



Advancing Drug Development. Improving Lives. Together.

June 2025

Welcome to C-Path's BmDR Quarterly Newsletter!

This newsletter is to inform and connect all involved in C-Path's Biomarker Data Repository (BmDR). Your participation is essential to advancing the effort to better understand and qualify biomarkers. Collaboration remains key to the success of BmDR, and we encourage you to stay engaged with and contribute to our collective efforts.

In this edition, we are excited to highlight the work the BmDR team has accomplished over the past three months and explore how the group can positively impact the patient community. This includes recent presentations and workshops led or attended by the BmDR Communications and Publications Committee, showcasing the team's progress and plans for the future.

The involvement of those with lived experience is vital to ensure that BmDR addresses the real issues individuals and families face. Our goal is for the data and findings we collect to be relevant and useful to patients, helping them tailor their care and maintain their health. The BmDR Community Engagement Committee works directly with people who are living with kidney disease, their supporters, and researchers to gather input and ensure the team's work remains patient-centered. The committee also champions collaboration, community, and variation across the datasets collected and maintained in the repository.

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



Katrina Peron, MS, RAC

Associate Director
Predictive Safety Testing Consortium

Why was BmDR created?

BmDR started as a test project in 2019 at C-Path with support from the U.S. Food and Drug Administration (FDA). It officially launched in 2023 to help scientists better understand and use new tests (called biomarkers) that show if a drug is hurting the kidneys. A goal of BmDR is to collect information from many different kinds of people – of different ages, genders, races, backgrounds, and health conditions – both in the U.S. and around the world. This helps make sure the data is fair, complete, and useful for everyone with kidney disease.

For additional questions on BmDR, view the [Technical](#) and [Patient-Focused FAQs](#).

Video Resource: [BmDR DAP Overview February 2025](#)

BmDR Co-Chair Corner: What is the Impact on Those with Lived Experiences?

“BmDR brings us closer to a world where each patient has a personalized “early-warning kidney injury defense” in place that complements your office visit standard-of-care blood and urine testing. BmDR intends to bring you better data and smarter science to personalize your treatment plans and anticipate your future kidney health state.” - Gary Friedman

“BmDR brings us closer to a world where patients benefit from truly personalized therapies, built on better data and smarter science.” - Glenda Roberts



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

Recent Events

The BmDR team presented and attended several conferences throughout the first half of the year.

Connect with:



Nicholas King, MS
Executive Director, PSTC



The [AKI: From Bench to Bedside Conference](#) was held in May and was a great opportunity to engage directly with junior faculty, trainee nephrologists, and leading clinicians and researchers working at the intersection of acute kidney injury (AKI) science and translational application. For the BmDR team, it was an opportunity to showcase the repository's value in unifying diverse, high-quality datasets from both clinical and nonclinical sources — a critical step in enabling

more sensitive and predictive tools for drug safety. The event also helped build momentum around future data contributions and collaborations, reinforcing the importance of BmDR as a centralized, trusted resource in the advancement of AKI research and therapeutic development.

Thanks to Joseph Bonventre for including an overview of qualified biomarkers and supporting studies during his presentation.

KHI: Innovation through Collaboration



Kidney Innovation Conference May 21-22, 2025 | Washington, DC



Katrina Peron, MS, RAC
Associate Director, PSTC



Gary Friedman
BmDR Co-Chair



Being part of [Kidney Innovation Conference](#) was especially important for the BmDR team as it aligned with C-Path's mission to drive progress through multi-stakeholder partnerships. The event brought together key voices from across the kidney health ecosystem, including regulators, clinicians, researchers, and patient advocates — with patients at the forefront — to explore how collaboration can accelerate innovation. For the BmDR team, it was a vital opportunity to highlight how the repository supports biomarker qualification efforts by providing a secure, standardized platform for aggregating and analyzing biomarker data from diverse sources. The team specifically shared awareness of novel biomarkers with EMA and FDA Letters of Support and Context of Use qualifications. Participation in this forum not only helped build new connections and foster trust among potential data contributors but also emphasized the critical role of data transparency and integration in advancing kidney safety science. It reinforced the value of BmDR as a shared resource that supports

evidence generation and regulatory decision-making for the benefit of the entire kidney community, and proved that opportunities for continued and deepening collaborations remain abound.

The KHI meeting also provided opportunities for academic and pharma colleagues to voice challenges to optimally integrate real-time and real-world renal healthcare data. NIH/NIDDK shared awareness of the collaborative workspace (currently supporting HRSA, NIDDK, SRTR, NCATS, AIM-AHEAD, and CMS) entitled “Renal Real-World Data Tenant.” The BmDR Oversight Committee has been invited to contribute to this endeavor which uses HL7/FHIR/VULCAN to integrate EHR, RWD, and existing “renal data lakes.” The value proposition is that BmDR’s de-identified patients’ biomarker data can potentially contextualize clinical understanding of non-BmDR patients, thereby facilitating longitudinal learnings relevant to Americans from all chronic kidney disease grades that do or do not progress to renal replacement.

AAKP and George Washington University: Global Summit on Kidney Disease Innovations

Global Summit on Kidney Disease Innovations
BmDR Session is now Live!

AAKP
THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

 <p>Glenda V. Roberts, MS BmDR Co-Chair, Director, Communications and Patient Engagement, Mount Sinai Center for Kidney Disease Innovation, Icahn School of Medicine</p>	 <p>Katrina Peron, MS, RAC Associate Director, PSTC, Critical Path Institute</p>	 <p>Gary Friedman, MD Clinical Co-Chair, C-Path, BmDR Oversight Committee, Retired Pharmaceutical Industry Executive</p>	 <p>Stefan Sultana, MD Renal Toxicity Expert, AstraZeneca</p>	 <p>Patrick Murray, MD Professor of Clinical Pharmacology at University College Dublin</p>	 <p>Joseph Bonventre, MD Chief, Renal Division, Brigham and Women's Hospital, Professor of Medicine at Harvard Medical School</p>
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Six BmDR members participated in the *Predictive Safety Testing Consortium Leads the Biomarker Data Repository* session at the **AAKP Global Summit** (May 22-23, 2025). The participants showcased how long-standing collaboration can lead to transformative scientific infrastructure. The session highlighted the work of the Predictive Safety Testing Consortium (PSTC) — a trusted model for multi-stakeholder collaboration — to the creation of the Biomarker Data Repository,

which will accelerate the qualification of novel kidney safety biomarkers as larger data sets are combined. The global summit's patient-centered focus created an opportunity to present how advances in kidney biomarkers are directly tied to real-world patient impact — enabling earlier detection of kidney injury and supporting more personalized approaches to care. Watch the recorded session [here](#).

ASN Kidney Week 2025

The BmDR team submitted an abstract for the [American Society of Nephrology \(ASN\) 2025 Kidney Week](#) on the current qualification of a kidney biomarker panel to make patient-level safety decisions in clinical trials. If you plan to attend ASN Kidney Week, we would love to connect with you!

Latest Developments

C-Path has a new landing page for the Critical Path Data and Analytics Platform (CP-DAP)! From here, you can enter the BmDR DAP to view the BmDR data collection and request datasets: <https://portal.cpdap.c-path.org/>

After the Predictive Safety Testing Consortium's Kidney Safety Project (KSP) team received a [positive determination letter from the FDA](#) on December 6, 2024, for the Qualification Plan for a Novel Biomarker Panel (NBMP), the team began conducting the statistical analysis plan. 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. While analyses are being conducted, the group is drafting the Full Qualification Package to be submitted to the FDA requesting qualification of the biomarker panel this year. Read the press release [here](#).

C-Path and [Boston Medical Center \(BMC\)](#) published results for six biomarkers that could improve the early and accurate detection of kidney injury, leading to both the development of safer medications and better health outcomes for all patients. The findings from this collaboration between PSTC and the Foundation for the National Institutes of Health Biomarkers Consortium Kidney Safety Biomarker Project Team were [published in Clinical Pharmacology & Therapeutics](#). These biomarkers may offer an approach to detect drug-induced kidney damage

earlier than existing standards for monitoring kidney health and can lead to more tolerable treatment options.

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](#).

Contributing to BmDR

The BmDR team is in talks with organizations for an additional ten 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, bmdr@c-path.org, [Nicholas King](#) or [Katrina Peron](#).

Upcoming Event

Register Now for C-Path's Global Impact Conference 2025! For 20 years, C-Path has been a trusted nonprofit that generates solutions to facilitate scientific and regulatory pathways that accelerate the development of therapies for people with unmet medical needs. Join the BmDR team at the 2025 C-Path Global Impact Conference (CGIC), September 9 – 11, at the Washington Marriott at Metro Center, D.C

CGIC is a unique opportunity to connect the dots across key initiatives within C-Path's valuable portfolio, dedicated to accelerating drug development for conditions in neurology, rare diseases, pediatrics, and more. We hope to see you there!

[Register now!](#)



Recent Publications:

[“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 Frenzl, 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 \(DAP\)](#)

[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](#)