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**C-PATH AND CDISC LAUNCH VERSION 1.0 OF THE POLYCYSTIC KIDNEY DISEASE THERAPEUTIC USER GUIDE**

**New guide to assist in the collection, aggregation, and submission of clinical trial data**

**Tucson, AZ , Austin, TX** - Critical Path Institute's (C-Path) Polycystic Kidney Disease Outcomes Consortium (PKDOC) (<http://www.c-path.org/pkd.cfm>) , the Clinical Data Interchange Standards Consortium (CDISC), and the PKD Foundation announced today the launch of version 1.0 of the Polycystic Kidney Disease (PKD) Therapeutic Area User Guide, a clinical data standard that provides guidance on the implementation of the CDISC Study Data Tabulation Model (SDTM) to represent PKD data in regulatory submissions. This user guide, when used with the SDTM, is intended to guide the organization, structure, and format of standard PKD clinical trial tabulation datasets submitted to a regulatory authority such as the US Food and Drug Administration (FDA). This clinical data standard has also been used to aggregate data from several PKD patient registries and observational studies to analyze disease progression in PKD. "The development of the PKD Data Standard represents a major step forward in the development of therapies for PKD," said Ron Perrone, Professor of Medicine at Tufts University School of Medicine, and Director of the Tufts Center for PKD and Co-Director of the PKDOC. "This kidney disease specific standard will shorten the time for initiation of clinical trials and will facilitate data interchange with regulatory agencies, thereby helping to speed the pace of therapeutics development and potentially improving outcomes for patients." Perrone is also a member of the PKD Foundation's Scientific Advisory Committee. The PKD Foundation provided funding for the PKDOC and the CDISC standards development effort.

CDISC standards are freely available via the CDISC website. To learn more about the PKD Therapeutic Area User Guide and to download the associated standards package, please visit the CDISC website: <http://www.cdisc.org/therapeutic>.

"This release marks another major milestone in the development of a set of global, platform-independent therapeutic area data standards. The way we were able to work with academic clinicians from Emory University, the Mayo Clinic, Tufts University and the University of Colorado-Denver to develop and reach consensus on PKD data elements was ground breaking for us.

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CDISC is delighted to have contributed its standards expertise to this project, which led to an improved process for therapeutic area standards development for the benefit of PKD patients, researchers, drug developers and regulatory agencies around the world,” said Bron Kisler, VP of Strategic Initiatives for CDISC. C-Path and CDISC formed a partnership in 2012 to establish the Coalition For Accelerating Standards and Therapies (CFAST), an initiative 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. CFAST seeks to bring together expertise from NIH Institutes, academic medical centers and patient foundations with that of global biopharmaceutical companies. CFAST continues to receive terminology expertise and support from the National Cancer Institute’s Enterprise Vocabulary Services (NCI EVS), including the PKD Project.

“This project would not have been possible without the generous support of the PKD Foundation and the many contributions by PKDOC member clinicians, scientists, C-Path and CDISC staff and volunteers. This team developed the data standard and converted legacy data to aggregate information from multiple sources which is now being used to develop new tools to analyze and understand PKD ,” said Martha Brumfield, CEO and President of C-Path.

#### **ABOUT PKD Foundation**

The PKD Foundation is a non-profit organization with a mission to promote programs of research, advocacy, education, support and awareness in order to discover treatments and a cure for polycystic kidney disease (PKD) and improve the lives of all it affects. PKD is one of the most common, life-threatening genetic kidney diseases affecting thousands in America and millions worldwide. It is estimated that one in 500 people have PKD. PKD is the fourth leading cause of kidney failure, and there is no treatment or cure. Visit [pkcure.org](http://pkcure.org) to learn more about PKD and the Foundation.

#### **ABOUT C-PATH**

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 improve human health and well-being by developing new technologies and methods to accelerate the development and review of medical products. An international leader in forming collaborations, C-Path has established global, public-private partnerships that currently include 1,000+ scientists from government regulatory agencies, academia, patient advocacy organizations, and dozens of major pharmaceutical companies.

#### **ABOUT CDISC**

CDISC is a 501(c)(3) global non-profit charitable organization, with over 300 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 freely available, industry-wide clinical research data standards. The CDISC standards enable the sharing and aggregation of of clinical data and streamline 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 have been shown to decrease the time and cost of medical research and improve data 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.*

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