# CRITICAL PATH INSTITUTE

# COALITION AGAINST MAJOR DISEASES

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*collaborate · innovate · accelerate*

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**PUBLIC RELEASE OF ALZHEIMER'S CLINICAL TRIAL DATA BY PHARMACEUTICAL RESEARCHERS**
**First Combined Pharmaceutical Trial Data on Neuro-degenerative Diseases;**
**Shared Resource from Unique Public-Private Partnership Will Help Accelerate Alzheimer's, Parkinson's, and Other Brain Disease Research**

**Washington, DC –** A new database of more than 4,000 Alzheimer's disease patients who have participated in 11 industry-sponsored clinical trials will be released today by the **Coalition Against Major Diseases (CAMD)**. This is the first database of combined clinical trials to be openly shared by pharmaceutical companies and made available to qualified researchers around the world.

It is also the first effort of its kind to create a voluntary industry data standard that will help accelerate new treatment research on brain disease, as patients with other related brain diseases are expected to be added. The level of detail and scope of this database will enable researchers to more accurately predict the true course of Alzheimer's, Parkinson's, Huntington's, and other neuro-degenerative diseases, thereby enabling the design of more efficient clinical trials. Patient identifiers will not be included in the database, thereby ensuring patient privacy.

CAMD is a formal consortium of pharmaceutical companies, research foundations and patient advocacy/voluntary health associations, with advisors from government research and regulatory agencies including the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the National Institute of Neurological Disorders and Stroke (NINDS), and the National Institute on Aging (NIA). CAMD is led and managed by the non-profit Critical Path Institute (C-Path), which is funded by a cooperative agreement with the FDA and a matching grant from Science Foundation Arizona.

"The U.S. Food and Drug Administration has supported and actively participated in this innovative and unprecedented public-private partnership from its inception," said Joshua Sharfstein, MD, Principal Deputy Commissioner, FDA. "The agency is strongly committed to CAMD and other regulatory science collaborations that can speed safe and effective treatments to the public."

In addition to sharing data, the pharmaceutical members of CAMD have agreed to use the new common data standard established for Alzheimer's disease by the standard-setting organization, CDISC, in their future submissions for drug approvals. The Clinical Data Interchange Standards Consortium (CDISC) is a global, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission, and archive of clinical research data and metadata. CDISC standards are vendor-neutral, platform-independent, and freely available via the CDISC website. This will add greater efficiencies to the FDA's review process and make it possible for new products to reach the market more quickly and with greater assurances of safety and effectiveness.

"This unprecedented data sharing is game-changing for companies that are developing new therapies for neuro-degenerative diseases," said Raymond Woosley, MD, PhD, President and CEO of Critical Path Institute (C-Path). "Scientists around the world will be able to analyze this new combined data from pharmaceutical companies, add their own data, and consequently better understand the course of these diseases."

Mark McClellan, MD, PhD, who launched FDA's Critical Path Initiative during his tenure as FDA Commissioner, also noted the need for better evidence. "Too many treatments fail in the last stages of research, wasting millions of dollars and years of research time. To get to faster, more efficient development of safe and effective treatments, we must have a better understanding of diseases at the molecular level. The CAMD database is a promising step in this process for neurodegenerative diseases," said Dr. McClellan, who is now the director of the Engelberg Center for Health Care Reform and Leonard D. Schaeffer Chair in Health Policy Studies at the Brookings Institution.

Roughly 6.5 million people in the U.S. are afflicted with Alzheimer's and Parkinson's diseases, with costs reaching as much as $175 billion annually. Worldwide there are already an estimated 30 million people with dementia alone. By 2050, the number will rise to over 100 million. Halting or slowing the progression of these diseases will prevent untold suffering and save tens of billions of dollars every year.

"Data sharing is the backbone of several CAMD projects designed to identify patients who might develop brain diseases, i.e., *before symptoms are apparent*," said Marc Cantillon, MD, Director of C-Path's Coalition Against Major Diseases. "Our goal is to develop tools to prevent or slow these diseases so patients can maintain independence and quality of life."

The CAMD database will allow researchers to design more efficient clinical trials that have the maximum chance of demonstrating if a new treatment is truly safe and effective. In addition, the coalition is identifying biomarkers that identify patients in the very early stages of Alzheimer's disease and Parkinson's disease.

According to Maria Isaac, MASc, MD, PhD, Scientific Administrator, Scientific Advice, Human Medicines Special Areas Sector of the European Medicines Agency (EMA), "Within the context of the Innovative Medicines Initiative (IMI) in Europe, the EMA is committed to similar goals as C-Path's consortia, i.e., to help biopharmaceutical drug development, for the benefits of patients. The Agency is especially interested in reviewing CAMD's Alzheimer's biomarkers and disease progression models."

"We are proud to be a member of this coalition," said Frank Casty, MD, VP Technical Evaluations, AstraZeneca Pharmaceuticals LP, and Co-Director of CAMD. "A healthier world must come from collaboration, in making better, deeper connections with all our stakeholders, and sharing skills and ideas to meet a common goal – improved health."

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**CAMD Members:** Abbott, Alliance for Aging Research, Alzheimer's Association, Alzheimer's Foundation of America, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, CHDI Foundation Inc, Eli Lilly and Company, F. Hoffmann-La Roche Ltd, Forest Research Institute, Genentech Inc., GlaxoSmithKline, Johnson & Johnson, National Health Council, Novartis Pharmaceuticals Corporation, Parkinson's Action Network, Parkinson's Disease Foundation, Pfizer, Inc., and sanofi-aventis US Inc.

**About CAMD:** CAMD members fully share pre-competitive data and knowledge that will more efficiently and safely speed development of new therapies and preventions for Alzheimer's, Parkinson's, Huntington's, and other debilitating neuro-degenerative diseases. CAMD's overall objective is to help scientists identify clinical and laboratory characteristics of patients who are pre-symptomatic and most likely to benefit from new therapies. For more information on CAMD and the database, visit http://www.c-path.org/CAMD.cfm.

**About Critical Path Institute (C-Path):** An independent, non-profit organization, C-Path's mission is to serve as the impartial facilitator of collaborative efforts among scientists from government, academia, patient advocacy organizations, and the private sector to support the U.S. Food and Drug Administration's regulatory science initiatives.

This involves creating faster, safer, and smarter pathways for innovative new drugs, diagnostics, and devices that will significantly improve public health.  Established in 2005, C-Path is headquartered in Tucson, Arizona, with offices in Phoenix, Arizona, and Rockville, Maryland.  Visit www.c-path.org for more information.

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