
C-Path's New Clinical Pharmacology & Therapeutics Publication Highlights Real-World Impact of FDA-Qualified Urine Biomarkers for Earlier Detection of Drug-Induced Kidney Injury

TUCSON, Ariz., January 28, 2026 — Critical Path Institute's® (C-Path) Predictive Safety Testing Consortium today announced the publication of a new peer-reviewed manuscript in [Clinical Pharmacology & Therapeutics](#). The paper describes the real-world implementation and impact of a U.S. Food and Drug Administration (FDA) qualified panel of six urine biomarkers for detecting drug-induced kidney injury (DIKI) in early clinical drug development.

The article, "Biomarkers of Drug-Induced Kidney Injury: Use in Clinical Trials and Recent Examples of Impact on Drug Development," was published online November 23, 2025, and is authored by consortium members Tanja Zabka (Genentech), Tom Chu (Genentech), Warren Glaab (Merck), Katrina Peron (C-Path), and Nicholas King (C-Path).

Kidney safety monitoring is essential throughout drug development, yet standard clinical laboratory tests can lack the sensitivity and specificity needed to detect nephrotoxicity early and to inform timely decision-making. Further, these urine biomarkers can complement standard lab tests to add confidence to the lack of a DIKI signal and provide more holistic pathomechanistic insight. This publication describes how a regulatory agency-qualified panel of six urine biomarkers, developed through a collaboration conducted and funded by C-Path, the Foundation for the National Institutes of Health, and FDA, is being used in early clinical programs to support monitoring of DIKI, or lack thereof.

The manuscript:

- Summarizes real-world, early clinical development case studies from multiple pharmaceutical companies illustrating how FDA-qualified DIKI biomarkers can support earlier and more sensitive monitoring of nephrotoxicity and inform "go/no-go" and dose decisions.
- Reports that the use of these non-standard-of-care biomarkers as prespecified safety endpoints in clinical trials registered on ClinicalTrials.gov has increased since FDA qualification in 2018.
- Describes the FDA-qualified panel, which includes clusterin, cystatin C, kidney injury molecule-1, N-acetyl- β -D-glucosaminidase, neutrophil gelatinase-associated lipocalin, and osteopontin (normalized to urine creatinine) and a composite measure or individualized approach used in early clinical trials.

"Drug-induced kidney injury has been a significant contributor to late-stage setbacks and avoidable development costs," said Nicholas King, M.S., Predictive Safety Testing Consortium Executive Director at C-Path. "This paper documents how qualified urine biomarkers are being used in practice to improve confidence in renal safety monitoring and support smarter early development decisions."

The article's first author, Tanja Zabka, Senior Fellow Pathologist at Genentech, said, "These collective learnings across industry partners are crucial to advancing these emerging and regulatory-endorsed biomarkers to our next generation of safety labs and to advance safety science — we encourage further engagement from the community."

C-Path's Biomarker Data Repository provides qualified industry and academic researchers access to a growing resource of contemporaneous biomarker data sets and analytics tools to help contextualize their own

results, confirm performance of qualified non-standard-of-care biomarkers, and support development of new contexts of use, including for emerging biomarkers.

The manuscript illustrates how these non-standard-of-care kidney injury biomarkers are already influencing drug development by enabling more sensitive monitoring of DIKI over time (including rise-to-peak and return to baseline), supporting earlier, better-informed decisions in clinical programs. Continued data generation and regulatory engagement are expected to expand adoption and future applications, including improved detection as well as potential prognostic and disease-progression monitoring to advance therapies for patients with kidney disease.

About Critical Path Institute

Critical Path Institute (C-Path) is an independent, nonprofit established in 2005 as a public-private partnership in response to the FDA's Critical Path Initiative. 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.

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About Predictive Safety Testing Consortium

The Predictive Safety Testing Consortium's goal is to obtain regulatory acceptance of novel drug safety tests. The consortium brings together pharmaceutical companies to share and validate innovative safety testing methods under advisement of the FDA, the European Medicines Agency, and the Japanese Pharmaceutical and Medical Devices Agency. Currently, the safety testing consortium is focused on developing and obtaining regulatory qualification of improved clinical safety biomarkers for use in drug development. For more information, visit the [Predictive Safety Testing Consortium](#) page.

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