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CRITICAL PATH INSTITUTE 20 YEARS OF IMPACT

Advancing Drug Development. Improving Lives. Together.

December 2025

Welcome to C-Path's BmDR Quarterly Newsletter!

This year's final newsletter provides an overview of 2025 accomplishments, our vision for 2026, and a preview of C-Path's first Biomarker Data Repository (BmDR) virtual workshop on December 12. Sustained growth and active engagement are critical as we collaborate to strengthen the science and application of kidney safety biomarkers. Collaboration across stakeholders — including clinicians, researchers, patients, regulators, and industry — remains at the heart of BmDR's mission, ensuring our efforts have the greatest possible impact on patient health. Our new series of virtual workshops is intended to increase awareness and encourage participation and contributions to BmDR to achieve these goals.

In this edition, we are excited to recap the BmDR team's time at the 2025 American Society of Nephrology (ASN) Kidney Week, where they showcased the power of shared data in biomarker discovery and qualification. We participated in partner meetings and presented two posters on BmDR work, detailed below.

In November 2025, C-Path's Predictive Safety Testing Consortium (PSTC) — home to the team behind the Biomarker Data Repository (BmDR) and its ongoing safety biomarker qualification efforts — received FDA qualification for glutamate dehydrogenase (GLDH) as a biomarker to enhance liver safety monitoring in clinical trials. Read more about the qualification here.

We also provide updates from PSTC's latest developments in the ongoing qualification