CRITICAL PATH INSTITUTE

Biomarker Data Repository

Overview

Founded in 2019, C-Path's Biomarker Data Repository (BmDR) advances qualification of novel biomarkers as drug development tools. The focus is on kidney safety biomarkers that have the potential to significantly improve the development of new therapies by detecting kidney injury with greater sensitivity and specificity. C-Path plans to work on other organ safety biomarkers, including liver, skeletal muscle, vascular, and pancreatic injury biomarkers.

The Problem

Safety biomarkers are biological markers that can be measured in a patient's blood, urine, or tissue samples to indicate the presence or absence of adverse effects caused by a drug or other therapeutic intervention. These biomarkers can be used to assess the safety of a drug in preclinical and clinical trials, as well as monitoring for injury while taking a treatment.

Unfortunately, when drugs fail early in clinical development, the reasons – including toxicity – may never be reported. The lack of information, including the lack of biomarker data repositories that gather these data and appropriately categorize them, hinders the progress of new medical therapies. Such repositories are centralized databases that store large amounts of de-identified information about biomarkers, including their clinical relevance, their association with disease, and their potential use as diagnostic or prognostic tools. These repositories enable researchers to access a wealth of information about biomarkers and their clinical utility, which is critical for advancing new therapies.

Without access to biomarker data repositories, researchers must collect and analyze biomarker data from scratch, which is time-consuming, resource-intensive, and can result in data sets too small to be reliably predictive.

The Solution

In 2019, C-Path began developing a repository (BmDR) for data on novel translational safety biomarkers from a variety of independent academic and corporate drug development qualifications, with the goal of accelerating qualification of novel biomarkers as tools for drug developers.

The BmDR provides stakeholders with large, reliable datasets on novel translational safety biomarkers from a variety of nonclinical and clinical study sources. Masked, de-identified data from multiple sponsors are being collected and stored in a secured repository. Once there is sufficient data, the data will be available to C-Path, FDA staff and other stakeholders to support research that leads to the submission of documents to global regulatory agencies to qualify novel safety biomarkers for new Contexts of Use (CoUs), to modify and expand existing CoUs and to identify appropriate exploratory safety biomarkers to advance drug development in the future.

Existing biomarker data will be used to significantly advance and accelerate understanding of the utility of novel safety biomarkers as drug development tools.

The initial focus of the BmDR is on kidney safety biomarkers. Many drugs are filtered through and eliminated via the kidneys, hence potential kidney toxicity is a key consideration in the development of novel drugs and a useful first step in standardized development of novel safety biomarkers.

The Impact

The BmDR confirms normal healthy volunteer reference ranges, analyzes the impact of key demographics on these ranges, and characterizes subject variability. The program also confirms biomarker changes due to kidney injury.

Appropriate datasets include kidney safety biomarker data from: clinical control arms, nonclinical control arms, nonclinical active arms, clinical treatment arms, basic study design elements and basic assay information. Ideal datasets for this pilot contain existing data (that have been submitted to the FDA) from regulatory submissions, including CTAs, INDs, and NDAs.

The program's initial focus is on kidney safety biomarkers, including:

- Albumin
- Clusterin

- Cystatin C
- Kidney Injury Molecule-1 (KIM-1)
- N-acetyl-?-(D)-Glucosaminidase (NAG)
- Neutrophil gelatinase-associated lipocalin (NGAL)
- Osteopontin

- Total protein
- Other relevant kidney safety biomarkers

Contact us

Please feel free to contact us if you have any questions or need additional information:
biomarker.repository@c-path.org

Initial Focus

The initial focus on kidney safety biomarkers, including:

- Albumin
- Clusterin
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- Kidney Injury Molecule-1 (KIM-1)
- N-acetyl-?-(D)-Glucosaminidase (NAG)

- Neutrophil gelatinase-associated lipocalin (NGAL)
- Osteopontin
- Total Protein
- Other Relevant Kidney Safety Biomarkers

The goals are to confirm the feasibility and value of this new collaborative effort, and evaluate resources needed for broad implementation; confirm normal healthy volunteer reference ranges, analyze the impact of key demographics on these ranges, and characterize subject variability; and confirm biomarker changes due to kidney injury.

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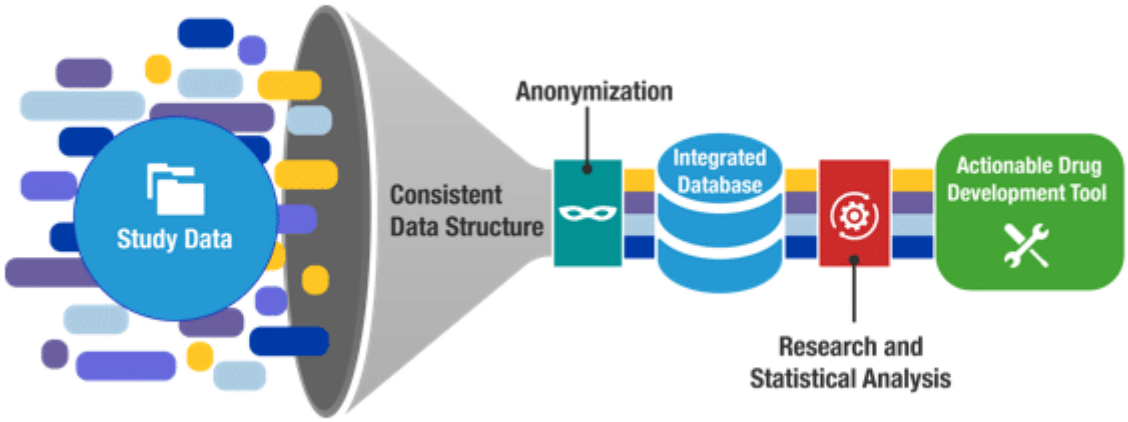

Team

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Resources

BmDR One-Pager

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Introduction to BmDR

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FDA Letter of Endorsement

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