

COALITION AGAINST MAJOR DISEASES

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collaborate · innovate · accelerate

FACT SHEET: Coalition Against Major Diseases

One of the greatest challenges facing biomedical science in the 21st century is the development of fundamentally better treatments for neurodegenerative diseases. The Coalition Against Major Diseases (CAMD) at [Critical Path Institute](#) (C-Path) is a unique public-private partnership of pharmaceutical companies, patient advocacy/voluntary health associations, and government research and regulatory agencies formed to tackle brain disease, including two of today's most devastating illnesses, Alzheimer's and Parkinson's diseases.

CAMD's focus is to create new tools and methods that can be applied *during the development process* of new treatments for these diseases, which up to this point, have remained beyond the reach of drug discovery and continue to result in added costs for treatment, chronic suffering, and lost lives.

By facilitating collaboration among scientists from the biopharmaceutical industry, academic institutions, government agencies, patient advocacy/voluntary health associations, and other key stakeholders, CAMD fosters innovative testing methods that lead to increased efficiency, safety, and speed in developing new therapies.

CAMD *shares knowledge and develops consensus* on new tools that will be submitted to the regulatory agencies and qualified as regulatory science to accelerate the drug development process for neurodegenerative diseases. The companies and patient advocacy groups have signed a common legal agreement to share precompetitive data.

Since February 2008, when CAMD launched initial technical activity in three major areas – data sharing, disease modeling, and biomarkers – it has already reached significant milestones in these areas. (See Accomplishments and Activities section for detailed information.)

Objectives

To create the ability to identify patients with neurodegenerative diseases before symptoms are apparent, and develop tools to prevent or slow these diseases so patients can maintain independence and quality of life.

- Create common data sharing standards to facilitate faster review by the U.S. Food and Drug Administration (FDA);
- Establish database of pharmaceutical clinical trial data as the first of multiple tools;
- Develop disease progression models to aid in the design of clinical trials; and
- Identify biomarkers for use in selecting patients who are still early in the disease progression for clinical trials.

Members

CAMD members include 12 pharmaceutical companies and seven patient advocacy/voluntary health associations, with advisors representing the FDA, European Medicines Agency (EMA), National Institute of Neurological Disorders and Stroke (NINDS), and National Institute on Aging. The Coalition was convened and launched in cooperation with the Engelberg Center for Health Care Reform at Brookings. (See Appendix A for detailed information on 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.

sanofi-aventis

Other Participants

CAMD also collaborates with several other organizations, including the Metrum Institute, Epihian, and the Clinical Data Interchange Standards Consortium (CDISC). (See Appendix B for detailed information on CAMD non-member participants.)

Accomplishments and Activities

- New data standards have been established with CDISC for Alzheimer's clinical trials. These are used by CAMD, but are also now published for use across industry and academia to allow for future data sharing and accelerated research and drug development.
- CAMD is working closely with NINDS to develop CDISC standards for Parkinson's clinical trials.
- Seven drug companies have shared patient-level control data from 11 Alzheimer's clinical trials. The companies have remapped their data to the new standard and combined them into a database now being actively used by CAMD to test initial scientific results before formal submission to the FDA. (To generate new data for this number of patients would cost millions of dollars and take more than six years in new clinical trials.)
- Parkinson's clinical trial data from NINDS, General Electric Healthcare, and Institute for Neurodegenerative Diseases is under evaluation by the new CDISC Parkinson's disease data standard. This data will be used to further develop and enrich a Parkinson's disease model first developed by the FDA.
- A quantitative disease model of the natural progression of Alzheimer's disease has been developed using data from the Alzheimer's Disease Neuroimaging Initiative. This model is now being tested and improved with the larger and precise regulatory standard database of industry clinical trial data with placebo treatment. The model will be used to help design new clinical trials. It will be submitted to the FDA and EMA for review later this year.
- CAMD is working to identify imaging, biochemical, genetic, and molecular biomarkers that have the greatest potential to uncover patient populations that are pre-symptomatic and more likely to benefit from new therapies.

Appendix A: CAMD Members and Advisory Organizations

Members

Abbott

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies, and new ways to manage health. Our products span the continuum of care, from nutritional products and laboratory diagnostics through medical devices and pharmaceutical therapies. Our comprehensive line of products encircles life itself - addressing important health needs from infancy to the golden years. Abbott has sales, manufacturing, research and development, and distribution facilities around the world, close to where our customers need us to be. We are recognized for our global reach and our ability to serve our customers around the world. In addition, Abbott prides itself on being a good place to work and strives to provide an environment that enables employees to succeed. We have been recognized as an outstanding employer in more than 20 countries around the world.

Throughout our 120+ year history, Abbott people have been driven by a constant goal: to advance medical science to help people live healthier lives. It's part of our heritage and continues to drive our work. Today, approximately 83,000 employees around the world share the passion for "Turning Science Into Caring." For more information, please visit <http://www.abbott.com>.

Alliance for Aging Research

The private, not-for-profit Alliance for Aging Research, founded in 1986, is the nation's leading advocacy organization for medical and behavioral research to improve the health and independence of Americans as they age. The Alliance also chairs the ACT-AD (Accelerate Cures/Treatments for Alzheimer's Disease) Coalition, a group of more than 50 not-for-profit organizations working to advance the development of transformational therapies against Alzheimer's disease. In 2009 the Alliance for Aging Research convened a working group of top Alzheimer's clinical experts to develop a consensus on the current utility of Alzheimer's disease biomarkers and additional research needed to provide sufficient evidence on markers showing promise for use as surrogate endpoints in Alzheimer's clinical trials. The Alliance joined the Coalition Against Major Diseases in 2008 and participates on CAMD's Coordinating Committee, Biomarker Subgroup, and Communications Committee. For more information, please visit <http://www.agingresearch.org>.

Alzheimer's Association

The Alzheimer's Association is the leading voluntary health organization in Alzheimer care, support, and research. Our mission is to eliminate Alzheimer's disease through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health. Our vision is a

world without Alzheimer's. For more information, please visit <http://www.alz.org/index.asp>.

Alzheimer's Foundation of America

The Alzheimer's Foundation of America (AFA) is a leading national nonprofit organization that focuses on providing optimal care to individuals with Alzheimer's disease and related dementias and their families, and unites 1,400+ member organizations that provide hands-on programs to meet the educational, emotional, practical, and social needs of families affected by Alzheimer's disease and related illnesses. AFA's services include a toll-free hot line, counseling by licensed social workers, educational materials, a free caregiver magazine, a national memory screening initiative, and professional training. For more information about AFA, call (toll-free) 866-AFA-8484, or visit <http://www.alzfdn.org>.

AstraZeneca Pharmaceuticals LP

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development, and commercialization of prescription medicines. AstraZeneca is a leader in gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology, and infectious disease medicines.

AstraZeneca has contributed de-identified patient data from a Phase 2 Alzheimer's disease clinical trial, details on the cognitive testing instruments used in its clinical trials that helped inform the data standard, and scientific expertise in multiple disciplines to the CAMD efforts.

For more information about AstraZeneca in the US or our AZ&Me™ Prescription Savings programs, please visit: <http://www.astrazeneca-us.com> or call 1-800-AZandMe (292-6363).

Bristol-Myers Squibb Company

Bristol-Myers Squibb is a global BioPharma company firmly focused on its mission to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases. Around the world, our medicines help millions of people in their fight against cancer, cardiovascular disease, diabetes, hepatitis B, HIV/AIDS, rheumatoid arthritis, and psychiatric disorders.

At Bristol-Myers Squibb, our BioPharma strategy uniquely combines the reach and resources of a major pharmaceutical company with the entrepreneurial spirit and agility of a successful biotech company. With this strategy, we focus on our customers' needs, giving maximum priority to accelerating pipeline development, delivering sales growth, and continuing to manage costs. For more information, please visit <http://www.bms.com>.

CHDI Foundation Inc.

CHDI Foundation, Inc. is a privately-funded, not-for-profit, virtual biotech company that is exclusively dedicated to rapidly discovering and developing therapies that slow the progression of Huntington's disease (HD). Our scientists work closely with a network of more than 600 researchers in academic and industrial laboratories around the world in the pursuit of these novel therapies, providing project management to ensure that our common goals remain in focus. This helps bridge the translational gap that often exists between academic and industrial research pursuits that adds costly delays to therapy development. In its role as a collaborative enabler, CHDI seeks to bring the right partners together to identify and address critical scientific issues and move drug candidates to clinical evaluation as rapidly as possible. In this regard, the goals of the CAMD and CHDI are aligned. We aim to use our current clinical data and expertise in HD to complement and strengthen CAMD's efforts in Alzheimer's and Parkinson's disease. Our activities extend from exploratory biology to the identification and validation of therapeutic targets, and from drug discovery and development to clinical studies and trials. More information about CHDI can be found at <http://www.chdifoundation.org>.

Eli Lilly and Company

Eli Lilly was founded in 1876, and is now the 10th largest pharmaceutical company in the world. Across the globe, Lilly has developed productive alliances and partnerships that advance our capacity to develop innovative medicines at lower costs.

Lilly Research Laboratories (LRL) is responsible for the discovery, development, and clinical evaluation of pharmaceutical products and for providing ongoing scientific support for marketed products. Discovering and developing innovative therapies for many of the world's unmet medical needs is at the core of LRL's mission. The most recent listing of sites has been revised to United States, Canada, China, England, Japan, Singapore, Spain, and a joint venture facility in Australia. In addition, LRL conducts clinical research in more than 50 countries around the world.

For more information, please visit <http://www.lilly.com>.

F. Hoffmann-La Roche Ltd

The Neuroscience group (CNS) at Roche is currently concentrating on psychiatric illness (e.g., anxiety, depression, and schizophrenia) and neurodegenerative diseases (Alzheimer's disease). We are developing medicines with novel mechanisms of action in depression and Alzheimer's, an area in which we are working to develop drugs both for symptom improvement and for slowing the progression of the disease. Other major research efforts are in multiple sclerosis and schizophrenia. As an innovator of products and services for the early detection, prevention, diagnosis, and treatment of diseases, we contribute on a broad range of fronts to improving people's health and quality of life. Roche is providing the first products that are tailored to the needs of specific patient groups. Our mission today and tomorrow is to create added value in healthcare by focusing on our expertise in diagnostics and pharmaceuticals. As a research-focused

healthcare company, Roche discovers, develops and provides innovative diagnostic and therapeutic products and services that deliver significant benefits to patients and healthcare professionals – from early detection and prevention of diseases to diagnosis, treatment, and treatment monitoring. Roche employs over 80,000 people and sells its products in over 150 countries. For more information, please visit <http://www.roche.com/index.htm>.

Forest Research Institute

Forest Laboratories supports the goal of improving the drug development process for major neurodegenerative diseases, such as Alzheimer's disease, and has co-operated with other interested stakeholders under the auspices of the Coalition Against Major Diseases (CAMD). Forest is represented on CAMD's coordinating committee and has contributed to the disease modeling workgroup in reviewing the proposed Alzheimer's disease progression modeling and simulation plan.

Forest Laboratories (NYSE: FRX) is a U.S.-based pharmaceutical company with a long track record of building partnerships and developing and marketing products that make a positive difference in people's lives. In addition to its well-established franchises in therapeutic areas of the central nervous and cardiovascular systems, Forest's current pipeline includes product candidates in all stages of development and across a wide range of therapeutic areas. The Company is headquartered in New York, NY. To learn more about Forest Laboratories, visit www.FRX.com.

Genentech, Inc.

Considered the founder of the biotechnology industry, Genentech has been delivering on the promise of biotechnology for more than 30 years, using human genetic information to discover, develop, manufacture, and commercialize medicines to treat patients with serious or life-threatening medical conditions. Today, Genentech is among the world's leading biotech companies, with multiple products on the market and a promising development pipeline. For more information, please visit <http://www.gene.com/gene/index.jsp>.

GlaxoSmithKline

They have a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better, and live longer. They are one of the few pharmaceutical companies researching both medicines and vaccines for the World Health Organization's three priority diseases – HIV/AIDS, tuberculosis and malaria, and are very proud to have developed some of the leading global medicines in these fields. Headquartered in the UK and with operations based in the US, they are one of the industry leaders, with an estimated seven per cent of the world's pharmaceutical market. They have a flair for research and a track record of turning that research into powerful, marketable drugs. They produce medicines that treat major disease areas such as asthma, virus control, infections, mental health, diabetes, and digestive conditions. In addition, we are a leader in the important area of vaccines and are

developing new treatments for cancer. For more information, please visit <http://www.gsk.com>.

Johnson & Johnson

Caring for the world, one person at a time... inspires and unites the people of Johnson & Johnson. We embrace research and science - bringing innovative ideas, products, and services to advance the health and well-being of people. Employees of the Johnson & Johnson Family of Companies work with partners in health care to touch the lives of over a billion people every day, throughout the world. Our Family of Companies comprises: the world's premier consumer health company, the world's largest and most diverse medical devices and diagnostics company, the world's fourth-largest biologics company, and the world's eighth-largest pharmaceuticals company. We have more than 250 operating companies in 60 countries employing approximately 114,000 people. For more information, please visit <http://www.jnj.com/connect/>.

National Health Council

The National Health Council is the only organization of its kind that brings together all segments of the health care community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 national health-related organizations and businesses, its core membership includes approximately 50 of the nation's leading patient advocacy groups, which control NHC's governance. Other members include professional and membership associations, nonprofit organizations with an interest in health, and major pharmaceutical, medical device, and biotechnology companies. For more information, please visit <http://www.nationalhealthcouncil.org>.

Novartis Pharmaceuticals Corporation

Novartis provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

Parkinson's Action Network

The Parkinson's Action Network (PAN) is the unified education and advocacy voice of the Parkinson's community – advocating for a cure. Through education and interaction with the Parkinson's community, scientists, policy and opinion leaders, as well as the public at large, PAN advocates for an increased and accelerated investment of public

resources to find a cure for the more than 1 million Americans who have Parkinson's disease. For more information, please visit <http://www.parkinsonsaction.org>.

Parkinson's Disease Foundation

The Parkinson's Disease Foundation® (PDF®) is a leading national presence in Parkinson's disease research, education and public advocacy. We are working for the nearly one million people in the U.S. living with Parkinson's by funding promising scientific research and supporting people with Parkinson's, their families and caregivers through educational programs and support services. Since our founding in 1957, PDF has funded over \$85 million worth of scientific research in Parkinson's disease, supporting the work of leading scientists throughout the world.

PDF's Executive Director, Robin Elliott, serves on the CAMD Coordinating Committee and is a member of the CAMD Biomarker Evaluation Workgroup. James Beck, PhD, our Director of Research Programs, is a member of the CAMD Disease-Progression Modeling Workgroup. For more information, please visit <http://www.pdf.org>.

Pfizer, Inc.

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and medicines that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us.

Alzheimer's Commitment – Pfizer recognizes the significant medical need in Alzheimer's disease and is committed to advancing valuable and innovative treatment options. We have a strong pipeline with a number of compounds in clinical development targeting different mechanisms that are thought to be important in the Alzheimer's disease process. We are proud to participate in the Coalition Against Major Disease (CAMD) by contributing data from our studies and the expertise of our scientists working in Alzheimer's disease. We hope this will help accelerate the discovery and development of new treatments for Alzheimer's disease. For more information, please visit <http://www.pfizer.com/home/>.

sanofi-aventis

One of sanofi-aventis' goals is to develop treatments to benefit patients with Alzheimer's disease and Parkinson's disease by advancing scientific knowledge. One way this can be expedited is through the involvement of sanofi-aventis U.S. with the Coalition Against Major Diseases (CAMD), in which the talents and expertise from sanofi-aventis and other contributors are joined in an environment that favors creativity and knowledge-sharing. Critical Path Institute's culture of openness and collaborative research is an ideal fit with sanofi-aventis' philosophy. Sanofi-aventis is confident this relationship will bring forth discoveries that will positively serve patients, which is the ultimate mission of the company.

Sanofi-aventis has more than 13,000 employees in the United States and about 105,000 employees worldwide.

Sanofi-aventis U.S. is an affiliate of sanofi-aventis, a leading global pharmaceutical company that discovers, develops, and distributes therapeutic solutions to help improve the lives of patients. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY). For more information, <http://www.sanofi-aventis.us>

Advisory Organizations

U.S. Food and Drug Administration (FDA)

The FDA is an agency within the Department of Health and Human Services and consists of centers and offices, which are listed in left menu [here](#).

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, products that emit radiation, and tobacco products.

The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable, and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

For more information, please visit <http://www.fda.gov>.

Engelberg Center for Health Care Reform at The Brookings Institution

The Engelberg Center for Health Care Reform provides data-driven, practical policy solutions that will foster high-quality, innovative care – care that is both more affordable and more effective at actually improving patient health. Through a variety of projects, the Center promotes the broad-based exchange of ideas to develop consensus around practical steps for health care reform. It also provides technical support for both

collaborative work among a wide range of health care stakeholders and actual implementation of reforms. The Center's overall focus is on key priority areas that are critical to the kind of reform that will improve not just the health care system, but the health of individual patients. Learn more at www.brookings.edu/healthreform.

European Medicines Agency (EMA)

The European Medicines Agency is a decentralised body of the European Union with headquarters in London. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. For more information, please visit <http://www.ema.europa.eu>.

National Institute of Neurological Disorders and Stroke (NINDS)

The National Institute of Neurological Disorders and Stroke (NINDS) conducts and supports research on brain and nervous system disorders. Created by the U.S. Congress in 1950, NINDS is one of the more than two dozen research institutes and centers that comprise the National Institutes of Health (NIH). The NIH, located in Bethesda, Maryland, is an agency of the Public Health Service within the U.S. Department of Health and Human Services. NINDS has occupied a central position in the world of neuroscience for more than 50 years. For more information, please visit <http://www.ninds.nih.gov>.

National Institutes on Aging (NIA)

NIA, one of the 27 Institutes and Centers of NIH, leads a broad scientific effort to understand the nature of aging and to extend the healthy, active years of life. In 1974, Congress granted authority to form NIA to provide leadership in aging research, training, health information dissemination, and other programs relevant to aging and older people. Subsequent amendments to this legislation designated the NIA as the primary Federal agency on Alzheimer's disease research. The Institute's mission is to:

- Support and conduct genetic, biological, clinical, behavioral, social, and economic research related to the aging process, diseases and conditions associated with aging, and other special problems and needs of older Americans.
 - Foster the development of research and clinician scientists in aging.
 - Communicate information about aging and advances in research on aging to the scientific community, health care providers, and the public
- For more information, please visit <http://www.nia.nih.gov>.

Appendix B: CAMD Non-Member Participants

Collaborating Organizations

Clinical Data Interchange Standards Consortium (CDISC)

Ephibian

Metrum Institute

Collaborating Scientists

Adam J. Simon
AJ Simon Enterprises LLC

Chris Edgar
United Biosource Corporation

Clifford R. Jack
Mayo Foundation for Medical Education and Research

David Holtzman
Washington University

David Russell
Institute for Neurodegenerative Disorders

Derek Hill
IXICO and UCL, University College London

Donald Grosset
Institute of Neurological Sciences and
University of Glasgow

Fred Wood
Octagon Research

Hugo Vanderstichele, PhD
Innogenetics
Principal Developer

John Morris
Washington University

Kaj Blennow
University of Goteborg, Sweden

Ken Marek
Institute of Neurodegenerative Disorders

Leslie M Shaw
Department of Pathology and Laboratory Medicine
University of Pennsylvania Medical Center

Marilyn Albert
Johns Hopkins School of Medicine

Michael Weiner
University of California, San Francisco (UCSF)

Nick Fox
UCL, Institute of Neurology, University College London

Paul Aisen
Director, Alzheimer's Disease Cooperative Study

Patricia E. Cole
ImagePace

Ronald Petersen
Mayo Clinic College of Medicine
Mayo Alzheimer's Disease Research Center

Todd Sherer, PhD
The Michael J Fox Foundation for Parkinson's Research

Wayne Kubick
Phase Forward