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Austin, TX – 30 March 2016 – The Clinical Data Interchange Standards Consortium (CDISC), the Critical Path Institute (C-Path) and TransCelerate BioPharma, Inc. ("TransCelerate") today announce the open availability of new and updated CDISC Therapeutic Area (TA) Standards in the areas of Chronic Obstructive Pulmonary Disease (COPD), Virology, and Diabetes. These TA standards, which will make it easier to share data, compare data across studies and analyze clinical research findings to streamline development of new therapies, were developed through the Coalition for Accelerating Standards and Therapies (CFAST). CFAST is a joint initiative of CDISC and C-Path, formed to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health, with input and assistance from such organizations as TransCelerate, the National Cancer Institute (NCI), the U.S. FDA and many others.

The new and updated TA standards will be available via the CDISC website, through User Guides and the Shared Health and Research Electronic Library (SHARE). SHARE enables electronic access to the standards and enables reuse of concepts across future TA standards with common concepts.

COPD affects an estimated 24 million people in the U.S. alone, and is the third leading cause of death. "We designed the COPD Therapeutic Area User Guide to enable advances that improve the quality of life for COPD patients," said Sherwood Barbee, who led the development of the COPD user guide as a CDISC Fellow and works in Lifecycle Safety at Quintiles. "The User Guide will allow for data to be analyzed across multiple COPD clinical trials, to uncover previously unavailable insights and information."

Virology v2.0 is an updated version of the original Virology v1.0 standard. This standard describes how to use the CDISC standards to consistently represent concepts relevant to a broad variety of virology-related studies, such as drug resistance testing. "With version 2 of the Virology user guide, we are building on recent development work covering microbial diseases and genetics, focusing on reusability of concepts across a broad field of research," stated Jon Neville, C-Path Assistant Director for Data Standards Architecture.

Diabetes is a complex disease that affects 29.1 million Americans, with 1.4 million new cases each year. There are many clinical assessments that indicate whether treatments are effective. The Analysis Dataset Model (ADaM) Supplement for Diabetes v1.0 is a supplement to the existing Diabetes Therapeutic Area Standard v1.0, and demonstrates the specific use of CDISC ADaM to create datasets to support the analysis of statistical endpoints common to diabetes trials for review by statisticians including statistical reviewers who review applications for new therapies at regulatory authorities in the United States and Japan. “The collaboration and partnership on this project will lead to increased consistency in analysis and reporting of key results from diabetes clinical trials,” said Isaac Swanson, data standards consultant, global statistical sciences at Eli Lilly and Company. “Using the ADaM supplement standards will help create efficiencies across trials, increase the speed of delivering clinical trial data and ultimately benefit the patients we serve.”

CDISC standards have been adopted and used in more than 90 countries, and will soon be required by regulatory authorities in the U.S. and Japan. To date, TA Standards have been developed for over 25 different disease areas, with most being developed under the CFAST program. Using these standards from the start of clinical research has been proven capable of saving both time and resources to conduct clinical research. Researchers working in the areas of COPD, Virology and Diabetes are encouraged to implement these standards into their processes.

About the organizations:

CDISC is a 501(c)(3) global non-profit charitable organization that streamlines research and enables connections to healthcare through the development of clinical research data standards. CDISC has developed a suite of standards to support clinical research from protocol through analysis and reporting. CDISC standards make it possible for data to speak the same language, empowering simple data collection and private sharing that makes the most of the valuable information offered by patients participating in research studies around the globe. Using CDISC standards from the start of studies enables Smarter Research to Unlock Cures (www.unlockcures.org), saving ~60% overall in terms of time and resources to conduct research. CDISC is the patient’s advocate, creating therapeutic area data standards for over 25 different disease areas that advance medical product development and various types of clinical research.

Critical Path Institute (C-Path) is an independent, non-profit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and the U.S. Food and Drug Administration (FDA). C-Path’s mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has now established ten global, public-private partnerships that currently include over 1,000 scientists from government and regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona. For more information, visit www.c-path.org.

TransCelerate BioPharma Inc. is a non-profit organization dedicated to improving the health of people around the world by accelerating and simplifying the research and development (R&D) of innovative new therapies. The organizations' mission is to collaborate across the global biopharmaceutical R&D community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high quality delivery of new medicines. TransCelerate evolved from discussions at various forums for executive R&D leadership to debate current issues facing the industry, and examine solutions for addressing agreed-upon common challenges. The founding member companies are AbbVie, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly and Company, GlaxoSmithKline, Johnson & Johnson, Pfizer, the Roche Group, and Sanofi. Additional members that have joined since the inception of TransCelerate include Allergan, Inc., Amgen, Astellas Pharma Inc., Biogen, EMD Serono, Inc. (a subsidiary of Merck KGaA, Darmstadt, Germany), Medgenics, Inc., Merck & Co., Inc., Novo Nordisk, Shionogi & Co., Ltd. and UCB.

Membership in TransCelerate is open to pharmaceutical and biotechnology companies with Research & Development operations. Executive offices are located in Philadelphia, PA. For more information, please visit http://www.transceleratebiopharmainc.com.

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