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***For immediate release –***

# CFAST Announces Parkinson's Disease Drug Development Milestone: Release and Availability of a PD Therapeutic Area Data Standard

**Tucson, AZ and Austin, TX – January 29, 2013** – The Coalition for Accelerating Standards and Therapies (CFAST), a joint effort between the Clinical Data Interchange Standards Consortium (CDISC) and Critical Path Institute (C-Path), in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS), announces the availability of an important new resource in the fight against Parkinson's disease (PD). Parkinson's disease is a debilitating condition that affects an estimated 1,000,000 in the U.S. and as many as 7,000,000 people worldwide.

This new resource, the Parkinson's disease CDISC Therapeutic Area Data Standard, provides a defined and consistent way to collect, store, and submit clinical trial data for PD. The new standard 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.

"The release of PD v1.0 is the culmination of work by a dedicated team of Parkinson's disease experts and reflects the high level of collaboration between NINDS and CFAST. We are excited that the development of these standards will significantly contribute to advancing PD drug development," says Dr. Diane Stephenson, Executive Director of C-Path's Coalition Against Major Diseases (CAMD). CAMD is one of C-Path's seven consortia and focuses on accelerating therapies for Parkinson's disease and Alzheimer's disease.

The U.S. Food and Drug Administration (FDA) has identified PD as one of several disease areas having a critical need for data standards, and will require the use of clinical data standards by 2017. "The new PD standard will be followed by many new therapeutic

area projects that will be developed under CFAST both to facilitate regulatory review and to enable greater sharing, pooling and ultimately increased understanding of data for multiple studies and therapies, to enable researchers to deliver new and improved therapies to patients," states Becky Kush, CEO of CDISC.

“There is significant unmet medical need for effective treatments for PD,” says Dr. Mark Gordon from Boehringer Ingelheim Pharmaceuticals, Inc. “The PD CDISC standards should contribute to alignment and consensus across the industry,” states Dr. Gordon.

Dr. Ken Marek of the Institute of Neurodegenerative Disorders who was engaged in development of the standards stated that, “the inclusion of biomarkers as well as clinical scales in the PD standard will assist with much needed standardization in future clinical studies.”

This release is the latest collaboration between CDISC and C-Path on the development of Therapeutic Area Data Standards. Scientists and researchers can access the standard on the CDISC site: http://www.cdisc.org/therapeutic.

**ABOUT CAMD:** The Coalition Against Major Diseases (CAMD) at Critical Path Institute (C-Path) is a unique public-private partnership of pharmaceutical companies, academia, patient advocacy/voluntary health associations, and government research and regulatory agencies formed to accelerate treatments for two of today's most devastating illnesses - Alzheimer's and Parkinson's diseases.

**ABOUT CFAST (Coalition For Accelerating Standards and Therapies)** CFAST was launched in October, 2012, as a partnership between CDISC and C-Path to accelerate clinical research and medical product development by facilitating the creation and maintenance of data standards, tools, and methods for conducting research in therapeutic areas important to public health.

**ABOUT C-Path (Critical Path Institute)**

C-Path was formed with public and private philanthropic support from the University of Arizona, the US Food and Drug Administration (FDA), and the Tucson community. Additional funding has been provided by Science Foundation Arizona (SFAz). C-Path is committed to improving human health and well-being by developing new technologies and methods to accelerate the development and review of medical products. An international leader in forming collaborations around this mission, C-Path has established global, public-private partnerships that include nearly 1,000 scientists from government regulatory agencies, academia, patient advocacy organizations, and 41 major biomedical companies. www.c-path.org

**ABOUT CDISC (Clinical Data Interchange Standards Consortium)**

CDISC is a non-profit organization with approximately 300 supporting member organizations from across the global clinical research and healthcare arenas. Through the efforts of volunteers, CDISC catalyzes productive collaboration to develop industry-wide data standards enabling the harmonization of clinical data and streamlining research processes from protocol through analysis and reporting, including the use of electronic health records to facilitate the collection of high quality research data. CDISC standards and innovations can substantially decrease the time and cost of medical research and improve quality, thus contributing to the faster development of safer and more effective medical products.  CDISC standards are freely available. www.cdisc.org

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