

Building the Foundation for Future PKD Breakthroughs: CDISC, PKD Foundation, and Critical Path Institute Expand Global Research Standard, New PKD Data Standard Aims to Multiply the Impact of Research Investments Worldwide

TUCSON, Ariz. and AUSTIN, Texas, September 4, 2026 — The Clinical Data Interchange Standards Consortium (CDISC), in partnership with the PKD Foundation and Critical Path Institute (C-Path), today announced the expansion of their collaboration to develop Version 2.0 of the Therapeutic Area User Guide for Polycystic Kidney Disease (TAUG-PKD). Announced in conjunction with PKD Awareness Day on September 4, the enhanced digital TAUG will help researchers worldwide generate more comparable, reusable, and regulatory-ready data, accelerating scientific discovery and therapeutic development for people affected by autosomal dominant polycystic kidney disease (ADPKD) and, for the first time, autosomal recessive polycystic kidney disease (ARPKD).

High-quality data standards are essential to research infrastructure. By enabling data from studies, registries, and clinical trials to be collected and structured consistently, the PKD Therapeutic Area User Guide helps maximize the value of research investments, strengthens collaboration across organizations, and creates a foundation for future breakthroughs. As scientific discoveries accelerate, investments in shared research infrastructure are becoming increasingly important to ensure that valuable research data can be connected, reused, and translated into meaningful advances for patients. Therapeutic area user guides provide one such foundation, benefiting the entire disease community.

For patients and families affected by PKD, greater data consistency means researchers can learn more from every study, helping transform individual research efforts into collective progress toward new treatments. Originally developed through a collaboration among the Critical Path Institute's Polycystic Kidney Disease Outcomes Consortium (PKDOC), CDISC, and the PKD Foundation, Version 1.0 of TAUG-PKD incorporated data collected through patient registries, observational studies including CRISP, and landmark clinical trials such as HALT-PKD. The TAUG has supported the pooling and analysis of data across studies and contributed to regulatory review activities, including the qualification of total kidney volume as a biomarker for disease progression for ADPKD.

As clinical research increasingly relies on interoperable data and advanced analytics, TAUG- PKD v2.0 reflects a new generation of standards. It will no longer simply be a static document but part of a connected digital ecosystem that can evolve alongside the science and be consumed by modern technologies, including AI-enabled tools. This approach makes the TAUG more accessible, easier to maintain, and better positioned to support the future of clinical research.

“Every clinical study represents a significant investment by patients, researchers, funders, and sponsors. By making those data more reusable and connected, we can help ensure that each study contributes to a larger body of knowledge that accelerates the path toward better treatments.” said Bess LeRoy, Head of Standards Innovation at CDISC. “By combining modern CDISC standards with digitally connected biomedical concepts, this update creates infrastructure that supports collaboration across researchers, registries, sponsors, and regulators. The result is higher-quality evidence, greater efficiency, and faster progress toward new treatments.”

PKD TAUG Version 2.0 extends CDISC Foundational Standards and provides researchers, sponsors, patient registries, and research organizations with a common framework for collecting and organizing PKD research data. The updated guide reflects advances in PKD science, terminology, and implementation experience gained since the original publication while incorporating CDISC's 360i principles through digitally connected biomedical concepts that support greater automation and interoperability throughout the clinical research lifecycle.

The scope of Version 2.0 has also expanded to include Autosomal Recessive Polycystic Kidney Disease (ARPKD), reflecting growing scientific interest and therapeutic development efforts in this rare form of the disease. Standardized data collection will help researchers better understand disease progression, compare outcomes across studies, and generate stronger evidence to support future treatment development.

By creating a common approach to data collection and organization, the updated standard makes it easier for researchers across institutions, countries, and studies to share, compare, combine, and reuse data. This reduces duplication of effort, improves data quality, supports more efficient regulatory review, and enables more powerful analyses that can reveal new insights into disease progression, treatment response, and patient outcomes.

“Funding data standards is one of the highest-leverage investments a foundation can make because it multiplies the value of every future research study. A common data standard transforms individual studies into a shared scientific resource,” said Sorin Fedeles, Executive Director, Rare and Orphan Disease Program, Critical Path Institute. “Expanding the PKD Therapeutic Area User Guide to include ARPKD will enable researchers to generate stronger evidence from collective data, creating new opportunities to accelerate therapeutic development and improve outcomes for patients.”

“The PKD Therapeutic Area User Guide creates a common language for research that allows data to be more effectively shared, compared, and reused,” said Dr. Ron Perrone on behalf of the PKD Foundation. “By including both ADPKD and ARPKD, this update strengthens the research ecosystem and helps ensure that every study contributes more effectively to improving outcomes for patients and families affected by PKD.”

The TAUG-PKD v2.0 reflects a shared commitment by CDISC, the PKD Foundation, and Critical Path Institute to ensure that data generated today can continue driving discoveries for years to come. By enabling collaboration, data sharing, and evidence generation across the global research community, the standard helps create a stronger foundation for innovation, bringing researchers, funders, clinicians, and patient advocates together to accelerate progress toward better therapies for people living with PKD. TAUG-PKD v2.0 is being developed through collaboration among CDISC, the PKD Foundation, and Critical Path Institute, with additional information about release timing and availability to be shared as the work progresses.

About CDISC

The Clinical Data Interchange Standards Consortium (CDISC) creates clarity in clinical research by convening a global community to develop and advance data standards of the highest quality. CDISC standards enable the collection, sharing, and analysis of clinical research data in ways that improve efficiency, increase interoperability, and accelerate the generation of evidence needed to advance human health.

About Critical Path Institute

The Polycystic Kidney Disease Outcomes Consortium (PKDOC), a program of [Critical Path Institute](#), brings together patients, researchers, industry, regulators, and advocacy organizations to accelerate therapeutic development for polycystic kidney disease.

About PKD Foundation

[The PKD Foundation](#) is dedicated to finding treatments and a cure for polycystic kidney disease while improving the lives of those affected by the disease through education, advocacy, research, and support.