TATA ELXSI

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SAFETY & PHARMACOVIGILANCE SERVICES

Proactive | Thorough | Effective

Trends

Rising incidences of Adverse Drug Reactions (ADRs) have brought biotechnology and pharmaceutical companies under pressure to not only manufacture safer drugs but also monitor the effects of the drugs to ensure patient safety. Various regulatory agencies such as the FDA and European Medicines Agency (EMA), and global organizations such as the WHO have taken initiatives to ensure that the industry evolves to improve the efficacy of drugs and health outcomes for patients.

In the digital age, patients are taking active role in their own wellness and health management. Penetration of digital health has led manufacturers to monitor multi-channel health related interactions. Proactive monitoring of these channels could provide early warnings of new adverse events.

As the industry is shifting from reactive to proactive pharmacovigilance, manufacturers are scaling their internal practices to meet global regulatory expectations. Managing drug risk throughout drug's lifecycle can avoid catastrophic outcomes such as brand damage, drug recall, class action suits, etc.

Opportunities

Drive operational efficiency to fulfil increased demand for drug safety and monitoring
Intelligent automation of labour-intensive high volume tasks such as narrative generation, narrative analysis (including case extraction & creation), QC assessment, casualty assessment and touchless case processing of non serious cases. This can have positive impact on overall efficiency.

Additionally, labour arbitrage outsourcing and transaction-based model could further lower manufacturer's operational cost.

Evolving regulatory standards, volume surges, and increasing complexities
Manufacturers could manage volume surges arising out of evolving global regulatory requirements and growing product portfolio through capacity scalability and flexibility. Furthermore, as the data complexity increases, manufacturers would need to establish multi-disciplinary expertise across various specialties.

Meticulous safety documentation and reviews for timely submission, product launch & retaining market share
Companies are consolidating and standardizing internal processes to streamline safety documentation while ensuring increased visibility and predictability with centralized program management.

Consumer Benefits

- 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 further improve manufacturers' ability to promote & protect patient health and well-being

IMPLEMENTATION FRAMEWORK

PLANNING

- Define roles and responsibilities
- Process documentation
- Contingency planning
- Initiate performance measurement indicators
- Training onshore/offshore resources
- Continual audits to initiate process development
- Pilot process to improve productivity, quality and reduce turnaround time

DESIGN MODEL

- Establish scope
- Process formulation
- Competencies review
- Establish robust pharmacovigilance key decision drivers: Resource, approach, process and technologies
- SOPs, training, systems and KPIs design

EXECUTE

- Monitoring process establishment at a steady rate
- Define strategic goals, metrics and sub metrics
- Identify key performance Indicators (KPIs) such as turnaround time, error rate, thresholding for critical, major and minor categories, regulatory compliance, productivity, volume
- Feedback mechanism

QUALITY ASSESSMENT

- Steady and continual implementation
- SPOCs for safety and risk management services
- Case processing (triage/duplicate search, pre-submission QC, data entry, follow up, narrative writing, medical review)
- Submission

SAFETY SERVICES | **SIGNAL DETECTION** | **LITERATURE SURVEILLANCE**

AGGREGATE REPORT SERVICES | **ICSR SERVICES** | **QPPV SERVICES**

Service Assets

Interdisciplinary team of drug safety physicians, QPPV, PV SMEs and regulatory experts

Standard SOPs & customizable templates

Custom AI Solutions

Ecosystem: Partnerships & Alliances

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
- Expert program and project managers for setting up processes, and training employees as per local and global regulatory requirements for effective management of volume surges
- 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% operational cost through automated pharmacovigilance workflow

- Reduced manual efforts over a period of 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

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