PRA Health Sciences

FACT SHEET

Pharmacogenomics (PGx)

Pharmacogenomics aims to develop rational means to optimize drug therapy with respect to the patient's genotype, ensuring maximum drug efficiency with minimal adverse effects. A deeper understanding of different groups and populations improves pharmacovigilance, clinical trials, and the real-world therapeutic efficiency of drugs.

Executive Summary

Throughout the history of drug development, treatments were tested and approved based on what works for most people. As medical and biopharmaceutical technologies advance, however, the healthcare community has come to understand that each patient is unique. We can achieve far more effective outcomes by treating them as individuals.

The concept of personalized medicine is rapidly expanding, thanks to the use of genomic data, biomarkers, and new technologies. Pharmacogenomics is a discipline that is now widely adopted across the research and medical communities. Pharmaceutical companies are increasingly making use of pharmacogenomics to increase the success rate in their research and development endeavors.

Pharmacogenomics is an all-encompassing, genome-wide association approach, incorporating genomics and epigenetics while also addressing the effects of multiple genes on drug response.

Pharmacogenetic studies benefit clinical trials in 3 ways:

- **Optimizing pharmacovigilance by identifying the percentage of individuals at risk of adverse drug reactions**
- **Recommending therapeutic dosage regimens of specific drugs for specific populations**
- **Improving clinical trials by stratifying populations based on genetic differences in ethnic and cultural identities and their susceptibility to drug activity**

PRA is committed to providing the most effective treatment options for patients. The pharmacogenomics group has the advantage of working across a wider range of therapeutic targets than any of our clients, which allows us to offer a broad range of experience and knowledge.

Key Features

The pharmacogenomics team provides:

STRATEGIC CONSULTATION

Assessing feasibility during a drug development program saves time and resources and helps navigate the unique complexities and challenges of pharmacogenomics programs.

REGULATORY ADVISING

Our team has a strong understanding of the diverse and evolving country-specific regulatory and legal complexities in the pharmacogenomics environment. We are equipped to guide you through these processes and guarantee positive outcomes.

DATA COLLECTION, STORAGE, AND PROCESSING

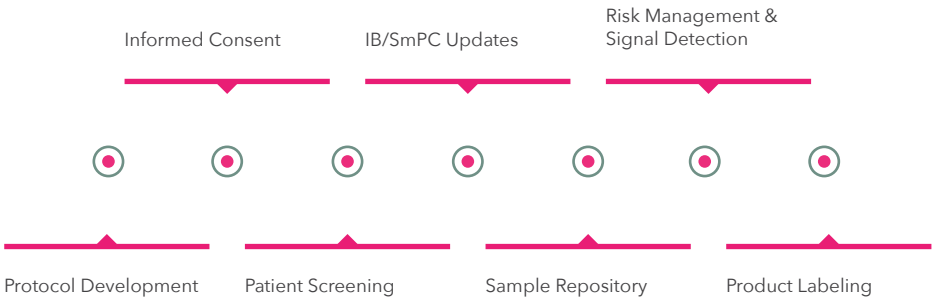
With our in-depth knowledge of genomic data collection, storage, and processing requirements, we ensure that clients can navigate ever-evolving country-specific regulatory and legal complexities with ease.

"Personalised therapy is closer than we think. It's in our DNA. Now is the time to embrace it."

ANDREW PURCHASE
Director, Patient Safety Operations, PV and Patient Safety

Expertise & Experience

Throughout the entire product lifecycle, it's important to give pharmacogenomic considerations to the following activities:



Commitment to Patients

Delivering the right drug to the right person at the right time is the central ethos of pharmacogenomics as a discipline. Through our work, we accelerate drug development across both research applications and clinical uses. Advances in pharmacogenomics ensure that biopharmaceutical drug treatments can move past the one-dose-fits-all approach to a more personalized method of prescribing—ultimately eliminating trial-and-error procedures and allowing physicians to consider a patient's genetic makeup and how this may affect the efficacy of current or future treatments.

By contributing to the acceleration of personalized medicine and individualized treatments, pharmacogenomics helps us as an industry become more patient-centric, focusing on a whole individual rather than an entire patient population. As we continue to identify subpopulations who may have either increased or decreased sensitivity to specific medicinal products and treatments due to genomic factors, we greatly reduce the risk of side effects and significantly increase the therapeutic benefit to the patients.

Next Steps

To learn more about how our pharmacogenomics team can help improve your clinical study, please contact us at purchaseandrew@prahs.com.