CRITICAL PATH INSTITUTE

Advancing Drug Development. Improving Lives. Together.

BmDR
BIOMARKER DATA REPOSITORY

Dear DIKI Biomarker Workshop Participants & BmDR Enthusiasts,

Nicholas King
Executive Director, PSTC

On behalf of everyone at C-Path, I want to extend my sincere appreciation to you for continuing to accomplish the goals set out by the 2022 Drug-Induced Kidney Injury (DIKI) Biomarker Workshop! This past year we worked to draft the governance charter for the Biomarker Data Repository (BmDR) and continued to reach out to additional contributors to expand the BmDR. I am excited about the work on the horizon for BmDR this upcoming year; we will go into more detail later in the newsletter.

I'm happy to inform you that the governance charter is now complete, and we formed the inaugural BmDR Oversight Committee comprised of participants from academia, patient groups, non-profit organizations, and pharmaceutical companies.

The inaugural BmDR Oversight Committee members are:

Name	Organization
Craig Ostroff	Mill Street Consulting LLC
Frank Dieterle	Novartis
Gary Friedman*	Retired Pharmaceutical Industry Executive
Glenda Roberts*	University of Washington
Jai Radhakrishnan	Columbia University
Joseph Bonventre	Harvard University
Nicholas King	Critical Path Institute
Patrick Murray	University College Dublin
Richard Knight	AAKP
Katrina Peron	Critical Path Institute
Stefan Sultana	AstraZeneca
	**Committee Co-Chair*

Finally, we requested input from clinicians and our BmDR Oversight Committee Co-Chairs on the importance of developing improved tools to predict and detect drug-induced kidney injury.

The presentations and recordings from the 2022 DIKI Biomarker Workshop are available here:

Event web page
Patient Voices and Workshop Recordings
Day 1 Video Recording
Day 2 Video Recording

International 2022 Drug-induced Kidney Injury Biomarker Workshop
MAY 23-24 | VIRTUAL FORMAT

Sincerely,

Nicholas King,
Executive Director, Predictive Safety Testing Consortium

Plans for 2024

This year will focus on expanding the volume and capabilities of the Biomarker Data Repository (BmDR). First, we are reaching out to consortia, academic researchers, and companies with relevant data sets to contribute. Next, we will build and deploy a data and analytics platform (DAP) for review and interrogation of the data. If you'd like to see an example of another C-Path DAP, please visit this link: https://portal.rdca.c-path.org. The BmDR DAP is estimated to be ready for public access by July 2024; once deployed, we will provide access instructions.

The BmDR Oversight Committee is busy working in sub-committees focused on communication and publications, patient and community engagement, and legal and technical components of the BmDR. We are refining our communication and publication strategy for this year, with this newsletter being the first in our communication strategy. We will have more publication and communications details in the next newsletter. The legal sub-committee is updating components of the data contribution and use agreements, while the technical sub-committee is determining the appropriate clinical study data sets to obtain to support the initial focus of the BmDR on drug-induced kidney injury.

Clinicians' Voices

Dr. Jai Radhakrishnan (Columbia University) – "Clinicians can use the findings of the Drug Induced Kidney Injury Biomarker Workshop in several ways to inform drug development and clinical practice. Predictive biomarkers can be used in patients receiving potentially nephrotoxic drugs. This allows for timely intervention if signs of kidney injury arise- If a drug is known to cause kidney injury, predictive biomarkers could inform clinicians about possibly using alternative drugs with lower nephrotoxic potential. Biomarkers may influence regulatory agencies in their assessment of drug safety and approval processes. Biomarkers identified in the workshop can be used for recruitment in clinical trials allowing for enrichment of patients who are at the highest risk of acute kidney injury. Clinicians can use the information from the workshop to educate patients about the potential risks associated with specific medications. This empowers patients to make informed decisions about their treatment options. Clinicians can collaborate with researchers and other healthcare professionals to integrate the workshop findings into clinical practice, which could lead to the creation of guidelines, protocols, and educational materials for healthcare providers."

Dr. Kirtida Mistry (US FDA) – Kidney Safety Biomarkers: Need for Pediatric Data: "Drug-induced kidney injury is an important concern that must be addressed during the drug development process. The currently available tools that are widely used for detecting such injury are, however, limited and not sensitive or specific for detecting kidney injury at an early and reversible stage. The Critical Path Institute's drug-induced kidney injury initiative is an important project that aims to advance this field and their Biomarker Data Repository (BmDR) aims to advance the qualification of biomarkers of drug-induced kidney injury.

New drugs are being developed to treat serious diseases in children, including products for which there is concern for potential kidney toxicity. Current monitoring relies on traditional tools, which are suboptimal; hence, improved tools are needed for predicting and detecting kidney injury at an early and reversible stage in trial participants and to better ensure the safety of the pediatric patients who participate in trials of new products that may cause kidney toxicity. Moving forward, it is critical that the community obtain data on promising biomarkers of kidney injury in pediatric patients and share these data to advance our understanding of the performance of these biomarkers as early indicators of drug-induced kidney injury to better ensure the safety of children in clinical trials."

Biomarker Data Repository (BmDR)

The BmDR Governance Charter team drafted and finalized a charter for the BmDR, which includes the composition and selection criteria for the BmDR Oversight Committee. The inaugural BmDR Oversight Committee was confirmed in September 2023. The BmDR Oversight Committee then nominated and confirmed Oversight Committee Co-Chairs, Glenda Roberts and Gary Friedma, to lead the group for the next two-year term. We thank the entire BmDR Oversight Committee for championing this effort, and specifically Gary and Glenda as they lead the group during this transformative time. The Co-Chairs shared their sentiments below:

> *"Establishment of the BmDR represents a unique opportunity to democratize novel injury biomarker data, thereby fulfilling FDA and EMA charges to encourage and expand exploration of novel injury biomarker data within the context of standard injury biomarkers. The BmDR Oversight Committee co-chairs are honored and committed to ensure that aggregation of clinical trial data, peer-reviewed academic publications data, and "real-world data (RWD)" utilizing these biomarkers to advance understanding of their potential utility for patients and their families as well as clinical researchers globally."*

~Gary Friedman

> *"It's exciting to see members of the pharmaceutical 'industry and academic researchers offering their data to help identify and improve the clinical utility of additional biomarkers. The prospect of identifying new biomarkers for the prediction or timely detection of DIKI should have a direct impact on patient care. As a person living with kidney disease, I hope that the insights gained from these biomarkers will be available to all patients, and that no one will be denied access because of cost."*

~Glenda V. Roberts

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) or Katrina Peron (kperon@c-path.org).

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