BmDR
CRITICAL PATH INSTITUTE

c-path.org/programs/bmdr

BIOMARKER DATA REPOSITORY PILOT

A REPOSITORY FOR NOVEL BIOMARKER DATA

C-Path's PSTC is developing a repository for data on novel translational safety biomarkers from drug development programs.

The initial pilot focuses on kidney safety biomarkers, including:

- Albumin
- Clusterin
- Cystatin C
- KIM-1
- Total Protein
- NAG
- NGAL
- Osteopontin
- Other Relevant Kidney Safety Biomarkers

BIOMARKER DATA REPOSITORY PARTICIPATION

As a sponsor, you can join with other innovative companies simply by sharing non-proprietary data using instructions on the C-Path website **www.c-path.org**.

C-Path has set up a simple governance process that protects all submitted data through sponsor-directed data use agreements.

Please feel free to contact Critical Path Institute if you have any questions or need additional information: **info@c-path.org**

PSTC
PREDICTIVE SAFETY TESTING CONSORTIUM
CRITICAL PATH INSTITUTE

C-PATH'S PREDICTIVE SAFETY TESTING CONSORTIUM (PSTC)

Critical Path Institute's (C-Path'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:

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

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

PSTC is one of many consortia of C-Path, a nonprofit organization dedicated to accelerating drug development by catalyzing the development of tools to advance medical innovation and regulatory science. C-Path has a proven history of administering large data repositories in a neutral, pre-competitive, secure, and confidential manner.

c-path.org/programs/pstc

BIOMARKER DATA REPOSITORY PILOT **GOALS**

- Provide industry with new drug development tools (Kidney Safety Biomarkers). Existing biomarker data could be used to significantly advance and accelerate understanding of the utility of novel biomarkers as drug development tools.
- Confirm normal healthy volunteer reference ranges, analyze the impact of key demographics on these ranges, and characterize subject variability.
- Confirm biomarker changes due to kidney injury.
- Confirm the feasibility and value of this new collaborative biomarker repository effort, and evaluate resources needed for broad implementation.

BIOMARKER DATA REPOSITORY **USE**

Masked, de-identified data from multiple sponsors will be collected and stored in a secured repository administered by C-Path. The data will then be available to C-Path and FDA staff to support research that leads 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

Our ultimate goal is to accelerate qualification of novel biomarkers as new tools for drug developers.

APPROPRIATE **DATASETS** FOR THE PILOT

- Kidney safety biomarker data from:
  - Clinical control arms
  - Nonclinical control arms
  - Nonclinical active arms
  - Basic study design elements
  - Basic assay information
- Data suitable for the database includes existing data (that have been submitted to the FDA) from regulatory submissions including CTAs, INDs, and NDAs.

BENEFITS OF CONTRIBUTING TO THE BIOMARKER DATA REPOSITORY

Contributors 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 summary, non-proprietary data will be available, so each participating organization's intellectual property is protected.

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