



**CRITICAL PATH INSTITUTE AND CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM  
ANNOUNCE RELEASE OF DATA STANDARD FOR ALZHEIMER'S DISEASE RESEARCH**

First in a series of therapeutic area data standards

**Tucson, Arizona, October 17, 2011** – Critical Path Institute (C-Path) and Clinical Data Interchange Standards Consortium (CDISC) today announced the release of version 1.0 of the Alzheimer's disease (AD) Therapeutic Area Standard (SDTM AD/Mild Cognitive Impairment User Guide). This was developed for the clinical research community to facilitate analysis and learning from clinical studies for treatment or prevention of AD.

The User Guide outlines a standardized set of data elements so that pharmaceutical companies and other medical researchers can more easily, and consistently, collect data that can be reliably pooled and compared.

Lynn Hudson, PhD, C-Path's Chief Scientific Officer and Executive Director of C-Path's Coalition Against Major Diseases (CAMD) noted, "Ultimately, this will result in increased efficiencies so that the U.S. Food and Drug Administration (FDA) and other regulatory agencies can more quickly and accurately review new applications for AD therapies, making it possible for medicines to reach patients more quickly and with greater assurances of safety and effectiveness."

This is an early and landmark outcome from a joint C-Path/CDISC project to formalize and publish the CDISC AD standard based on the elements used in CAMD's groundbreaking AD data repository. Collaborators in CAMD, which include global stakeholders from C-Path, CDISC, the AD clinical community, the pharmaceutical industry, government agencies, academia, and patient advocacy associations, reached consensus on the relevant pooled data domains, terminology, and definitions.

Early last year, seven of CAMD's member organizations agreed to share their data from eleven recent AD clinical research studies and allowed it to be standardized, pooled, and made available to qualified researchers around the world. They invested significant in-kind resources to remap the retrospective data to the new format that is now the CDISC standard. Those organizations included Abbott Laboratories, Alzheimer's Disease Cooperative Study, AstraZeneca Pharmaceuticals LP, GlaxoSmithKline, Johnson & Johnson, Pfizer, and sanofi-aventis. C-Path worked with another collaborator, Ephemian, a Tucson, Arizona-based company that specializes in software development, databases, web solutions and information security, to build a secure online data repository.

Today, the database contains data from over 4,100 AD subjects mapped to the CDISC standard. Its level of detail and scope will enable researchers to more accurately project the course of mild cognitive impairment (MCI) as it progresses to AD, thereby enabling the design of more efficient clinical trials that have the maximum chance of demonstrating whether a new treatment is truly safe and effective.

CAMD members and scientists around the world use the database to develop mathematical models to better track the course of MCI and AD in patients generally, as well as in genetically-defined subsets.

Roughly 5.3 million people in the U.S. alone are afflicted with AD, with costs reaching as much as \$175 billion

annually. Worldwide, it afflicts 30 million people, a number that is expected to quadruple by 2050. Halting or slowing the progression of this disease will prevent untold suffering and save tens of billions of dollars every year. “Pooling clinical data is a powerful way to gain new insights and leverage the efforts of companies that are developing new therapies,” said Raymond Woosley, MD, PhD, President and CEO of C-Path. “Scientists around the world can now use the combined, standardized data from clinical trials to better understand the true course of Alzheimer’s disease in patients.”

According to Rebecca Kush, PhD, President and CEO of CDISC, “Standards are essential to ensure that data can be aggregated for high quality research and robust analyses. Their value to companies and scientists increases substantially when they are used at the earliest stages of planning for a clinical trial, in the preparation of the protocol and the case report forms (including eCRFs). Adoption of core CDISC standards and the complementary new AD supplement, will enable far more rapid launch of clinical research studies of AD, and will also minimize or eliminate costly back-end data remapping (legacy data conversion). We are delighted to work with C-Path on this project and look forward to similar initiatives for additional therapeutic areas.”

Bron Kisler, Vice President of Strategic Initiatives of CDISC, pointed out that data standards will promote efficiencies in making progress against this disease. “If one trial cannot be reliably compared to another, we lose valuable information and often repeat costly mistakes. It would be like trying to accurately compare distances when they are variably represented and recorded in miles, kilometers, leagues, yards, and light years. If we are ever going to stave off Alzheimer’s disease, we need to be able to clearly study and learn from every piece of data.”

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**ABOUT CRITICAL PATH INSTITUTE (C-PATH):** An independent, non-profit organization established in 2005 with public and private philanthropic support from the Southern Arizona community, Science Foundation Arizona (SFAz), and the U.S. Food and Drug Administration (FDA), C-Path is committed to improving health and saving lives by accelerating the development of safe, effective medicines. An international leader in forming collaborations around this mission, C-Path has established global, public-private partnerships that currently include over 1,000 scientists from government regulatory agencies, academia, patient advocacy organizations, and thirty five major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona, with offices in Phoenix, Arizona, and Rockville, Maryland. For more information, visit [www.c-path.org](http://www.c-path.org) and follow us on Facebook. Click [here](#) to view a video showing why the work of C-Path is essential.

***The C-Path Vision: Creating collaborations that advance scientific innovations to improve human health and save lives by accelerating the development of safe, effective medicines.***

**ABOUT CDISC:** The Clinical Data Interchange Standards Consortium (CDISC) is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata to streamline clinical research. The CDISC mission is to *develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.* CDISC standards are vendor-neutral, platform-independent and freely available via the CDISC website. Additional information on CDISC can be found on the CDISC website at [www.cdisc.org](http://www.cdisc.org).

***The CDISC Vision: Informing patient care and safety through higher quality medical research.***

**ABOUT CAMD:** C-Path’s Coalition Against Major Diseases is a unique public-private collaboration of pharmaceutical companies, patient advocacy/voluntary health associations, and government research and

regulatory agencies formed to share pre-competitive data and knowledge that will more efficiently and safely speed development of new therapies and preventions for Alzheimer's, Parkinson's, and other debilitating neurodegenerative diseases. CAMD works to provide tools that will help scientists identify clinical and laboratory characteristics of patients who are pre-symptomatic, and therefore most likely to benefit from new therapies. For more information on CAMD, visit <http://www.c-path.org/CAMD.cfm>.

**CAMD MEMBERS:** Abbott Laboratories, Alliance for Aging Research, Alzheimer's Association, Alzheimer's Foundation of America, AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Eisai Inc., Eli Lilly and Company, F. Hoffmann-La Roche Ltd, Forest Research Institute, Genentech Inc., GE Healthcare, GlaxoSmithKline, Johnson & Johnson, Michael J. Fox Foundation, National Health Council, Novartis Pharmaceuticals Corporation, Orion Corporation, Pfizer, Inc., sanofi-aventis US Inc., and Teva Pharmaceutical Industries, Ltd.

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