks** • *Sudhir Sivakumaran (C-Path, Associate Director, CPAD)* • *Michael Gold (AbbVie, Vice President, Neuroscience Development)*
SESSION I: Building Alignment & Vision for the Future – C-Path Data Sharing Initiative ***Moderator: Martha Brumfield (C-Path, Special Advisor and Past President & CEO)***	
8:20 – 9:05 am	**Industry Data Sharing Initiative – Strategy and Early Successes** • *Samantha Budd Haeberlein (Biogen, Vice-President, Late Stage Clinical Development Unit Head)* • *Billy Dunn (FDA, Director, Division of Neurology Products)*

9:05 – 10:05 am	**Early Successes – Clinical Studies and Data Sharing Experiences** • **DIAN:** *Eric McDade (Washington University School of Medicine, Associate Professor)* • **TOMMORROW Trial:** *Robert C. Alexander (Takeda, Vice-President & Head, Global Clinical Science Neuroscience TAU)* • **Idalopirdine Trials:** *Mads Dalsgaard (H. Lundbeck A/S, Senior Vice President, Head of Experimental Medicine and Clinical Development)* • **STEADFAST Trials:** *Aaron Burstein (vTv Therapeutics, Senior Vice President, Clinical Development)*
10:05 – 10:10 am	**"Data Sharing Pioneer" Awards**
10:10 – 10:30 am	**Panel Discussion -– Lessons Learned in Data Sharing** *All Speakers*
10:30 – 10:45 am	**Break**
SESSION II: CPAD's Quantitative Modeling Strategy ***Moderator: Klaus Romero (C-Path, Executive Director, Clinical Pharmacology & Quantitative Medicine)***	
10:45 – 11:05 am	**The Future is Now: CPAD's Modeling Strategy** *Klaus Romero (C-Path, Executive Director, Clinical Pharmacology & Quantitative Medicine)*
11:05 – 11:45 am	**Learnings Across Quantitative Approaches at C-Path** • **Modeling multiple clinically relevant measures across a disease continuum: Learnings from the Duchenne Muscular Dystrophy – Regulatory Science Consortium (D-RSC):** *Jane Larkindale (C-Path, Executive Director RDCA-DAP and D-RSC)* • **Critical Path for Parkinson's Disease (CPP) Consortium:** *Diane Stephenson (C-Path, Executive Director CPP)*

11:45 – 12:45 pm	**Panel Discussion** *All Speakers* • *Malidi Ahamadi (Merck, Principal Scientist, Modeling & Simulation)* • *Ping He (Biogen, Medical Director)* • *Kevin Krudys (FDA, Senior Clinical Analyst for Quantitative Analysis and Modeling, Division of Neurology Products)* • *Nitin Mehrotra (Merck, Senior Principal Scientist & Therapeutic Area Lead for Neuroscience, Quantitative Pharmacology and Pharmaco-metrics)* • *Ivan Nestorov (Biogen, Senior Director, Head of Pharmacometrics)* • *Vikram Sinha (Merck, Vice President & Head, Quantitative Pharmacology & Pharmacometrics) – Remote Participation*
12:45 – 1:45 pm	**Lunch**
Session III: Current Tools and New Initiatives **Moderator: *Sudhir Sivakumaran (C-Path, Associate Director, CPAD)***	
1:45 – 2:00 pm	**Updates to Existing Tools and the Clinical Trial Simulator for Pre-Dementia** *Klaus Romero (C-Path, Executive Director, Clinical Pharmacology & Quantitative Medicine)*
2:00 – 2:15 pm	**Cutting-edge Approaches to Model Multiple Measures through a Machine Learning Framework** *Jagdeep Podichetty (C-Path, Scientific Director, Quantitative Medicine)*
2:15 – 2:45 pm	**Measurement Gaps: Essential Next Steps to Identify Potential Solutions (Triangulation Approach)** • **Integration of Existing Information Regarding Clinically Meaningful Aspects of Disease at Specific Stages in the Continuum** • **Inventory of Existing Measures** • **Determination of Measurement Gaps** *Klaus Romero (C-Path, Executive Director, Clinical Pharmacology & Quantitative Medicine)*
2:45 – 3:00 pm	**Unlearn.AI – Overview** *Charles Fisher (Unlearn.AI Inc., Founder & CEO)*

3:00 – 3:45 pm	**Panel Discussion** *All Speakers* • *Robert C. Alexander (Takeda, Vice-President & Head, Global Clinical Science Neuroscience TAU)* • *Eric Bastings (FDA, Acting Director, Division of Neurology Products)* • *Michael Gold (AbbVie, Vice President, Neuroscience Development)* • *Kevin Krudys (FDA, Senior Clinical Analyst for Quantitative Analysis and Modeling, Division of Neurology Products)* • *Diane Stephenson (C-Path, Executive Director CPP)*
3:45 – 4:00 pm	**Break**

SESSION IV:

Solving Industry Needs Through Data Sharing: From Prevention to Treatment of Dementia

Moderators:

- *Martha Brumfield (C-Path, Special Advisor and Past President & CEO),*
- *Samantha Budd Haeberlein (Biogen, Vice-President, Late Stage Clinical Development Unit Head)*
- *Billy Dunn (FDA, Director, Division of Neurology Products)*
- *Klaus Romero (C-Path, Executive Director, Clinical Pharmacology & Quantitative Medicine)*
- *Sudhir Sivakumaran (C-Path, Associate Director, CPAD)*

4:00 – 4:50 pm	**Working Roundtable Discussion** *All Workshop Attendants*
4:50 – 5:00 pm	**Closing Remarks** *Sudhir Sivakumaran (C-Path, Associate Director, CPAD)*