

# Coalition Against Major Diseases (CAMD)

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## Research Areas



### Tool Development

Regulatory



### Biomarker Research

## At a Glance

- Status: **Active Consortium**
- Year Launched: **2009**
- Initiating Organization: **Critical Path Institute**
- Initiator Type: **Nonprofit foundation**
- Location: **International**

## Abstract

The [Coalition Against Major Diseases](#) (CAMD) is a consortium aimed at creating new tools and methods that can be applied during the development process of new treatments for cognitive decline and dementia. While the primary focus is Alzheimer's Disease, the disease with greatest unmet medical need, the consortium is also engaged in understanding both the common elements of dementia across other neurodegenerative diseases/conditions (e.g., Parkinson's Disease, Multiple Sclerosis, Traumatic Brain Injury), as well as identifying which domains of cognitive performance specifically are affected. CAMD is one of eleven consortia of the Critical Path Institute (C-Path), a nonprofit organization that is dedicated to accelerating drug development by delivering on the mission outlined by the U.S. Food and Drug Administration's (FDA's) critical path initiative.

## Mission

CAMD has a mission to develop new technologies and methods to accelerate the development and review of medical products for neurodegenerative diseases. CAMD works to identify patients with neurodegenerative diseases at very early stages and to advance the creation of Drug Development tools to be used in clinical trials aimed to prevent or slow these diseases so that patients can maintain

independence and quality of life.

CAMD is active in three major areas: data sharing, quantitative disease modeling, and biomarkers. More recently the consortium has engaged in the development of a data repository that will make use of Digital Biomarkers [data acquired from devices that measure biological information]. The consortium focuses on sharing precompetitive patient-level data from the control arms of legacy clinical trials, the prospective acquisition of data from pre-competitive, 'pay-to-know' projects, developing new tools to be submitted to the regulatory agencies, and developing consensus data standards.

Specific goals include the following:

- Establish a database of pooled control arm data from industry clinical trials
- Develop quantitative disease progression models for dementia (e.g Alzheimer's disease) and make them available for scientists
- Define data standards (Clinical Data Interchange Standards Consortium, CDISC) for neurodegenerative diseases
- Increase educational awareness for major pharmaceutical companies to utilize CDISC standards for all medical products for neurodegenerative diseases
- Identify imaging, biochemical, molecular biomarkers, and objective clinical outcome measures using Digital Biomarker technology platforms that have the greatest potential to identify early onset dementia patient populations
- Submit the evidence necessary for FDA and the European Medicines Agency (EMA) to officially designate CAMD's tools as "qualified for use" in drug development
- Align with other precompetitive consortia focused on brain diseases to avoid duplication of effort and to synergize to enhance collaborations

## Consortium History

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In 2008, C-Path, in collaboration with the Engelberg Center for Health Care Reform at the Brookings Institution, formed CAMD, which includes members from FDA, EMA, National Institutes of Health (NIH; National Institute on Aging and National Institute of Neurological Disorders and Stroke), academia, patient groups, and industry. CAMD's focus is AD and PD, which share common challenges for development of effective treatments.

CAMD actively contributes to harmonization and integration across the public and private sectors. Active collaborations and frequent communications exist between CAMD and the Foundation for the NIH (FNIH), Alzheimer's Association, and other Alzheimer's disease advocacy organizations, Alzheimer's Disease Neuroimaging Initiative (ADNI), Alzheimer's Disease Cooperative Study, NYAS, Alzheimer's Prevention Initiative, Innovative Medicines Initiative, Pharmaceutical Research and Manufacturers of America, Global CEOi, and the International Society for CNS Clinical Trials and Methodology.

## Structure & Governance

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CAMD is governed by C-Path's Executive Committee. The executive director of CAMD is a staff member of C-Path and has subject-matter expertise. In addition to the executive director, C-Path also employs a project manager, project coordinators, and in kind resources are provided by the sponsoring organizations.

A Coordinating Committee develops CAMD's global mission, values, and objectives and provides oversight and high-level guidance for all activities. Its membership is composed of representatives of each member organization, currently 18 industry member companies, 4 patient advocacy groups, representatives of FDA, EMA, and government scientific and health agencies, the CAMD executive director, and member co-director. This committee is responsible for overseeing the priorities and resources of the consortium and sets short- and long- term objectives to be carried out across the disease state initiatives.

For disease-specific guidance, CAMD partners with many academic leaders who provide key scientific expertise through mutually beneficial collaborations.

CAMD coordinates its research activities through several working groups that provide advice, support, and review across multiple activities and project teams.

## Financing

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As the umbrella organization of CAMD, C-Path's revenue is generated mostly from membership dues and grants. C-Path also receives financial support through a contract with FDA. The membership fees

are subsidizes to share costs and covers the costs of some but not all of the projects, so CAMD has implemented a pay-per-project strategy for new projects. Members who vote to support new projects share the costs.

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## Intellectual Property

Each CAMD member signs a common legal agreement prior to participation in the consortium. Typically, CAMD output is within the precompetitive space. According to the membership agreement, the content and information from the consortium is deemed confidential to members, and all external disclosures are approved by members.

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## Patent Engagement

External nonprofit patient groups interact with each of CAMD's working groups to help set priorities for gathering and interpreting data, provide information to aid patient care and clinical trial enrollment, and play a prominent role in external communications. These patient organizations include the Alzheimer's Drug Discovery Foundation, Alzheimer's Association, Alzheimer's Foundation of America, US Against Alzheimer's Network, and Parkinson's UK.

In addition to active patient group participation, CAMD's clinical trials database currently includes data from 6,500 individual patients.

CAMD acts as a trusted and neutral third party that is able to convene consortia of industry, academia, patient stakeholders, regulators, and government in precompetitive collaborations. The iterative involvement of FDA and EMA for guidance and official recognition through formal qualification of drug development tools is a hallmark of C-Path/CAMD.

The CAMD website lists the following accomplishments:

- First imaging biomarker for AD trial enrichment qualified by EMA
- First and largest open database of CDISC-aggregated clinical trial data for AD (6,500 individual patients over 22 clinical trials)
- First drug-disease trial model and clinical trial simulation tool to receive a positive decision by

regulatory authorities

- Quantitative disease model of the natural progression of AD has been developed using data from ADNI, published literature, and CAMD placebo clinical trial database
- In 2010, CAMD released a new database of more than 3,500 AD patients who participated in 11 industry-sponsored clinical trials. This was the first database of combined clinical trials for AD to be openly shared by pharmaceutical companies and made available to qualified researchers. At present the CAMD database consists of clinical data from 6,500 subjects derived from the placebo arm of 24 clinical trials.
- In 2010, CAMD developed consensus data standards for AD in collaboration with CDISC. CDISC is a nonprofit standards 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. The AD CDISC standard represented the first therapeutic area standard and set the stage for FDA's request of CDISC standards for more than 50 diseases.
- In 2013, CAMD helped to develop a PD Therapeutic Standard. This effort focused on creating standards for the collection, storage, and submission of clinical trial data for PD and was an effort between the Coalition for Accelerating Standards and Therapies (CFAST), CDISC, and C-Path, in collaboration with NINDS.
- Regulatory milestones for CAMD include a qualification opinion with EMA for the use of low baseline hippocampal volume for patient enrichment in predementia trials (2011) and in 2013 positive regulatory decisions from FDA and EMA for the use of a clinical trial simulation tool to aid in trials for mild to moderate stages of AD.

## Data Sharing

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CAMD works with member companies to share precompetitive information including control arm patient-level data from clinical trials and active-treatment patient-level data from failed trials. Data are housed in the C-Path Online Data Repository (CODR, <http://www.c-path.org/CAMDcodr.cfm>). CAMD members dedicate in-kind resources to remap all the placebo data to the AD CDISC standard. All CAMD members and regulators have access to the unified clinical trial database, and members agreed to make the data available to qualified researchers in order to foster new discoveries. Requestors for the data must be qualified investigators who agree that the data will only be used for scientific investigation or the planning of clinical research studies, and must fill out a simple request form for review.

In 2013, C-Path announced the availability of the “Parkinson’s disease CDISC Therapeutic Area Data Standard,” which defines standards for the collection, storage, and submission of clinical trial data for PD. This new resource will help researchers combine and evaluate data from multiple studies, streamline the efficiencies of new clinical trials, and aid the evaluation of new drugs and treatments for PD. In 2015, there has been endorsement to establish a fully dedicated consortium entitled “Critical Path for Parkinson’s” which will represent a spin off of CAMD with similar infrastructure and governance.

## Links/Social Media Feed

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## Sponsors & Partners

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