



**Dear BmDR Enthusiasts,**

Thank you for your continued interest, participation, and contributions to the Biomarker Data Repository (BmDR). The BmDR Oversight Committee and sub-committees have been busy executing our communications and publications strategy and connecting with research and patient groups involved in kidney disease. This quarter we have updates on progress towards this year's goals and detail the BmDR team's presence at the American Society of Nephrology (ASN) Kidney Week 2024. If you plan on attending ASN Kidney Week and would like to connect, please reach out to Nicholas King ([nking@c-path.org](mailto:nking@c-path.org)), Katrina Peron ([kperon@c-path.org](mailto:kperon@c-path.org)), or Gary Friedman ([gfriedman@c-path.org](mailto:gfriedman@c-path.org)).

We are also excited to announce that C-Path is now a member of the Kidney Health Initiative (KHI)! KHI was created by ASN and US Food and Drug Administration (FDA) as a public-private partnership that would enhance patient safety and foster innovation in kidney disease. Their mission is to catalyze innovation and the development of safe and effective patient-centered therapies for people with kidney diseases. To review the current list of KHI members, please visit the [KHI website](https://www.khi.org/). We look forward to this partnership and the opportunities it opens up for both groups.

Sincerely,



**Nicholas King**  
Executive Director  
Predictive Safety Testing Consortium



**Katrina Peron**  
Associate Director  
Predictive Safety Testing Consortium (PSTC)

**Latest Developments**

The BmDR Data and Analytics Platform (DAP) for review and interrogation of data has been developed. You can use [this link](#) to create an account to view and request datasets. Further instructions and details on how to request datasets and analyze them will be reviewed in the next newsletter. With this foundation in place, the BmDR team continues to focus on expanding the volume and capabilities of the repository. Outreach continues to consortia, academic researchers, and companies with relevant data sets to contribute. We have additionally been attending meetings and conferences to spread the word about BmDR and elicit data contributions.

The BmDR team has been busy working in sub-committees focused on communications and publications, community engagement, and legal and technical components of the BmDR. The communication and publication strategy for the upcoming year has been finalized, with these newsletters being one component, along with a manuscript detailing the BmDR strategy, and different resources to aid in BmDR education and awareness. We will present two posters at this year's American Society of Nephrology's (ASN's) Kidney Week, further detailed in the next section.

The BmDR legal sub-committee finalized the data contribution agreement template to be used for data contributions into the BmDR, and language for data use which qualified researchers must agree to prior to accessing data from the BmDR DAP. The technical sub-committee continues to assess the appropriate clinical study data sets to obtain to support the BmDR on drug-induced kidney injury (DIKI).

**C-Path Global Impact Conference**



**C-PATH 2024**  
GLOBAL IMPACT CONFERENCE  
WASHINGTON, DC | SEPT 9-11

**Transforming Translational Sciences: From Biomarkers to New Approach Methodologies**  
September 11, 2024 | 1:30-2:30 PM ET

**Speakers:**  
 Nicholas King, MS, Executive Director, PSTC, C-Path  
 Graham Marsh, PhD, Scientific Director, PSTC, C-Path  
 Danilo Tagle, PhD, Director, Office of Special Initiatives, NCATS, NIH  
 Tina Morrison, PhD, Director, Office of Regulatory Science and Innovation, FDA  
 David Strauss, PhD, MD, Acting Chief Scientist, FDA  
 Madhu Nag, MBS, PhD, Chief Scientific Officer, Insphero

The inaugural C-Path Global Impact Conference, #CGIC24, taking place from September 9-11 in Washington, D.C.

Join Nicholas King on September 11 at 1:30 p.m. ET as he leads a discussion on Transforming Translational Sciences: from Biomarkers to New Approach Methodologies. This session will also include information on BmDR.

**American Society of Nephrology (ASN) Kidney Week 2024**

BmDR Oversight Committee members Nicholas King, Katrina Peron, and Gary Friedman will be attending [ASN Kidney Week 2024](#) in San Diego, California from October 23-27. They will be presenting two posters, detailed below. Members will also be attending the Kidney Precision Medicine Project (KPMP) Industry Roundtable on Wednesday, October 23, 2024. More information and a link to express interest in attending the KPMP Industry Roundtable is included below. Note that space at the industry roundtable is limited, and attendance will be confirmed by KPMP closer to the event date.

- Adjudication Methodology to Assess Novel Urine Biomarkers Panel Detection of Nephrotoxicant Exposure in Presence or Absence of KDIGO-Defined AKI to Support Biomarker Qualification**

**Session Date, Time:** October 25, 2024, from 10:00 AM to 12:00 PM  
**Poster Board #:** FR-PO102  
**Presenter:** Nicholas King
- FAIR Access to Reusable Novel Biomarker Study Electronic Case Report Forms with Metadata Annotation and Statistical Analysis Plan Template for Biomarker Qualification**

**Session Date, Time:** October 26, 2024, from 10:00 AM to 12:00 PM  
**Poster Board #:** INFO09-SA  
**Presenter:** Gary Friedman



**KICK START KIDNEY WEEK!**  
Kidney Precision Medicine Project (KPMP)

**INDUSTRY ROUNDTABLE**

Wednesday, October 23, 2024, 2-6 PM  
San Diego, CA

[REGISTER NOW](#)

**AGENDA**

- Explore novel ways to access, integrate and analyze diverse data sources, including new clinical, genomic, proteomic, and imaging data.
- Foster collaboration between KPMP researchers and representatives from industry.
- Emphasize patient- and community-centered research and drug development.

**More Info:**  
[ashveena@nephrology.washington.edu](mailto:ashveena@nephrology.washington.edu)  
[kpmp.org/industry](https://kpmp.org/industry)

Please note that there is a space limit for the industry roundtable, and they want to ensure a range of participants in the room, so the [signup form](#) is a form to express interest and does not guarantee attendance.

**Physicians' Voices**

“As a physician who takes care of patients who develop acute kidney injury (AKI), and as a biomedical researcher who studies mechanisms and outcomes of AKI, the Biomarker Data Repository (BmDR) is an incredibly valuable resource. By assembling and collating available real-world data from clinical studies and trials, these data become readily available to a broad group of investigators. I especially appreciate the efforts to make these data accessible to many different interested parties, including industry, patient groups, academicians, and the FDA. There are currently no FDA approved treatments for AKI, and this resource hopefully can contribute to making successful treatments available to patients in need.” ~ Dr. Jonathan Himmelfarb



**Jonathan Himmelfarb**

**Co-Chair Corner**

Last quarter's "Co-Chairs Corner" focused upon adjudication (plus standard biomarker) patient-level acute kidney injury (AKI) novel biomarker by clinical experts for the purposes of supporting a Biomarker Qualification Plan regulatory submission. US FDA biomarker qualification guidance states:

“Qualification of a biomarker means that within a stated context of use (COU), the biomarker has been demonstrated to reliably support a specified manner of interpretation and application in drug development. Once qualified, the biomarker information is made publicly available and may be used in multiple drug development programs under its qualified COU.” ~ Gary Friedman

**Read more about the biomarker qualification program [here](#).**

Notably absent from this guidance is parallel development of harmonized use of any qualified biomarker(s) by health care professionals (HCP) within the practice of medicine — a potential downstream benefit to subspecialists overseeing patients with solid organ (e.g. hepatic or renal) dysfunction for whom prognostication about the pace of organ functional decline would be invaluable.

To progress from adjudication of AKI presence/absence in drug development to adjudication of ongoing vs. quiescent subclinical parenchymal injury will require robust patient-level data sets across the full age spectrum, demographic subgroupings, KDIGO eGFR strata, and the breadth of human disease. Fortunately, a generalized definition of “adjudication” is informative regarding this next leap forward:

“ADJUDICATION: the act of judging a case, competition, or of making a final decision based upon available information.” ~ Merriam Webster

The quantity of “available information” is a dynamic variable. One of the missions of the C-Path BmDR Oversight Committee is to identify academic researchers and pharma partners using the C-Path/PSTC biomarker panels to continue ingesting patient-level biomarker data sets. Our intent is to ensure that qualified researchers have an ever-expanding pool of high quality (novel plus standard biomarkers) data to increase the likelihood that the first COU for C-Path/PSTC qualified biomarker (based upon data from 100s of study participants) leads to follow-on COU based upon accruing data from thousands to tens of thousands of unique patients. Mathematical model-driven statistical analysis plans are currently in development to identify opportunities to “fill in” baseline characteristics gaps—demography (age, gender, race), KDIGO eGFR strata, type of kidney injury—to augment qualified researchers’ and medical/clinical subspecialty societies’ pursuit of patient-level decision-making COUs. ~ Glenda V. Roberts & Gary Friedman



**Glenda V. Roberts**



**Gary Friedman**

If you are interested in participating in the BmDR Oversight Committee or one of the sub-committees, please contact Nick King ([nking@c-path.org](mailto:nking@c-path.org)) or Katrina Peron ([kperon@c-path.org](mailto:kperon@c-path.org)).

**Adjudicator's Corner**

Adjudication is the process of wherein trained healthcare practitioners (physicians and non-physicians) evaluate serial biomarkers data (standard and novel biomarkers) over time to discern presence and or absence of clinical acute kidney injury (AKI) as well as the presence or absence of sub-clinical injury.

Currently, C-Path's PSTC Adjudicators are guiding development of manuscripts to provide guidance and support strategies for potential harmonized use of the novel kidney safety urine biomarkers panel by Nephrologists and professional Nephrology societies globally.

**Patrick T. Murray, MD, FASN, FRCPI, FJFICMI, (Professor of Clinical Pharmacology, University College Dublin School of Medicine, Consultant Physician, Nephrology & Clinical Pharmacology, Mater Misericordiae University Hospital, Dublin, Ireland):**



**Patrick T. Murray**

“Peer-reviewed journal publication of biomarker qualification plan (regulatory agency submission) components in reader-friendly language can support qualified researchers’ pursuits of next step novel biomarkers (NBM) qualifications. Providing NBM data in tables and figures, including thresholds, as well as learning phase ROC analyses was beneficial to PSTC Adjudicators, and we anticipate these tables and figures will support professional societies’ consensus recommendations going forward.

As with the exponential rise in the use of POCUS (clinical care ultrasound) to elucidate AKI mechanisms, NBM usage in the academic trials and in clinical practice can continue to provide high-quality evidence to advance Nephrologists’ assessment of acute (and perhaps chronic) kidney injury. We anticipate that drug-associated AKI (DA-AKI)—an increasingly more prevalent term than drug-induced AKI (or DIKI)—as well as radiocontrast-associated (CA-AKI), sepsis-associated (SA-AKI), and other AKI causalities will be elucidated in real-time through combined use of standard renal functional biomarkers, NBMs, urine microscopy advances, and bedside radiologic diagnostics going forward.”

**At a Glance**

[BmDR Website](#)  
[BmDR DAP](#)

If you have any questions about BmDR, please email [bmdr@c-path.org](mailto:bmdr@c-path.org).

Help support our mission.

**MAKE A GIFT TODAY**



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[c-path.org](https://www.c-path.org)



[FDA Acknowledgment](#)