

SAFETY & PHARMACOVIGILANCE SERVICES

Proactive | Thorough | Effective

Trending

Rising incidences of Adverse Drug Reactions (ADRs) have brought biotechnology and pharmaceutical companies under pressure to manufacture safer drugs and monitor the effects of the medicines to ensure patient safety. Increasing hazards associated with adverse drug reactions will further upsurge the need for effective pharmacovigilance services.

Pre-marketing surveillance involves data collection regarding adverse drug reactions from the pre-clinical screening to phases III clinical trials. Linking pre-marketing with human safety information is one of the emerging trends in pharmacovigilance outsourcing.

Small and medium-sized companies rely on contract research organizations for performing PV activities as they do not have a

separate facility to ensure drug safety. Awareness regarding adherence to Good Clinical Practice (GCP) leads to increased demand for pre-marketing PV outsourcing services.

Opportunities & Challenges

Drive operational efficiency to fulfill increased demand for drug safety and monitoring

PV of clinical trials and identifying the safety information from limited controlled patient information is a challenge. Expert PV processors and domain experts are required to analyze clinical trial data to identify product signal/risk. To reduce the cost and increase the efficiency of the PV process, pharmaceutical companies are looking for an end-to-end PV outsourcing model.

Meticulous safety documentation and reviews for timely submission, product launch & retaining market share

Over the years, PV has moved from reactive to proactive plan and execution phase. Pharmaceutical companies have started to proactively manage signal, risk and perform risk mitigation from the early clinical trial phase. Companies are consolidating and standardizing internal processes to streamline safety documentation while ensuring increased visibility and predictability with centralized program management.

Evolving regulatory standards, volume surges, and increasing complexities

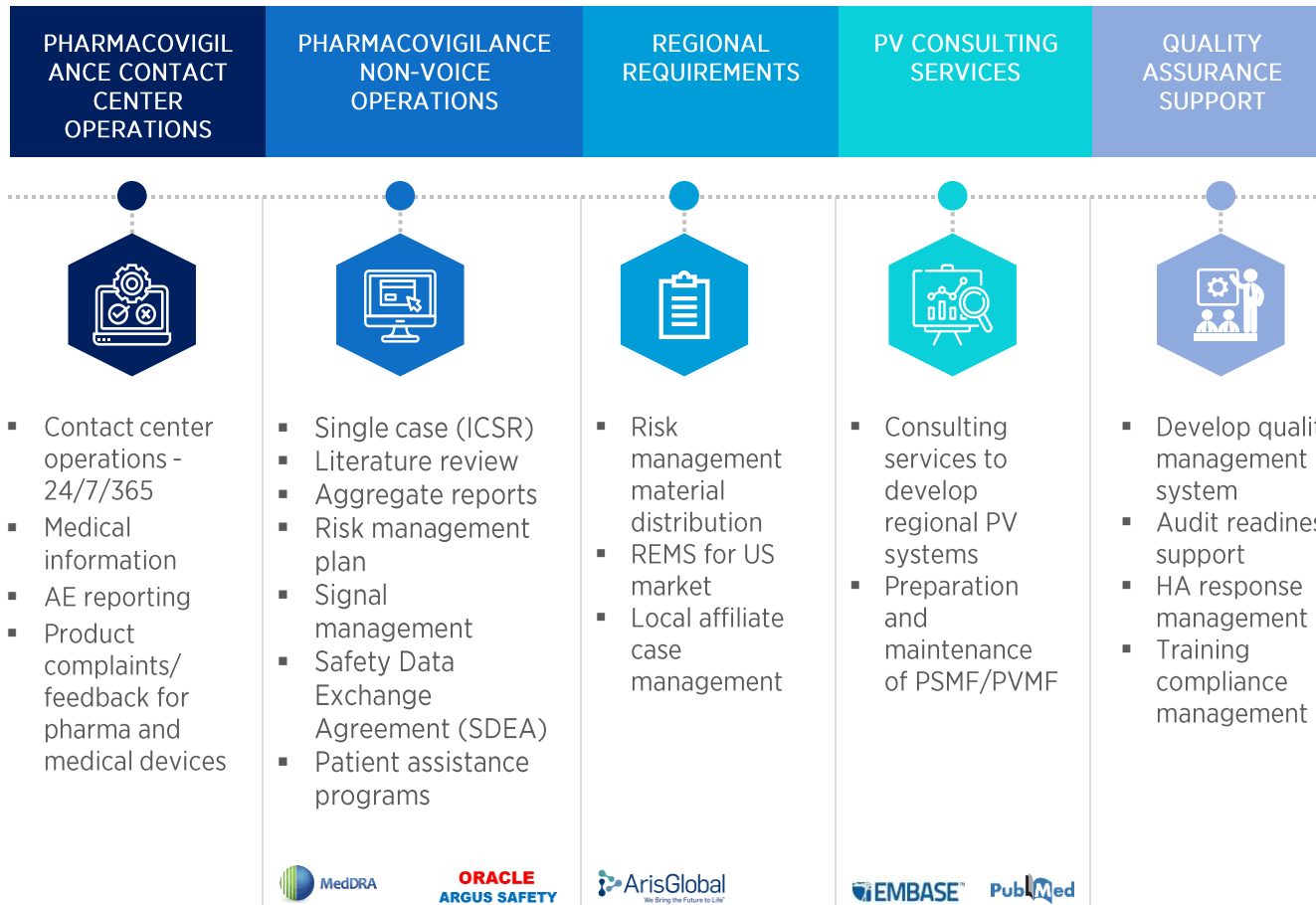
To reduce the recurrent in-house cost of PV activities, a centralized operation in cost-effective regions like India focuses on reducing expenditure and increasing efficiency. Furthermore, as the data complexity increases, manufacturers would need to establish multi-disciplinary expertise across various specialties.



Benefits for the consumers

- Improved benefit-risk assessment of the drugs & risk management programs leading to improved patient outcomes
- Faster & real-time detection of safety signals leading to the optimum use of therapies & enhanced patient safety
- Rigorous & proactive active data collection and processing have the potential to improve further manufacturers' ability to promote & protect patient health and well-being

Safety & Pharmacovigilance Services



Service Assets



Differentiators

- Home grown automation and intelligence platform for quick turn-around time and improved operational efficiency
- End-to-end pharmacovigilance service portfolio ensuring meticulous quality control and timely submissions
- A diverse team of data managers, statisticians, medical doctors, and certified clinical research professionals across all therapeutic areas to deliver high quality and error-free safety services
- Agile processes, domain expertise, and robust written SOPs for ensuring streamlined PV services
- In-depth analysis and review by expert medical professionals (MDs and PhDs) to guarantee optimal benefit-risk profile and achieve better patient outcomes

Cases

Reduced up to 70% manual efforts and 50% cost savings through automated pharmacovigilance workflow

- Reduced manual efforts over 4 months in data entry, validation, and triaging
- Reduced the number of review cycle for QC check

High-quality end-to-end case processing achieved 100% compliance with consistent and effective management of volume fluctuations

- Detailed process map for case intake, data entry, medical review to manage > 200 cases per day
- Effective management of volume surges up to 120% while achieving 100% compliance rate