Critical Path Institute Rebrands One of Its First Consortia to Highlight Focus on Alzheimer's Disease

Critical Path for Alzheimer's Disease (CPAD) consortium's refined, refocused mission centers on accelerating therapy development for AD and related forms of dementia

TUCSON, Ariz., November 5, 2018 — The Critical Path Institute (C-Path) is pleased to announce that its Critical Path for Alzheimer's Disease (CPAD) consortium has refined and refocused its mission in celebration of the consortium's 10-year anniversary. One of C-Path's first consortia, previously known as the Coalition Against Major Diseases (CAMD), earlier this year was rebranded to CPAD, a name that better reflects the consortium's more focused approach to its work, which centers on speeding the drug development process for Alzheimer's disease (AD) and mechanistically-related dementias.

"The original CAMD consortium, launched in 2008, marked a ground-breaking development for C-Path," said C-Path President and CEO Martha A. Brumfield, Ph.D. "In the years since, CPAD has been doing exemplary work in a number of areas including data sharing, disease modeling, and biomarker development, and this year's name refresh was a natural fit given the primary focus on Alzheimer's disease."

CPAD is a public-private partnership established to create new tools and methods that can be applied to increase the efficiency of the development processes leading to treatments for Alzheimer's, the most common and devastating form of dementia globally, as well as other neurodegenerative diseases that share similar characteristics with AD and progress to dementia. To further grow and strengthen the initiative, CPAD forged a partnership in 2016 with the Global Alzheimer's Association Interactive Network (GAAIN), an open-access data resource portal that provides scientists with rapid access to AD research data.

"Data sharing is the cornerstone for enabling advances in regulatory sciences that provide a gateway to new innovative treatments for patients with dementias related to AD," said Stephen Arneri?, Ph.D., Executive Director of CPAD. "We are incredibly proud of all the great work the CPAD consortium has accomplished. We are also excited to continue our work in Alzheimer's disease, in collaboration with our members and regulators, to pave the way for early diagnosis, treatments, and better quality of life for individuals affected by AD."

Since inception, major milestones for CPAD include:

- A qualification opinion granted by the European Medicines Agency (EMA) for the use of low-baseline hippocampal volume (HV) for patient enrichment in pre-dementia trials (2011)

- Development and publication of the first Clinical Data Interchange Standards Consortium (CDISC) therapeutic area user guide for AD (v1.0 in 2011; v2.0 update in 2013) in partnership with CDISC.
- The first drug-disease trial model and clinical trial simulation tool endorsed by the U.S. Food and Drug Administration (FDA) and qualified by the EMA for mild and moderate AD (2013)
- Recognition of the consortium, in FDA Letters of Support encouraging the further study and use of cerebrospinal fluid (CSF) analytes A?$_{1-42}$, Total-Tau, Phospho-Tau, and low-baseline HV, measured by magnetic resonance imaging (MRI), as exploratory prognostic biomarkers for enrichment in AD trials (2015)
- Received an EMA Letter of Support encouraging industry sponsors to share the patient-level data from completed phase II and III clinical trials, including active and control arms, with CPAD, allowing CPAD to complete development and validation of a proposed quantitative novel methodology in drug development and encouraging dissemination and access to the current version of the CPAD model for implementation by sponsors actively designing clinical trials in amnestic Mild Cognitive Impairment

In addition, CPAD recently added four datasets, generously provided by international pharmaceutical company Servier, to the Critical Path Institute Online Data Repository (CODR): Critical Path for Alzheimer's Disease (CPAD) Consortium Database.

Launched in 2013, the CPAD database is the first and largest open database of CDISC-standardized clinical trial data for AD. It stores patient-level, control-arm data collected from clinical trials conducted by consortium member companies. These trials include the testing of treatments already available on the market, as well as experimental drugs at different stages in the drug development pipeline, up to and including termination. The database contains trial participant information including demographics, (*APOE*)-?4 genotype, concomitant medications, cognitive function test scores and more. All data are curated, fully de-identified, HIPAA compliant, and remapped to a common data standard that allows for analysis across all studies.

In total, the CPAD repository now houses 28 publicly-available datasets, containing 6,955 individual patient records – all openly available to CPAD members and qualified researchers around the world who request access to use CODR data to accelerate improvements in AD drug development research (https://codr.c-path.org/main/acceptTerms.html).

"The recent award of a new funding grant will support the expansion of the CODR database with the addition of data from more AD clinical trials and leaves CPAD poised to capitalize on its early successes," Brumfield said. "The CPAD consortium has facilitated a broad spectrum of foundational research that, in combination with ongoing analysis of CODR data, will support current and future efforts to design efficient clinical trials to test experimental treatments and more rapidly identify potential therapies able to prevent AD or halt its progression."

Learn more about the work done by CPAD, the leadership team, collaborators and more at c-path.org.

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About Critical Path Institute

C-Path (Critical Path Institute) is an independent, nonprofit organization established in 2005 as a public and private partnership. C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader

in forming collaborations, C-Path has established numerous global consortia that currently include over 1,500 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path is headquartered in Tucson, Ariz., with additional staff in multiple remote locations. For more information, visit www.c-path.org.

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