New Biomarkers Could Improve Early Detection, Monitoring of Kidney Injury

Leading global kidney safety consortium and researchers publish results on six biomarkers of kidney injury that could help lead to the development of safer medications and improve patient outcomes.

TUCSON, Ariz. March 6, 2025 — Critical Path Institute® (C-Path) and Boston Medical Center (BMC) published results for six biomarkers that could improve the early and accurate detection of kidney injury, leading to both the development of safer medications and better health outcomes for all patients. The results leverage the collaborative expertise and investment of C-Path's Predictive Safety Testing Consortium's (PSTC) Nephrotoxicity Working Group, and the Clinical Evaluation and Qualification of Translational Kidney Safety Biomarkers Project, a public-private partnership managed collaboratively by the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium Kidney Safety Biomarker Project Team.

Drug-induced kidney injury, or nephrotoxicity, is a common complication in clinical medicine that happens when certain drugs at certain doses damage the kidneys. Nephrotoxicity can occur with multiple types of medicines, including anti-inflammatory, antibacterial, antiretroviral, or chemotherapeutic medicines and can lead to therapies being discontinued or restricted from patients. The findings from this collaboration were published recently in *Clinical Pharmacology & Therapeutics*. Sushrut Waikar, M.D., MPH, first author on the paper, said that these biomarkers may offer an approach to detect drug-induced kidney damage earlier than with existing standards for monitoring kidney health and can lead to more tolerable treatment options.

"Current biomarkers can be too slow at showing early signs of kidney injury," said Waikar, Chief of Nephrology and Interim Medicine Chair at BMC. "These biomarkers, which can be measured in the urine, could help clinicians detect kidney damage within 24 hours of injury, enabling more timely monitoring during drug development and better treatment of patients who are at risk in clinical settings."

The research team examined urinary levels of protein biomarkers in healthy volunteers and patients undergoing treatment for mesothelioma with a chemotherapy drug that is known to have toxic effects on the kidneys. This enabled the researchers to better understand how kidney function changes in response to injury.

The team assessed performance of six promising biomarkers to detect drug induced kidney injury with more sensitivity and specificity than traditional markers. Most of the assessed biomarkers are generated in the kidneys themselves in response to injury or inflammation. This enables detection of kidney injury quicker than current biomarkers, like serum creatinine, which can sometimes take several days to reach abnormal levels.

The research team now hopes to assess whether these biomarkers can be used more broadly to monitor kidney health in healthy volunteers during phase 1 clinical trials.

Earlier detection of kidney damage could allow clinicians to intervene sooner, reducing the risk of long-term damage and improving patient outcomes across all settings. "These biomarkers have the potential to make a real difference in how we monitor kidney health and manage patients at risk for kidney damage," said Waikar, who is also the Norman G. Levinsky Professor of Medicine at Boston University Chobanian & Avedisian School of Medicine. "We are hopeful that these findings will contribute to better strategies for preserving kidney function and improving patient care, as well as advancing drug development."

“Collaboration is key to advancing new tools for drug safety and patient care,” said Nicholas King, PSTC’s Executive Director at C-Path. “By bringing together experts across sectors, we can assess and validate promising biomarkers, helping to accelerate their use in drug development. This study highlights how working together leads to meaningful progress in detecting and preventing kidney injury.”

Waikar is a consultant on nephrotoxicity biomarkers for drugs in development for Vertex, PepGen, and Ikena.

About C-Path’s Predictive Safety Testing Consortium (PSTC)

C-Path’s Predictive Safety Testing Consortium (PSTC) was founded in 2006 to serve as a pre-competitive collaboration for the independent assessment, advancement, and validation of novel drug safety tests. PSTC was formed and officially announced by Health and Human Services Secretary Michael Leavitt, U.S. Food and Drug Administration (FDA) Commissioner Dr. Andrew von Eschenbach, and FDA Deputy Commissioner Dr. Janet Woodcock. Upon its inception, Woodcock described the consortium as “unprecedented” and a “shining example” of the type of work the FDA would like to see conducted. PSTC’s goal is to obtain regulatory acceptance of novel drug safety tests. PSTC brings together pharmaceutical companies to share and validate innovative safety testing methods under advisement of the FDA, its European counterpart, the European Medicines Agency, and the Japanese Pharmaceutical and Medical Devices Agency. Currently, PSTC is focused on developing and obtaining regulatory qualification of improved clinical safety biomarkers for use in drug development.

About Critical Path Institute

Founded in 2005, as a public-private partnership in response to the FDA’s Critical Path Initiative, Critical Path Institute® (C-Path) celebrates its 20th anniversary as a vital, independent, nonprofit. **C-Path’s mission is to lead collaborations that advance better treatments for people worldwide**. Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path’s global headquarters is located in Tucson, Arizona and C-Path’s Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

About the FNIH Biomarkers Consortium

The Foundation for the National Institutes of Health’s Biomarkers Consortium leads cross-sector efforts to validate and qualify biomarkers that accelerate the development of new therapeutics and health technologies. The core operations of the Biomarkers Consortium are supported through its contributing membership program, which includes the National Institutes of Health, the U.S. Food and Drug Administration, private industry, and not-for-profit organizations. Read more about the project **here.**

About Boston Medical Center

Boston Medical Center models a new kind of excellence in healthcare, where innovative and equitable care empowers all patients to thrive. We combine world-class clinicians and cutting-edge treatments with compassionate, quality care that extends beyond our walls. As an award-winning health equity leader, our diverse clinicians and staff interrogate racial disparities in care and partner with our community to dismantle systemic inequities. And as a national leader in research and the teaching affiliate for Boston University Chobanian & Avedisian School of Medicine, we’re driving the future of care.

Media Contacts:

Roxan Triolo Olivas
C-Path

520.954.1634
rolivas@c-path.org

Kissy Black
C-Path
615.310.1894
kblack@c-path.org