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July 23, 2015

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Austin, TX – 23 July 2015 – The Clinical Data Interchange Standards Consortium (CDISC), the Critical Path Institute (C-Path), and TransCelerate BioPharma, Inc. are pleased to announce that data standards for clinical research in the areas of Schizophrenia, Hepatitis C and Dyslipidemia have been published for use on the CDISC website. These three Therapeutic Area (TA) standards were developed per the CDISC global, consensus-based Standards Development Process through the collaborative Coalition for Accelerating Standards and Therapies (CFAST) Initiative, a partnership of CDISC and C-Path.

These new data standards were developed to streamline clinical research processes, describing the most common data needed for research studies to assess the safety and efficacy of therapies for Schizophrenia, Hepatitis C and Dyslipidemia. CDISC TA standards strive to represent research data unambiguously, using consistent terminology that can be accessed through the NCI Enterprise Vocabulary Services. CDISC standards implemented at the start-up stage of research studies can save significant cost and resources. They also enable data aggregation and comparisons of data across studies, leading to higher quality research and more rapid advancements in medicine.

“The CDISC Hepatitis C project provided a true collaborative effort to help standardize data collection for trials in subjects with chronic Hepatitis C virus infection,” said John Owen, Hepatitis C Project Manager for TransCelerate BioPharma, Inc. “Knowing that this standardization will lead to expedited submissions to regulatory authorities, hence faster drug availability to patients, only motivates us more.”

“The CDISC Dyslipidemia work effort was an enjoyable, transnational collaboration that should improve the collection of data in anti-dyslipidemia clinical trials,” said Dr. Jennie Jacobson (Eli Lilly and Company). “Interacting with the highly experienced team, including clinical experts Drs. Martin Benson (ICON Clinical Research), Vladimir Kryzhanovski (Eli Lilly and Company), John Vincent (Pfizer, Inc), and others to develop the standard, knowing that it will help expedite drug development and improve patient care in this important therapeutic area was very rewarding.”

“I really enjoyed working on the Schizophrenia project and learned a lot more about the importance of data standards and CDISC,” stated Dr. Virginia Stauffer, Clinical Research Advisor with Eli Lilly and Company and a medical expert on the Schizophrenia project.

“As we continue to develop new therapeutic area standards, we are finding that the number of data concepts that are common across different therapeutic areas continues to increase,” stated Rhonda Facile, CDISC VP of Standards Development. “Adding this re-use value to the utility of the CDISC electronic library (SHARE)

will continue to improve accessibility and usefulness of these standards. Ultimately, they lead to better insights from clinical research to help us all, especially patients with these diseases."

These three therapeutic area standards will be available via the CDISC website, through User Guides and the Shared Health and Research Electronic Library (SHARE). SHARE will enable electronic access to the standards and enable re-use of concepts across future therapeutic area standards with common concepts.

These standards were developed with support in part by grant 1U24FD005036-01 from the U.S. FDA.

About CDISC

CDISC is a 501(c)(3) global non-profit charitable organization, with over 350 supporting member organizations from across the clinical research and healthcare arenas. Through the efforts of volunteers around the globe, 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. The CDISC standards and innovations can significantly decrease the time and cost of medical research and improve quality, thus contributing to the faster development of safer and more effective medical products and a learning healthcare system. The CDISC Vision is *to inform patient care and safety through higher quality medical research*.

About Critical Path Institute

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 eleven 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.

About TransCelerate BioPharma, Inc.

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 www.transceleratebiopharmainc.com.

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