U.S. Food and Drug Administration Awards Contract to Critical Path Institute for Kidney Transplant Database

Patient-level data will inform the creation of drug development tools and speed development of new immunosuppressive treatments

TUCSON, Ariz., December 12, 2018 — The U.S. Food and Drug Administration (FDA) has awarded a contract to Critical Path Institute (C-Path) in support of a new project to create a database of patient-level clinical trial data that will be used to inform the design of drug development tools (DDTs). C-Path's Transplant Therapeutics Consortium (TTC) will carry out the work, which aims to accelerate the development of immunosuppressive drugs for the treatment of individuals who receive kidney transplants.

The new integrated database will serve as a foundational resource to enable and accelerate creation of DDTs, including quantitative drug development platforms, clinical trial simulation tools and biomarkers that support the development of novel immunosuppressive drugs.

"Lack of an integrated and standardized database that captures the complex heterogeneity of kidney transplant patients has posed a significant challenge in kidney transplant drug development," explained TTC Executive Director Inish O'Doherty, Ph.D. "The FDA's support for creating such a database will have a long-term positive impact in this rare disease by providing a foundational resource for the development of novel drug development tools."

Funding received through the new FDA contract will be used in conjunction with TTC membership fees to develop the database, which will include existing patient-level data from immunosuppressive drugs clinical trials, patient registries and longitudinal observational studies in kidney transplantation. The data will be acquired from clinical trials conducted by pharmaceutical and biotech companies, academic researchers and the National Institutes of Health.

"We are honored to receive FDA support of, and collaboration on, this new project," said C-Path President and CEO Martha Brumfield, Ph.D. "FDA funding, in combination with the resources and expertise of TTC, will enable development of much-needed tools for the scientific community and, most importantly, will ultimately lead to improved medical outcomes for kidney transplant patients."

The TTC, established in March 2017, with founding members the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS), and led by C-Path, is a collaboration among professional transplant societies, pharmaceutical industry stakeholders and regulatory agencies. TTC's long-term goal is to accelerate development of immunosuppressive drugs for transplantation by providing DDTs designed to solve the issues that have hindered advancement in this field. TTC initially is focused on DDTs for use with kidney transplantation.

About Critical Path Institute

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 major 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.

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