

## **How C-Path’s Biomarker Data Repository Brings Patients to the Table to Discuss Biomarkers and Their Impact**

By: Claire Bassetti

C-Path publicly launched its Biomarker Data Repository (BmDR) in 2023 to advance the qualification of novel biomarkers as drug development tools. A biomarker is a measurable sign in the body that helps doctors and researchers understand what’s happening with your health. It could be something like blood pressure, a blood test result, or a molecule in your body that shows how well a treatment works, or if there’s a problem like an illness or injury.

BmDR’s initial focus on kidney safety biomarkers has the potential to significantly improve the development of new therapies by detecting kidney injury with greater sensitivity and specificity than current methods. As the biological rationale for these safety biomarkers is better understood, they may have applications for patients with kidney disease to diagnose diseases earlier or more sensitively detect and monitor physiological improvements due to new, or in development, therapies.

The data repository provides participants with large, reliable datasets on emerging translational safety biomarkers from diverse sources of non-clinical and clinical studies. De-identified data from multiple sponsors are collected and stored in this secure repository. C-Path makes the data available to FDA staff and other stakeholders to support research that expands the biological understanding of emerging safety biomarkers.

To advance the BmDR initiative, C-Path’s Predictive Safety Testing Consortium (PSTC) established four committees in January 2024, each focusing on a key aspect of the repository — Community Engagement, Communications and Publications, Legal, and the Technical Working Group. These committees provide a collaborative forum for industry representatives, patients, clinicians, academics, and other stakeholders to align on project objectives.

The Community Engagement Committee has benefitted from the involvement of patient representative, including Richard Knight, Immediate Past President of American Association of Kidney Patients (AAKP) and Patient Representative, and Glenda V. Roberts, Director of Communications and Patient Engagement at Mount Sinai’s Center for Kidney Innovation and the Kidney Precision Medicine Project. Both served on the committee since its inception, offering valuable insights from their experiences. In August 2024, the committee welcomed Dave White, a seasoned advocate with extensive leadership roles, including service on the boards of the AAKP, the Kidney Health Initiative, and the Veterans Transplantation Association. Mr. White is the former Chair of the Kidney Health Initiative’s Patient and Family Partnership Council, a member of PCORI’s Advisory Panel on Patient Engagement, and a voting member of the FDA’s Patient Engagement Advisory Committee.

During the October 14 BmDR Community Engagement Committee meeting, these patient representatives shared their perspectives on the transformative potential of BmDR, bringing invaluable expertise and lived experience to the discussion.

“The reason this is really important to me is because the more biomarkers we can identify that help us assess the impact of drugs and therapies on our kidneys, the greater the likelihood we’ll have more treatments and

therapies developed, but also the likelihood that we can identify the drugs that are more likely to put us at risk, so we can avoid those,” Glenda said. “For me, the biggest benefit since we are not in drug trials, is understanding what impact it has on biomarkers. This helps us understand what impact it is likely to have on people living with kidney diseases.”

BmDR’s work embodies C-Path’s mission to lead collaborations that accelerate drug development and advance better treatments for people worldwide. C-Path doesn’t develop therapies; C-Path generates solutions to facilitate scientific and regulatory pathways that accelerate the development of therapies for people with unmet medical needs.

At a recent BmDR Community Engagement Committee meeting, Dave remarked about the frustrations patients face when treatments take too long to become available. “This takes me back to 2017 when I was with the Kidney Health Initiative, and we were in the midst of co-creating the Kidney Health Initiative’s renal replacement therapy roadmap. One of the Patient Advisory Committee members became so frustrated that she quit because she couldn’t understand why it took so long to be cured and have adequate treatments. We, as a team, didn’t really know how to explain it either. That would have been the perfect time to explain the BmDR and what we are trying to develop.”

The discussion on the impact of the BmDR naturally expanded to include an exploration of biomarkers — their functions, significance, and the factors that influence them. Biomarkers play a critical role in drug development, serving as tools to evaluate drug safety in both preclinical and clinical trials and to monitor for potential injury during treatment. Glenda emphasized the importance of demystifying biomarkers, highlighting the need to help people understand what biomarkers are, what qualifies as a biomarker, and why they are essential in advancing medical research and patient care.

“When you start using terms that people do not understand and you start talking about impact, if you haven’t taken the time to explain what’s being impacted, whether its biomarkers, or genes, it’s hard for patients to understand and relay the information to their families. So that causes a reduction in participation of trials,” Glenda stated.

Dave added, “The way that drugs interact with kidneys [is the language that needs to be used when speaking about Kidney biomarkers]. That is the best approach for reaching people — people who basically don’t even know what a biomarker is. I was a seasoned patient advocate and still did not understand what a biomarker was because no one explained it to me in lay language.”

“If we don’t know what biomarkers consist of, you can certainly believe that there are many other patients that don’t know,” Richard commented.

These remarks emphasized the need to make health information and services findable, understandable, and usable by our intended audiences. One of the exercises the committee is currently working on is a key influencer chart to make sure it speaks to different audiences effectively and in the applicable language. BmDR is working to be a resource that patients can use to understand their biomarkers and how they are impacted through the different data sets. Existing biomarker data will be used to significantly advance and accelerate understanding of the utility of novel biomarkers as drug development tools.

Richard puts this under the broad umbrella of precision medicine. “The deeper we go, and the more options we have, the better job we can do at describing the disease. We need to be able to have a broader understanding, because we are not scientists or medical experts. Sometimes you have to look at something several times before it clicks,” he added.

These conversations highlight the unique value of BmDR and how it is already making an impact in positive ways through committee meeting discussions. The PSTC and BmDR teams are thankful for Glenda’s, Richard’s, and Dave’s leadership in the Community Engagement Committee and helping advance the BmDR.

If you are interested in participating in any BmDR committee, contact Nick King ([nking@c-path.org](mailto:nking@c-path.org)) or Katrina Peron ([kperon@c-path.org](mailto:kperon@c-path.org)). The data repository is now accessible through C-Path's Data Analytics Platform which can be [accessed here](#).

To learn more visit, [C-Path's BmDR program page](#).



**Dave White**, a proofreader at an international law firm.

When I heard the words “your kidneys are no longer working” during an emergency room visit in 2009, I was not ready or willing to accept the news. My first six months as a dialysis patient were challenging and scary, and I am fortunate to have a loving family and support system that did not give up on me when I tried to give up on myself.

A care plan meeting in 2010 changed my attitude and my future. My dialysis care team worked with me to develop a plan of care that empowered me to reach my full potential as a person living with a serious illness. Most importantly, I was told I had to own the plan for it to work. Thankfully, I listened, took charge of my health, and eventually thrived on dialysis before receiving a kidney transplant from a deceased donor in 2015.

I serve as an Expert Advisory Panelist with the Kidney Transplant Collaborative, on the National Committee for Quality Assurance's Committee on Performance

Measurement, am a Founding Member of the Alliance for Person-Centered Care, and am a Voting Member of the FDA's Patient Engagement Advisory Committee, its first and only advisory committee whose members are all patients, caregivers, and representatives of patient organizations. I serve or have served in leadership roles with the American Association of Kidney Patients, the Kidney Health Initiative, the Light Collective, the Patient Advocate Foundation and the National Patient Advocate Foundation, PCORI, Quality Insights Renal Network 5, and the Veterans Transplantation Association.

I believe the best way to eliminate disparities in health outcomes is to empower communities to take collective responsibility for their own well-being.

**Glenda V. Roberts**, Mount Sinai Center for Kidney Innovation, Patient Representative



Glenda V. Roberts is a dedicated activist with a passion for kidney research and the well-being of individuals living with kidney disease. Her extensive involvement in numerous national and international transformative research and healthcare initiatives aims to enhance patient outcomes. Drawing from her personal experience with kidney disease, she has become a powerful advocate for the patient's perspective, consistently elevating the patient's voice in research endeavors.

In addition to serving on over 15 patient advisory committees, Glenda has authored, co-authored, or been featured in more than 50 kidney-related publications. She co-chairs the APOLLO Community Advisory Council, directs

communications for the Kidney Precision Medicine Project, chairs an industry patient advisory committee, and serves on the Kidney Health Initiatives Board of Directors. She is also the inaugural co-chair of the Critical Path Institute's Biomarker Data Repository Governing Committee. Glenda has contributed her expertise to several organizations and initiatives focused on improving outcomes and increasing patient centricity, including Kidney Disease Improving Global Outcomes (KDIGO), the International Society of Nephrology (ISN) Global Kidney Trials, the American Society of Nephrology (ASN), the National Kidney Foundation (NKF), and the NKF-ASN Taskforce for Reassessing the Use of Race in Diagnosing Kidney Disease. Her work underscores her commitment to improving kidney health globally.

Glenda's contributions have been recognized with several prestigious awards, including the President's Volunteer Service Award from Presidents Trump and Biden in 2020 and 2022, respectively. She is the first patient to receive both the President's Award from the American Society of Nephrology and the Celeste Castillo Lee Patient Engagement Award from the National Kidney Foundation. These acknowledgments reflect her significant contributions to the field and her unwavering commitment to patient engagement advocacy.

Before joining Mount Sinai as the inaugural Director of Communications and Patient Engagement for the Mount Sinai Center for Kidney Innovation, Glenda amassed over 35 years of experience as an Information Technology executive at global companies like Microsoft and General Electric. She also served as the Executive Director of the Seattle Transplant House and dedicated 6.5 years to the University of Washington (UW), where she was the Director of External Relations, Communications, and Patient Engagement for both the Kidney Research Institute (KRI) and the Center for Dialysis Innovation (CDI). In these roles, her commitment to treating patients as equal research partners fostered a deep sense of trust within the community.



**Richard A. Knight, MBA** is a kidney transplant recipient of eighteen years and a former hemodialysis patient. He is the Past President of the American Association of Kidney Patients (AAKP) and serves on numerous advisory boards and committees. Richard is an Adjunct Instructor at Bowie State University and a founding member of BSU's College of Business Advisory Council. Additionally, he is a Board Member of the Personalized Medicine Coalition, advocating for the adoption of personalized medicine to benefit patients and health systems. Richard has held significant roles, including membership on the National Diabetes and Digestive and Kidney Diseases (NIDDK) Advisory Council, Co-Chair of the NIDDK Strategic Plan Stakeholder Engagement Subgroup, and participation in the Steering Committee for

NIDDK's Kidney Precision Medicine Project (KPMP) and the Scientific Registry of Transplant Recipients (SRTR) Visiting Committee. He has also contributed to nine Center for Medicare and Medicaid Services (CMS) Technical Expert Panels (TEPs). Currently, Richard co-chairs the NIDDK KPMP's Community Engagement Committee and serves on the Xenotransplantation Advisory Committee and the Collaborating Leaders to Address Racism with Interventions for Equity-Kidney Disease (CLARIFY-KD) Project. He is a member of the International Society of Nephrologists' Patient Liaison Advisory Group (PLAG) and the Critical Path Institute's BioMarker Data Repository Governing Committee. Richard's commitment has been recognized with the President's Volunteer Service Award from President Trump in 2020 and the President's Lifetime Achievement Award from President Biden in 2022. In 2017, he received the American Society of Nephrologists President's Award.

As an international advocate for kidney patients, Richard frequently speaks on topics such as increasing diversity in clinical trials and restructuring healthcare systems to offer more innovative patient choices. His work has been published in peer-reviewed journals, including the Clinical Journal of the American Society of Nephrology, Nature, Clinical Transplantation, the American Journal of Kidney Disease, and Patient

Education and Counseling.