

C-Path, FNIH Announce Clinical Development User’s Guide for Kidney Safety Biomarkers



TUCSON, Ariz., March 14, 2019 — The Critical Path Institute’s (C-Path) Predictive Safety Testing Consortium (PSTC) today announced availability of the User’s Guide: Kidney Safety Composite Measure Biomarker for Use in Clinical Development.

Authored by the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium Kidney Safety Biomarker Project Team and PSTC’s Nephrotoxicity Working Group, the Guide provides drug development companies with important information about implementing the [first ever clinical safety biomarker qualified by the US Food and Drug Administration \(FDA\)](#). The qualification applies to a single composite measure of six urine biomarkers, to be used in conjunction with traditional measures of kidney function, a major milestone that will improve the detection of drug-induced kidney injury in early phase drug development.

“Drug-induced kidney injury is a key safety issue that can slow the development of new therapies,” explained John-Michael Sauer, Program Officer of C-Path’s Biomarkers Program and PSTC Executive Director. “While qualification of the composite measure kidney safety biomarker is an important accomplishment, its true impact will be realized as the biomarker is implemented by drug developers in Phase 1 clinical trials to inform clinicians and investigators in their work.”

Included in the [User’s Guide](#) is information about why the biomarker is important, its context of use, how it should be used, how results should be interpreted, mode of measurement and methodologies drug developers can use to calculate and apply the biomarker to detect kidney injury during Phase 1 clinical trials.

For more information about the FNIH Biomarkers Consortium’s Clinical Evaluation and Qualification of Translational Kidney Safety Biomarkers Project, [click here](#).

For more information about PSTC’s ongoing work to improve drug safety and accelerate development of new therapies, click [here](#).



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 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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