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Austin, TX – 18 April 2017 – The Clinical Data Interchange Standards Consortium (CDISC) today announced the release of Major Depressive Disorder (MDD) Therapeutic Area User Guide v1.0. The MDD standard is freely available on the CDISC website. Therapeutic Area User Guides provide research professionals with guidance on how to represent patient data in clinical research to improve quality, efficiency and cost effectiveness, enabling smarter research to unlock cures.

According to the World Health Organization, an estimated 350 million people of all ages suffer from depression globally. Depression is the leading cause of disability worldwide, and is a major contributor to the overall global burden of disease.

“We congratulate the team on the release of the Major Depressive Disorder (MDD) Therapeutic Area User Guide! Including MDD, a record number of 10 Therapeutic Area User Guides were released in 2016. We would like to recognize the tremendous effort put forth by all CDISC standards development teams and thank them for their dedication throughout the year. We are making great strides in increasing the breadth of clinical data standards available to support research,” said Brooke Hinkson, Head, Global Clinical Data Standards at Merck and lead of the TransCelerate BioPharma (“TransCelerate”) Clinical Data Standards initiative.

This CDISC Therapeutic Area standard was developed through the Coalition For Accelerating Standards and Therapies (CFAST) initiative, a partnership of CDISC and the Critical Path Institute (C-Path), with participation from the U.S. NIH National Cancer Institute Enterprise Vocabulary Services (NCI-EVS), the U.S. Food and Drug Administration (FDA), TransCelerate, the Japan Pharmaceutical and Medical Devices Agency (PMDA) and other stakeholders 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.

CDISC standards have been adopted and used in more than 90 countries, and are required for submissions to the U.S. FDA and Japan PMDA. To date, Therapeutic Area standards have been developed for over 25 disease areas. CDISC standards make it possible for data to speak the same language, empowering data

collection and sharing that makes the most of the valuable information offered by patients participating in research studies around the globe.

About CDISC

CDISC is a 501(c)(3) global, non-profit organization that develops data standards to foster smarter research and enable connections to healthcare. CDISC standards allow data to speak the same language, by providing common formats for data collection, data sharing and data analyses to make the most of the valuable information offered by patients participating in research studies around the globe, enabling researchers to discover new treatments, find breakthroughs, and unlock cures. CDISC standards are required for regulatory submissions to the U.S. FDA and Japan PMDA, are endorsed by the China CFDA, and are requested for use by the European Innovative Medicines Initiative (IMI). The suite of CDISC standards is freely available on the CDISC website.

CDISC is funded through the generous support of over 400 member organizations from pharmaceutical, biotech, clinical research organizations, regulatory agencies, academia, and healthcare, as well as through grants, authorized CDISC Education courses, events and charitable contributions. To find out more about how to support CDISC and get involved, please visit www.cdisc.org and www.unlockcures.org.

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