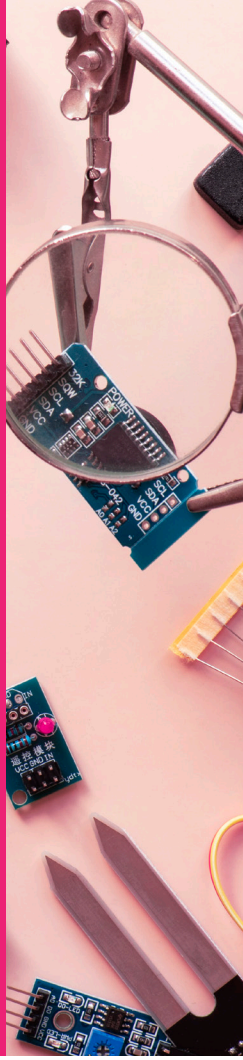
PRA Health Sciences

FACT SHEET



Pharmacovigilance & Patient Safety

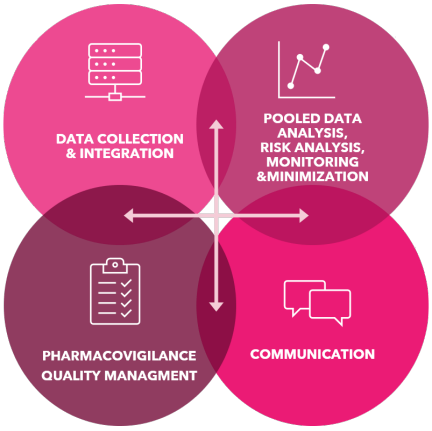
Consumers (patients), their relatives, and the healthcare providers who serve them are key observers of drug and medical device related adverse events that occur worldwide. Pharmacovigilance and patient safety (PVS) experts detect and assess this critical information to minimize risk to patients from potentially unsafe medicinal products. Now more than ever, regulatory authorities emphasize the importance of a comprehensive safety infrastructure. It is imperative to develop a risk management and minimization strategy that covers the entire product life cycle.

At PRA, we apply versatile technologies and targeted data collection to safety reports received from multiple sources. From in-depth analysis of reported events, both individually and cumulatively, risk identification, management and minimization, to regulatory compliance for safety reporting as well as safety communication, we provide a comprehensive range of pharmacovigilance services throughout the product life cycle (including patient safety).

PVS Services

- Local case intake
- Case processing (pre & post authorization)
- Safety regulatory intelligence
- Literature review
- Argus safety database

- Governance system
- QPPV-LPPV
- PV system master file
- Procedures, technology
- Training, audit
- Quality and performance
- Vendor management



- Signal detection and assessment
- Benefit-risk evaluation, risk management and minimalization
- Periodic safety reporting
- Post authorization safety studies
- Labeling

- Regulatory authorities
- HCP, patients
- Ethics committees
- Client / Internal Stakeholders

One Team with One Goal: Patient Safety

We take time to understand each client's specific needs and provide strategic flexible solutions to ensure that your PVS system operates in the most optimal and efficient way. Our services, which includes all activities from case intake through safety surveillance, benefit-risk evaluation and risk management, can be customized to your needs while ensuring regulatory compliance and adherence to global and local requirements. While our team of 800 people are located worldwide, we pride ourselves on our "one team, one goal" philosophy. We operate within a global framework to support the advancement of patient safety. Our leaders take a hands-on approach and ensure that every person associated with a project is fully trained in project documents such as product safety profiles, protocols, processes, and applicable regulations.

Dedicated Technology Infrastructure Delivers Expert Systems Function

We understand that efficiency and accuracy are crucial elements of all safety functions, and innovative use of technology enables us to achieve that consistently. We established our own Pharmacovigilance Systems team to manage our safety technology, allowing safety work and associated processes to be lean, transparent, and efficient. Our team developed a quality tracking, control, and Key Performance Indicator (KPI) system; a case tracking system to capture and track activities associated with case processing; and a flexible, modular reporting system to generate ad hoc reports from PRA's safety database. PRA uses Oracle Argus™ (Argus) for processing Individual Case Safety Reports (ICSR). The database is functional for drugs, vaccines, and medical devices. Argus is a fully validated, 21 CFR Part 11 compliant system that is maintained at a secure hosting facility and accessed through a secure Internet connection.

Key Features

- 800 global PVS employees working at Drug Safety Centers or regionally-based in over 20 countries
- PVS employees can work in either PRA or Client systems and follow PRA or Client SOPs as needed
- Engaged in 40+ preferred functional service provider (FSP) partnerships, working at Drug Safety Centers or Regionally-based, in over 20 countries
- PRA uses DistillerSR for their literature screening and surveillance tool
- Use of Orbit system to track all steps of Development Safety Update Reports (DSURs), Periodic Benefit-Risk Evaluation Reports (PBRERs) for regulatory compliance, safety signals, Risk Management Plans (RMPs) and REMS, full transparency and inspection readiness
- Use of TIBCO Spotfire® to detect safety signals and trends as early as possible in order to manage and minimize risks to patients
- For Safety Regulatory Intelligence, PRA gathers information and documents from various sources relevant to pharmacovigilance services (i.e., Agency Websites and Cortellis™ Drug Discovery Intelligence) and maintains a proprietary Country Intelligence (CI) Database
- 80+ Countries are within our proprietary central repository of regulatory pharmacovigilance requirements, providing regulatory expertise in Phase I - IV/ post-marketing PVS obligations

Expertise and Experience

For over 25 years, PRA has provided comprehensive pharmacovigilance services across all phases and key therapeutic areas. Clients who choose PRA acquire not only additional safety personnel but also a dedicated, nimble team fully concerned with their needs and patient safety. We provide pharmacovigilance and patient safety knowledge, therapeutic experience, and consulting services throughout the product life cycle.

"Globally deployed, our teams deliver expert services with local knowledge. Our understanding of local cultures and their nuances helps us dig deeper and more effectively identify adverse events–some of which might go unreported without this awareness. We are committed to ensuring the highest levels of patient safety."

SABINE RICHTER
Vice President, Pharmacovigilance & Patient Safety

Next Steps

To learn more about our Pharmacovigilance and Patient Safety services and experience please contact our team at SMAPVSinquiries@prahs.com