C-Path Launches Acute Kidney Injury Project with Support from FDA

Project aims to develop improved predictive and detection tools for kidney injury

TUCSON, March 25, 2021 — Acute kidney injury (AKI) is a global, and potentially fatal, public health concern impacting nearly 13 million people per year. Defined clinically as an acute decrease in kidney function, AKI is associated with significant morbidity, mortality, and costs, with annual estimated health care expenditures ranging from $6.6 to $10 billion in the United States. AKI can be caused by dehydration, certain infections, and low blood flow to the kidneys, but it can also be caused by medications. This is known as drug-induced kidney injury (DIKI).

DIKI is of paramount concern when developing new drugs, but today's widely used methods for predicting and detecting such injury are not sufficiently specific or sensitive which creates obstacles and inefficiencies during drug development. Better tools are needed for identifying DIKI to improve patient safety during clinical trials, detect injury at an early and reversible stage, and more accurately inform drug developers about the performance of new therapies. To address this challenge, the Critical Path Institute (C-Path) announced today that it has launched the Acute Kidney Injury Project, in partnership with the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, Office of Translational Science and the Division of Cardiology and Nephrology, aimed at developing a suite of prognostic tools to improve the prediction and detection of DIKI.

"Since 2005, C-Path has been a catalyst for the development of novel approaches in medical innovation," said John-Michael Sauer, Ph.D., Senior Vice President of C-Path's Translational and Safety Sciences Program. "The objective of this integrated AKI initiative is to bring key opinion leaders from the nephrology community together to identify an action plan for leveraging recent successes and current innovative work across several stakeholder groups to advance the field, including the pharmaceutical industry which is positioned to propel this effort by sharing data from clinical and nonclinical studies."

To launch this effort, an Acute Kidney Injury Working Group (AKI WG) has been established with representation from FDA, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the American Society of Nephrology (ASN) and Kidney Health Initiative (KHI), representatives from academic research programs and pharmaceutical industry, and individuals living with AKI.

"Having experienced AKI personally, I know firsthand the impact it has on a patient and their family. Patient insight information is vitally important for the scientific community to understand as they work to identify DIKI as early as possible and to clearly explain implications for those who are affected," explained Richard Knight, MBA, President of the American Association of Kidney Patients. "I am honored to be engaged in this endeavor as we create an intersection for patients, families, academia, the pharmaceutical industry and health authorities to collaborate effectively toward shared, patient-centered goals."

One of AKI WG's near-term deliverables is to convene a public workshop dedicated to identifying how academia, health authorities, patient advocates, and the pharmaceutical industry can collaborate and share knowledge from past and future studies to generate novel tools, including systems that allow for an accurate simulation of kidney injury in the lab and in computers, as well as non-invasive tests for patients. "Technological advances now enable large-scale datasets to be captured from individuals with and without

AKI, which presents an incredible opportunity," shared Mattias Kretzler, M.D., Professor of Computational Medicine & Bioinformatics and Professor of Internal Medicine at University of Michigan Medical School and co-chair of the AKI WG. "The power of coordinated data sharing has been demonstrated in addressing unmet medical needs for other medical challenges. The time is now to apply this collaborative and holistic approach to advance the development of predictive models of drug-induced kidney toxicity."

The AKI Project will focus primarily on the development of predictive tools for DIKI, but it is anticipated this initiative will also feed into, synergize with, and offer support for current and future efforts to develop tools to advance drug development for other causes of AKI and ultimately improve the care of AKI patients.

Researchers, clinicians, and pharmaceutical companies interested in learning more about how to participate in the AKI Project can email Dr. Sauer at jsauer@c-path.org.

Critical Path Institute is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) and is 55% funded by FDA/HHS, totaling $14,575,306, and 45% funded by non-government source(s), totaling $11,916,747. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government. For more information, please visit FDA.gov.

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Critical Path Institute (C-Path) 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 more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path US is headquartered in Tucson, Arizona and C-Path, Ltd. EU is headquartered in Dublin, Ireland, with additional staff in multiple other locations. For more information, visit c-path.org and c-path.eu.

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