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 effort for a panel of kidney safety biomarkers, as well as progress on several manuscripts currently underway as part of BmDR's publication and communication strategy. These publications aim to expand the reach of BmDR findings and further establish the repository as a resource for the global kidney research community. This progress reflects the momentum we've built together

and the opportunities ahead to strengthen the repository's role in advancing safe and effective therapies.

As always, the involvement of people affected by kidney disease is central to our mission. By combining robust data, scientific rigor, and patient perspectives, the BmDR team continues to move the field forward toward impactful solutions for unmet needs in kidney health. If you're interested in joining one of the BmDR Committees, participating in workshops, or sharing your expertise, please contact us at bmdr@c-path.org.

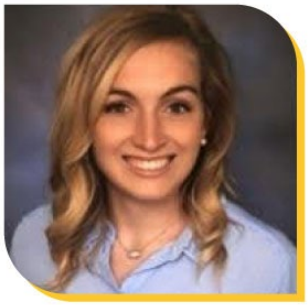
Sincerely,

Nicholas King, MS

Executive Director
Predictive Safety Testing Consortium
nking@c-path.org

Katrina Peron, MS, RAC

Associate Director
Predictive Safety Testing Consortium
kperon@c-path.org



Claire Bassetti

Communications and Engagement Manager
Predictive Safety Testing Consortium
cbassetti@c-path.org

Q&A: How does BmDR operate?

BmDR works by collecting and including deidentified data on emerging safety biomarkers' studies (clinical and nonclinical). The initial focus of BmDR is on kidney injury biomarkers. Research groups and pharmaceutical companies can contribute their data into BmDR through a secure process, where it is then stored on the Data and Analytics Platform (DAP). Qualified researchers can then request access to the data. Once approved, they may examine the data for new applications in clinical practice and drug development to pursue regulatory qualifications of the biomarkers. When biomarkers are qualified, they have set ranges of values and determined contexts of use that may be used during clinical trials for drugs, and throughout the entire drug development process to monitor safety and effectiveness.

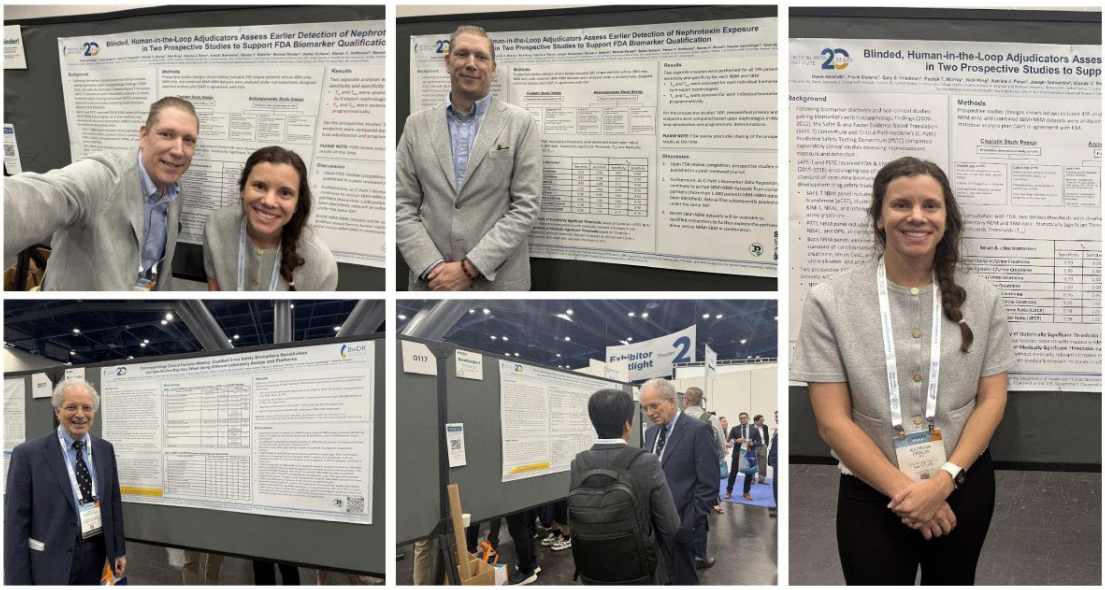
Video Resources:

1. What is the Biomarker Data Repository?
2. What Are Biomarkers and Why Are They Important?

For additional questions on BmDR, view the Technical and Patient-Focused FAQs.

ASN Kidney Week 2025 Recap

The American Society of Nephrology (ASN) 2025 Kidney Week occurred in November 2025. BmDR Oversight Committee (OC) members Joseph Bonventre, Nicholas King, and Katrina Peron attended and presented two posters detailing BmDR's work on collating and analyzing kidney safety biomarkers. One provided an onconephrology example where two different labs measured qualified urine kidney biomarkers, and the other summarized the adjudication process from an in-process qualification of a panel of non-standard-of-care biomarkers. BmDR OC members attended the KPMP Industry Roundtable, where we participated in a technical walkthrough of the KPMP Tissue Atlas. Nicholas King also provided an overview of the biomarker qualification process to members of C-Path's Polycystic Kidney Disease Outcomes Consortium (PKDOC) at their annual symposium.



Co-Chair Corner: BmDR Year in Review & Patient Impact

With the systematic completion of multiple non-clinical and clinical studies, along with rigorous regulatory engagement, **2025 is the Year the Biomarker Data Repository Went Live**. This milestone reflects years of collaborative effort and positions the repository as a central resource for advancing kidney biomarker science.

The accumulation of paired datasets — standard-of-care biomarkers (SBM) alongside non-standard-of-care biomarkers (NBM) (data from the same individual allowing for direct comparison) — has begun, with thousands of datapoints already available for qualified researchers. These robust datasets are now being accessed for independent analyses, creating opportunities to evaluate biomarker performance across age groups, diverse demographics, and the full spectrum of baseline kidney function.

BmDR's active status and progression was made possible through the collaboration, guidance, and input of industry, academic, and biostatistics leaders across North America and Europe. In parallel, the BmDR Oversight Committee and BmDR Data Analytics Platform (DAP) provide governance and technical infrastructure to ensure that qualified researchers can advance investigations with rigor and transparency.

For the first time, a group of qualified researchers composed primarily of patient partners with kidney disease is accessing BmDR datasets. Their lived experience offers unique insight into how paired biomarkers reveal kidney health over time, and their analyses may guide future applications in clinical care. Imagine a patient who joins a clinical trial informed by BmDR data. Because researchers have already demonstrated how novel biomarkers track kidney injury, the patient and their nephrologist can discuss results and participation with greater confidence. This exchange, grounded in real trial data, demonstrates how the repository can already be used to shape the patient–clinician conversations today.

In this way, the repository contributes to building trust by elevating patient voices in research, supports earlier interventions through insights shared from clinical trial participation, and empowers patients to make informed choices that strengthen collaboration with their nephrologists. As these trailblazers illuminate the path forward, BmDR provides the evidence base to accelerate biomarker validation and ensure that hidden kidney damage no longer remains unseen.

Gary Friedman

BmDR Oversight Committee
Co-Chair, Retired Pharmaceutical Industry Executive

Glenda Roberts

BmDR Oversight Committee
Co-Chair, Director, Communications and Patient Engagement:
Mount Sinai Center for Kidney Disease Innovation; Icahn School of Medicine

Latest Developments

The FDA has **qualified glutamate dehydrogenase (GLDH) as a safety biomarker** to detect drug-induced liver injury (DILI) in clinical trials. The qualification represents a major advancement in drug safety science and marks the

culmination of transformative collaborative work led by PSTC, in collaboration with C-Path's Duchenne Regulatory Science Consortium (D-RSC), global partners across academia, industry and regulatory agencies. GLDH was identified as a promising alternative to current standard biomarkers (serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST)) because it is expressed primarily in the liver, with only trace amounts found in muscle. Unlike ALT and AST, GLDH levels are not affected by muscle damage, making it a more specific indicator of liver cell injury. FDA's qualification means GLDH may now be used in clinical trials to help diagnose liver injury in participants with muscle disease or suspected muscle degeneration — an important advancement for drug developers, and for patient safety. Over time, the intention is that GLDH will be incorporated more broadly across the drug development process as a standard tool to evaluate liver health. Read the full press release here.

After PSTC's Kidney Safety Project team received a positive determination letter from the FDA in December 2024 for the Qualification Plan for a Novel Biomarker Panel (NBMP), the team began executing the statistical analysis plan (SAP). The SAP has been completed, and the team is now drafting the Full Qualification Package to be submitted to the FDA by January 2026, requesting qualification of the NBMP. This work will demonstrate how the NBMP can be used in conjunction with standard laboratory tests to indicate response to DIKI. Qualification of the NBMP would support early detection, monitoring, and potential reversibility of kidney injuries during clinical trials. Read the press release here.

PSTC and BmDR continue to execute their publication strategy!. The manuscript titled "Biomarkers of Drug-induced Kidney Injury: Use in Clinical Trials and Recent Examples of Impact on Drug Development" co-authored by PSTC and BmDR members was accepted for publication by *Clinical Pharmacology & Therapeutics* (https://ascpt.onlinelibrary.wiley.com/doi/10.1002/cpt.70134). This paper highlights the use of qualified kidney biomarkers in clinical trials and by pharmaceutical companies in early clinical development decision making and demonstrates the impact of the qualification effort. Additional manuscripts in process detail:

1. BmDR strategy

2. How to use the qualified kidney biomarker Composite Measure

3. How the BmDR is relevant to patients

4. The expert adjudication process utilized in the current kidney biomarker qualification

By the Numbers

New Data

This month, two Data Contribution Agreements (DCA) have been executed with organizations for their data to be added to the BmDR DAP. One study measured kidney injury biomarkers in normal healthy volunteers (NHV), chronic kidney disease patients, and kidney transplant pediatric subjects. The other dataset measured kidney injury biomarkers after mesothelioma surgery and cisplatin administration. These datasets will be available on the DAP in early 2026.

Enter the BmDR DAP to view the BmDR data collection and request datasets: https://portal.cpdap.c-path.org/.

Accessing Data on BmDR

Qualified researchers can request access to the BmDR DAP to review and interrogate data, as well as request specific datasets, using this link: https://portal.cpdap.c-path.org/. For further instructions and details on how to review and request datasets on the DAP, watch this video and attend our December workshop.

Contributing to BmDR

The BmDR team is in talks with organizations for an additional 10 clinical datasets, which will aid in our goal of expanding the volume and capabilities of

the repository. Outreach continues to consortia, academic researchers, and companies with relevant data sets to contribute.

Please consider contributing your data to BmDR. Populations of interest to the team include pediatric study populations. If interested in participating in any of the BmDR committees or to discuss contributing data, please contact bmdr@c-path.org, Nicholas King or Katrina Peron.

Upcoming Events

LAST CHANCE TO REGISTER! BmDR Virtual Workshop | December 12, 2025

BmDR will be hosting the inaugural virtual workshop titled BmDR: **A New Collective Resource to Drive Improvements in Kidney Health on Friday, December 12 at 2 p.m**. Eastern. The first session will set the stage for how BmDR supports innovation, collaboration and patient impact in biomarker science. The intention of the workshop is to broadcast what has been accumulated and analyzed in BmDR thus far and educate the community on what BmDR can be utilized for. We will review the structure of BmDR, what datasets are available for request on the Data and Analytics Platform and how that relates to what has been accumulated, reviewing example analyses that have been performed, and hearing a firsthand story from a chronic kidney disease patient. The workshop will include a panel of expert nephrologists, academics, and patient representatives, where they can address audience feedback in real time. If you have any questions ahead of the workshop, please send them to bmdr@c-path.org.

Register Now!

Recent Publications:

Advancing Health Equity in Kidney Disease through Sustainable Policy and Community Partnership:Patient Perspectives and Research Realities

Roberts, Glenda V. Advancing Health Equity in Kidney Disease through Sustainable Policy and Community Partnership: Patient Perspectives and Research Realities. Clinical Journal of the American Society of Nephrology:10.2215/CJN.0000000929, November 13, 2025. | DOI: 10.2215/CJN.0000000929

Special consideration: commentary on the 2025 FDA Bioanalytical Method Validation for Biomarkers.

Quadrini, K. J., Aubrecht, J., King, N. M. P., Fernandez-Metzler, C., Ni, Y. G., Sauer, J. M., ... Piccoli, S. P. (2025). Bioanalysis, 17(14), 899–900

Early and Sensitive Detection of Cisplatin-Induced Kidney Injury Using Novel Biomarkers.

Strader, M., Friedman, G., Benain, X., Camerlingo, N., Sultana, S., Shapira, S., Aber, N., & Murray, P. T. 2025. Kidney International Reports, 10(4), 1175–1187

Urinary Kidney Injury Biomarker Profiles in Healthy Individuals and After Nephrotoxic and Ischemic Injury.

Waikar, Sushrut S., Robin Mogg, Amanda F. Baker, Gyorgy Frendl, Michael Topper, Scott Adler, Nicholas MP King, Stefan Sultana, et al. 2025. Clinical Pharmacology & Therapeutics

Serum Glutamate Dehydrogenase Activity Enables Sensitive and Specific Diagnosis of Hepatocellular Injury in Humans.

Aubrecht, Jiri, David Potter, John Michael Sauer, Roscoe Warner, Kent Johnson, Mitchell R McGill, Katrina Peron, and Nicholas M P King. Toxicological Sciences, November 6, 2024.

Leveraging Biomarkers and Translational Medicine for Preclinical Safety - Lessons for Advancing the Validation of Alternatives to Animal Testing.

Hartung, Thomas, Nicholas M. P. King, Nicole Kleinstreuer, Marcel Leist, and Danilo A. Tagle. October 22, 2024. ALTEX - Alternatives to Animal Experimentation, 41(4):545–566

Qualified kidney injury biomarkers demonstrate value during early clinical drug development.

Ravindra KC, Fader KA, Potter D, Radi ZA, Friedman GS, Brenneman KA, Amin NB, Weiss R, Danto SI, Page K, Ramaiah SK, Vaidya VS. Toxicological Sciences. October 1, 2024, 201(2):206–215

At a Glance

BmDR Website

Past BmDR Newsletters and Resources

BmDR Data and Analytics Platform (DAP)

BmDR December 12 Workshop Registration

C-Path 2022 DIKI Workshop - Patient Perspective Videos

AAKP Global Summit on Kidney Disease Innovations – BmDR Session

If you have any questions about BmDR, please email bmdr@c-path.org.

Help support our mission. **MAKE A GIFT TODAY**

1840 E River Rd, Suite 100 | Tucson, AZ 85718 | (520) 547-3440 | info@c-path.org
c-path.org

FDA Acknowledgment