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New CDISC data standard aids development of therapies for Ebola virus

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The Clinical Data Interchange Standards Consortium (CDISC) and the Infectious Diseases Data Observatory (IDDO) announce the availability of a new standard to assist in the collection, aggregation and analysis of Ebola virus disease (EVD) research data. This standard is for use in EVD trials, leading to potential treatments and public health surveillance for this disease.

Ebola virus spreads through direct human-to-human contact and is often fatal, with a fatality rate that has ranged from 20% to 90% in past outbreaks. According to the WHO, the epidemic that began in 2014 in West Africa was "the largest and most complex Ebola outbreak since Ebola virus was first discovered in 1976." This singular outbreak resulted in over 11,000 fatalities, which is more than 7 times the fatalities of all previous outbreaks combined.

Version 1.0 of the CDISC Ebola Therapeutic Area User Guide (TAUG-Ebola) describes data concepts for use in Ebola clinical studies, so that investigators, data managers, statisticians, programmers and others that handle Ebola clinical trial data can understand the data and apply the standards appropriately. Having this data in CDISC standard format allows for more efficient aggregation and analysis of data collected from various studies across outbreak settings, thereby leading to an enhanced, automated process for developing evidence in evaluating Ebola treatments.

"There are many different actors involved in tracking, diagnosing,

treating and containing an outbreak. Sharing information across these disciplines is critical to understand and respond to a disease outbreak, and is particularly important in the case of Ebola which has such devastating consequences." said Laura Merson, Associate Director of the Infectious Diseases Data Observatory (IDDO), and a clinical trial expert who coordinated the project on behalf of IDDO. "The CDISC Ebola data standard is a significant step forward that will enable a more rapid cross-disciplinary response which can reduce the impact of the next epidemic."

Laura Merson will be a keynote speaker at the upcoming 2017 CDISC Europe Interchange, to be held 24-28 April in London, England. During her presentation, she will share her experiences on the importance of sharing biomedical research data to change the paradigm of clinical research as it relates to outbreaks to enable rapid research response.

CDISC standards are required for submissions to the U.S. Food and Drug Administration (FDA) and Japan Pharmaceuticals and Medical Devices Agency (PMDA), are endorsed by the China CFDA, are requested for use by the European Innovative Medicines Initiative (IMI), and use of the Therapeutic Area User Guides is strongly recommended. CDISC highly encourages immediate use of the Ebola virus standard in clinical studies to ensure streamlined medical research practices, enhanced data sharing opportunities, and more rapid results for patients suffering from this disease.

This CDISC Therapeutic Area User Guide was developed through the Coalition for Accelerating Standards and Therapies (CFAST) initiative, a joint initiative of CDISC and the Critical Path Institute (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. Development of the TA standards includes invaluable support

and advice from such organizations as the National Cancer Institute (NCI), Innovative Medicines Initiative (IMI), TransCelerate BioPharma, and regulatory agencies, including the U.S. Food and Drug Administration (FDA), the Japan Pharmaceutical and Medical Devices Agency (PMDA), and the European Medicines Agency (EMA).

Provided by Infectious Diseases Data Observatory