C-Path, CDISC Develop Standard to Represent Data for Animal Rule Studies

TUCSON, Ariz. and **AUSTIN**, Texas, October 15, 2019 — The Critical Path Institute (C-Path) and CDISC are pleased to announce the release of a global Foundational Standard that describes how to represent data for the natural history and efficacy studies conducted in animals submitted to applications under the U.S. Food and Drug Administration (FDA) regulations commonly known as the Animal Rule. The Animal Rule provides a regulatory mechanism for the approval of drugs and licensure of biological products when human efficacy studies are not ethical or feasible.

“The foundational data standard is an important tool that will help maximize the investment in Animal Rule studies,” said C-Path Chief Technology Officer and Data Collaboration Center (DCC) Director Rick Liwski. “The standard will ultimately streamline data reporting to the FDA to enhance learnings from these important animal studies, and will serve to accelerate therapies for humans.”

The standard, released in the form of an Implementation Guide and Model for data managers, statisticians, programmers and study managers, is freely available on the CDISC website. “We are quite excited about the release of this important standard that supports a regulatory submission mechanism vital to public health,” said David R. Bobbitt, MSc, MBA, CDISC President and CEO. ”Congratulations to all who have contributed their time and expertise to the development of this standard.”

CDISC Foundational Standards are the basis of a complete suite of data standards, enhancing the quality, efficiency and cost effectiveness of clinical research processes from beginning to end. Foundational Standards focus on the core principles for defining data standards and include models, domains and specifications for data representation.

About C-Path

C-Path (Critical Path Institute) is an independent, nonprofit organization established in 2005 as a public and private partnership. 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 established numerous global consortia that currently include over 1,500 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path is headquartered in Tucson, Arizona, with additional staff in multiple remote locations. For more information, visit www.c-path.org.

ABOUT CDISC

CDISC creates clarity in clinical research by convening a global community to develop and advance data standards of the highest quality. Required by the United States Food and Drug Administration (FDA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and adopted by the world's leading research organizations, CDISC standards enable the accessibility, interoperability, and reusability of data. With the help of CDISC standards, the entire research community can maximize the value of data for more efficient and meaningful research that has invaluable impact on global health. CDISC is a 501(c)(3) global nonprofit charitable organization and is headquartered in Austin, Texas, with hundreds of employees, volunteers, and member organizations around the world. www.cdisc.org.

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