CRITICAL PATH INSTITUTE 20 YEARS OF IMPACT

Advancing Drug Development. Improving Lives. Together.

September 2025

Welcome to C-Path's BmDR Quarterly Newsletter!

This newsletter is designed to inform and connect all involved in C-Path's Biomarker Data Repository (BmDR). Your continued engagement and contributions are essential as we work together to advance the understanding and qualification 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.

In this edition, we are excited to share a preview of the posters that the BmDR team will present at the 2025 American Society of Nephrology Kidney Week, which will showcase the power of shared data in biomarker discovery and qualification. We also bring you the perspective of a BmDR clinician attending ASN Kidney Week (Dr. Joseph Bonventre), who highlights the importance of BmDR in bridging data science with real-world patient care.

You'll also find updates from the Kidney Safety Project team'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.

For those interested in engaging more deeply, we've included guidance on how to access and contribute data to BmDR, along with highlights of recent publications and upcoming events relevant to our community, including a BmDR-hosted virtual workshop in December! These touchpoints reflect 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 individuals and families 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,

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What is a biomarker?

Biomarkers are biological indicators that provide essential insights into our kidney function, thereby enabling early intervention and personalized care. The timely use of kidney biomarkers, such as serum creatinine, cystatin C, blood urea nitrogen, and urinary albumin, which are a regular part of standard lab work, can significantly improve patient outcomes, reducing the likelihood of serious complications like kidney failure, and providing people living with kidney diseases with a better quality of life. Biomarkers can be used to assess a drug's safety in preclinical and clinical trials and monitor for injury while a person is taking treatment.

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

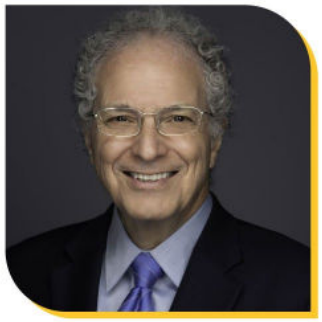
The American Society of Nephrology (ASN) 2025 Kidney Week is this November. Come see us in Houston, Texas at one of our posters which highlight the current qualification of a kidney biomarker panel to make patient-level safety decisions in clinical trials:

1. November 8, 2025: | 10:00 AM-12:00 PM | Poster Board #: **INFO15-SA, 4380461 Blinded, Human-in-the-Loop Adjudicators Assess Earlier Detection of Nephrotoxic Injury in Prospective Studies Supporting a U.S. Food and Drug Administration (FDA) Biomarker Qualification**
   Presenter: Owen Richfield, PhD

2. November 8, 2025: | 10:00 AM-12:00 PM | Poster Board #SA-PO0116, 4350039 Session Title: **AKI: Clinical Diagnostics and Biomarkers [PO0102-3] Onconephrology Clinical Decision-Making: Qualified Urine Biomarkers Sensitivities and Specificities May Vary When Using Different Laboratory Assays and Platforms**
   Presenter: Joseph Bonventre, MD

Clinician's Corner

Dr. Joseph Bonventre, Chief, Renal Division, Brigham and Women's Hospital, Professor of Medicine at Harvard Medical School, in collaboration with our academic members and collaborators, will present two posters at the upcoming American Society of Nephrology (ASN) meeting in Houston in early November.



Dr. Joseph Bonventre

It's clear that traditional methods of assessing impairment in kidney function are limited in their sensitivity. As a result, diagnosis is delayed with potentially long-term consequences of acute kidney injury. C-Path has been instrumental in bringing the pharmaceutical, regulatory, academic and patient communities together with a goal to synthesize data relating to urinary biomarker level changes due to drug-induced kidney injury (DIKI).

Data obtained in the US and previously brought to the FDA along with data from the European Union resulted in qualification in 2018 by the FDA of use of a panel of biomarkers in Phase 1 clinical studies. "Qualification" is a conclusion drawn by the FDA that a particular drug development tool, in this case urinary biomarkers, can be relied upon for a specific application in drug development and regulatory review. This qualification of six biomarkers (clusterin, cystatin C, Kidney Injury Molecule-1 (KIM-1), neutrophil gelatinase-associated lipocalin (NGAL), osteopontin and N-acetyl glucoaminidase has resulted in use of all, or a subset, in early clinical development of drugs being developed to treat diseases of various organs, since kidney injury can be an adverse consequence of any drug.

More recently, C-Path has teamed up with the Foundation for the National Institutes of Health (FNIH) and submitted a qualification package for evaluation by the FDA to gain qualification of the 6-component panel to allow for earlier detection of response of the kidney to DIKI in clinical trials. Qualification by the FDA will markedly enhance the use of these markers and bring them closer to BmDR's ultimate goal of using them routinely in clinical practice to improve patient safety.

One of the posters that will be presented at the 2025 ASN meeting summarizes data obtained in two studies of cisplatin toxicity, one by the Predictive Safety Testing Consortium (PSTC), coordinated by C-Path, and one by the European Safety-Related Biomarkers for the Efficacy and Toxicology (SAFE-T) consortium. Biomarker sensitivities and specificities, evaluated in PSTC and SAFE-T data, were

based upon use of median value or the upper limit of normal, respectively. Biomarkers were quantified by different vendors and assay platforms across the two consortia.

The second poster to be presented summarizes two prospective studies incorporated in the 2025 PSTC biomarker qualification package, which will be submitted to the FDA by the end of the year, to support the use of the 6-component panel in clinical trials. Blinded, independent assessments by two panels of three different adjudicators achieved 99.5% consensus when assessing the panel markers alone as indicators of kidney injury. These studies represent important steps toward moving the urinary biomarkers closer to clinical utility in becoming part of standard-of-care nephrology practice. The establishment of BmDR is making data sets available which will allow many more analyses by qualified researchers to increase confidence in the diagnostic utility of these biomarkers.

Latest Developments

After the Predictive Safety Testing Consortium's Kidney Safety Project team received a positive determination letter from the FDA in December of 2024 for the Qualification Plan for a Novel Biomarker Panel (NBMP), the team began conducting the statistical analysis plan (SAP). The SAP has been completed, and the team is now finalizing the Full Qualification Package to be submitted to the FDA this year, requesting qualification of the biomarker panel. Read the press release here. 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.

C-Path and Boston Medical Center 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 FNIH's 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.

The BmDR team is busy executing their publication strategy! This includes (but is not limited to) in-process manuscripts on:

1. How qualified kidney biomarkers are being applied in early clinical development decision making
2. BmDR strategy
3. Details and how to use the qualified kidney biomarker Composite Measure
4. How BmDR is relevant to patients
5. The expert adjudication process utilized in the current kidney biomarker qualification

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 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, Nicholas King or Katrina Peron.

Upcoming Events

Alamar Precision Biomarker Summit | October 1, 2025 | San Diego, CA

Join Alamar Biosciences and Key Opinion Leaders from local biotechs for a discussion on the latest advances in protein biomarker research with an introduction to NULISA: A precision proteomics platform with ultra-high sensitivity and high multiplex from blood. Learn how scientists are utilizing this novel technology to help advance their protein research.

AAKP's 50th Annual National Patient Meeting | October 3-5, 2025 | Fort Worth, TX

The American Associate of Kidney Patients (AAKP) National Patient Meeting, the largest kidney patient conference in the U.S. with a growing international audience, features a diverse lineup of speakers crossing all sectors of the kidney community, including the top influencers in kidney care from the U.S. Federal government, medical professionals, academia, private industry, and nonprofit professional organizations in the kidney community. The exhibit hall allows participants to engage with various kidney-related companies and organizations, and various other networking activities. There is also a virtual attendance option!

ASN Kidney Week 2025 | November 5-9, 2025 | Houston, TX

Join ASN and over 12,000 kidney professionals from across the globe at Kidney Week 2025 in Houston, TX. The world's premier nephrology meeting, Kidney Week provides participants exciting and challenging opportunities to exchange knowledge, learn the latest scientific and medical advances, and listen to engaging and provocative discussions with leading experts in the field.

SAVE THE DATE: BmDR Workshop | December 12, 2025 | Virtual

BmDR will be hosting a virtual workshop on December 12, 2025, where we will review the structure of BmDR, what datasets are available for request on the Data and Analytics Platform (DAP) 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 also include a panel of expert nephrologists, academics, and patient representatives, with time for live questions from attendees. The intention of the workshop is to broadcast what has been accumulated and analyzed in the BmDR thus far and educate the community on what BmDR can be utilized for. Registration details will be coming soon!

Recent Publications:

"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.

ICYMI | When the Game Changed: What Chronic Kidney Disease Taught Me About Men's Health

"Seeing as how this is a C-Path piece, I suppose it may be prudent to introduce myself to those in our community I have yet to meet: I'm Alexander Diegel, C-Path

Communications Guy. Or Assistant Director of Communications, if you're into "official" titles. You have hopefully read a story or press release of ours, but you may best know me as the wide-shouldered photographer blocking your view at one of our conferences so I can get the right shot (sorry about that). But let's dive into the most recent title I've gained, in addition to husband, father, and rugby player: A person living with chronic kidney disease (CKD). I would like to share my medical journey thus far, following the lead of the many who have shared their story with C-Path over the years for an Impact Story or presentation."

Read the full story here: When The Game Changed: What Chronic Kidney Disease Taught Me About Men's Health.

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.

By the Numbers

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

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FDA Acknowledgment