FDA Accepts Qualification Plan for Urine Biomarker Panel to Allow Earlier Detection of Response to Drug-Induced Kidney Injury in Clinical Trials

The Foundation for the National Institutes of Health (FNIH) and Critical Path Institute® (C-Path) announced that the Food and Drug Administration (FDA) has accepted the Qualification Plan (QP) for a urine biomarker panel to be used in conjunction with standard renal safety laboratory tests to indicate responses to drug-induced injury to the kidneys. The panel, which is intended for use in people with normal renal function, represents a major advancement in protecting the health of participants in early-phase drug development trials, where safety risks are often uncertain.

“This biomarker panel has the potential to significantly reduce the risk of acute kidney injury and chronic kidney disease during drug development, leading to safer, more precise treatments,” said Steve Hoffmann, Vice President, Science Partnerships, and Programmatic Lead for the Kidney Safety Project at the FNIH.

Current kidney safety tests, including serum creatinine, blood urea nitrogen, and cystatin C, often detect injuries too late to prevent severe damage. The new panel of eight urinary kidney safety biomarkers is intended to complement these standard methods, offering more specific and sensitive tools for early detection, monitoring, and potential reversibility of kidney injuries during clinical trials.

The QP acceptance is an achievement made possible through the Clinical Evaluation and Qualification of Translational Kidney Safety Biomarkers Project, a public-private partnership managed collaboratively by the FNIH Biomarkers Consortium Kidney Safety Biomarker Project Team and the C-Path Predictive Safety Testing Consortium’s (PSTC) Nephrotoxicity Working Group with financial support from Amgen, Inc., AstraZeneca, Critical Path Institute, Eli Lilly and Company, the FNIH, Johnson & Johnson, Merck, and Pfizer, Inc. The initiative brought together expertise from the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health, the FDA, academia, industry, and advocacy organizations.

“This regulatory milestone is a pivotal step forward in improving clinical safety biomarkers for use in drug development,” said Nicholas King, Executive Director, PSTC at C-Path. “Our continued focus on pre-competitive collaboration drives the independent assessment, advancement, and validation of novel drug safety tests, accelerating their adoption in drug development.”

The project team plans to submit a Full Qualification Package to the FDA for final approval of the biomarker panel in mid-2025.

Read more about the project **here.** Learn more about the FNIH Biomarkers Consortium **here** and the C-Path PSTC **here.**