BIOMARKER DATA REPOSITORY (BmDR)

c-path.org/bmdr

Biomarker Data Repository Participation

If you have general questions about contributing data to C-Path, visit **C-Path's Data Collaboration Center**. C-Path has set up a simple governance process that protects all submitted data through sponsor-directed data use agreements. Contact C-Path's BmDR team if you have any questions or need additional information: **bmdr@c-path.org**.

BmDR

C-Path's Predicative Safety Testing Consortium has developed a public repository for data on novel translational safety biomarkers from drug development programs.

The initial focus is on kidney safety biomarkers, including:

- Albumin
- Clusterin
- Cystatin C
- Kidney Injury Molecule-1 (KIM-1)
- Total Protein
- N-acetyl-beta-D-glucosaminidase (NAG)
- Neutrophil gelatinase-associated lipocalin (NGAL)
- Osteopontin
- Other relevant biomarkers

C-Path's Predictive Safety Testing Consortium

PSTC
PREDICTIVE SAFETY TESTING CONSORTIUM
CRITICAL PATH INSTITUTE

c-path.org/pstc

Critical Path Institute's Predictive Safety Testing Consortium (PSTC) is a public-private partnership that brings pharmaceutical companies together to share and validate safety testing methods under the advisement of worldwide regulatory agencies, including:

- U.S. Food and Drug Administration (FDA)
- European Medicines Agency (EMA)
- Japanese Pharmaceuticals and Medical Devices Agency (PMDA)

PSTC's primary goal is the qualification of novel translational safety biomarkers for use in clinical drug development trials.

Biomarker Data Repository Goals

- Collect and interrogate deidentified data on emerging translational safety biomarker studies (clinical and nonclinical) with an initial focus on kidney injury biomarkers
- Qualified researchers interrogate data for new applications in clinical practice and drug development
- Pursue novel or expanded regulatory qualifications of the biomarkers.

Biomarker Data Repository Use

Masked, deidentified data from multiple sponsors has been collected and stored in a secured repository administered by C-Path. The data is available to qualified researchers to support studies that lead to the submission of documents to worldwide regulatory agencies to:

- Qualify novel safety biomarkers for new Contexts of Use (CoUs)
- Modify and expand existing CoUs
- Identify appropriate exploratory biomarkers to advance drug development in the future

The ultimate goal is to accelerate regulatory acceptance and drug development implementation of emerging safety biomarkers.

By the Numbers

- **5** requestable clinical datasets
- **>450** subjects worth of data
- **>84,000** laboratory test observations

Benefits of Participating in the Biomarker Data Repository

Qualified researchers will have access to:

- Aggregated biomarker data and summary analyses, enabling collaboration and support of their drug development efforts.
- Reference ranges, medically relevant thresholds and other outputs from accumulated data on both conventional and novel biomarkers.

Only deidentified, non-proprietary data is available, so each contributing organization's intellectual property is protected, as well as patient health information.

Appropriate Datasets

- Kidney safety biomarker data from:
  - Clinical control arms
  - Nonclinical control arms
  - Nonclinical active arms
  - Basic study design elements
  - Basic assay information
- Data (that have been submitted to the FDA) from regulatory submissions including Clinical Trial Applications, Investigational New Drugs, and New Drug Applications

BmDR Structure

The BmDR Oversight Committee (OC) is composed of representatives from C-Path, academia, patient groups or advocates, non-profit organizations, societies and foundations, pharmaceutical industry, and other healthcare-related biotechnology companies. The OC is responsible for the functional, strategic, and tactical aspects of BmDR, and oversee four committees to execute on those tasks, including: Communications & Publications, Community Engagement, Legal, and a Technical Working Group.

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c-path.org/fda-acknowledgement

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