Transforming Pharmacovigilance

Processes Through Intelligent Automation

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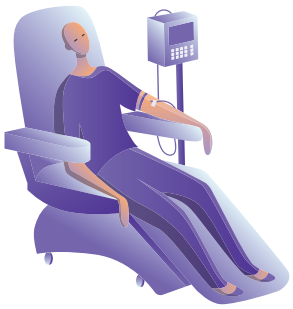
Abstract

The pharmacovigilance (PV) processes are pivotal to successful drug launches and post-market surveillance. Traditional pharmacovigilance involves manual case processing. It leads to inconsistent reporting of adverse events, miscoding, and huge backlogs due to the increased volume of adverse event data. The highly regulated nature of pharmacovigilance processes requires strict adherence to guidelines and the cost of manual errors or inconsistent reporting could be huge in terms of damage to market reputation, product withdrawal, and fines from the industry regulatory bodies. The COVID-19 pandemic has necessitated the increased focus on accelerated drug approvals and market surveillance, where enormous amounts of adverse events data are being generated daily. Hence, there is a need to rethink and transform the traditional manual-intensive pharmacovigilance processes through automation. Leveraging intelligent automation tools throughout the adverse event processing value chain could greatly reduce manual errors, increase process efficiency, and empower the pharmacovigilance leaders, managers, and associates to become "data analysts". Analysis of the captured adverse event data through advanced analytics solutions is crucial to generate actionable insights and predictions to improve drugs and prevent such events. This whitepaper examines the approach to transform the entire pharmacovigilance value chain through intelligent automation and provides a playbook for enterprises for a successful PV digital transformation.

Pharmaceutical firms face a critical need to streamline the costs of drug safety, increase process efficiency, decrease time-to-value for new drug launches, and smartly monitor adverse events during post-market surveillance. Due to the unparalleled huge volume of data for such events received in the digital-first age and increasing regulatory reporting requirements, it becomes imperative to rethink the current PV processes and adopt a digital-first approach by leveraging intelligent automation and advanced analytics solutions.



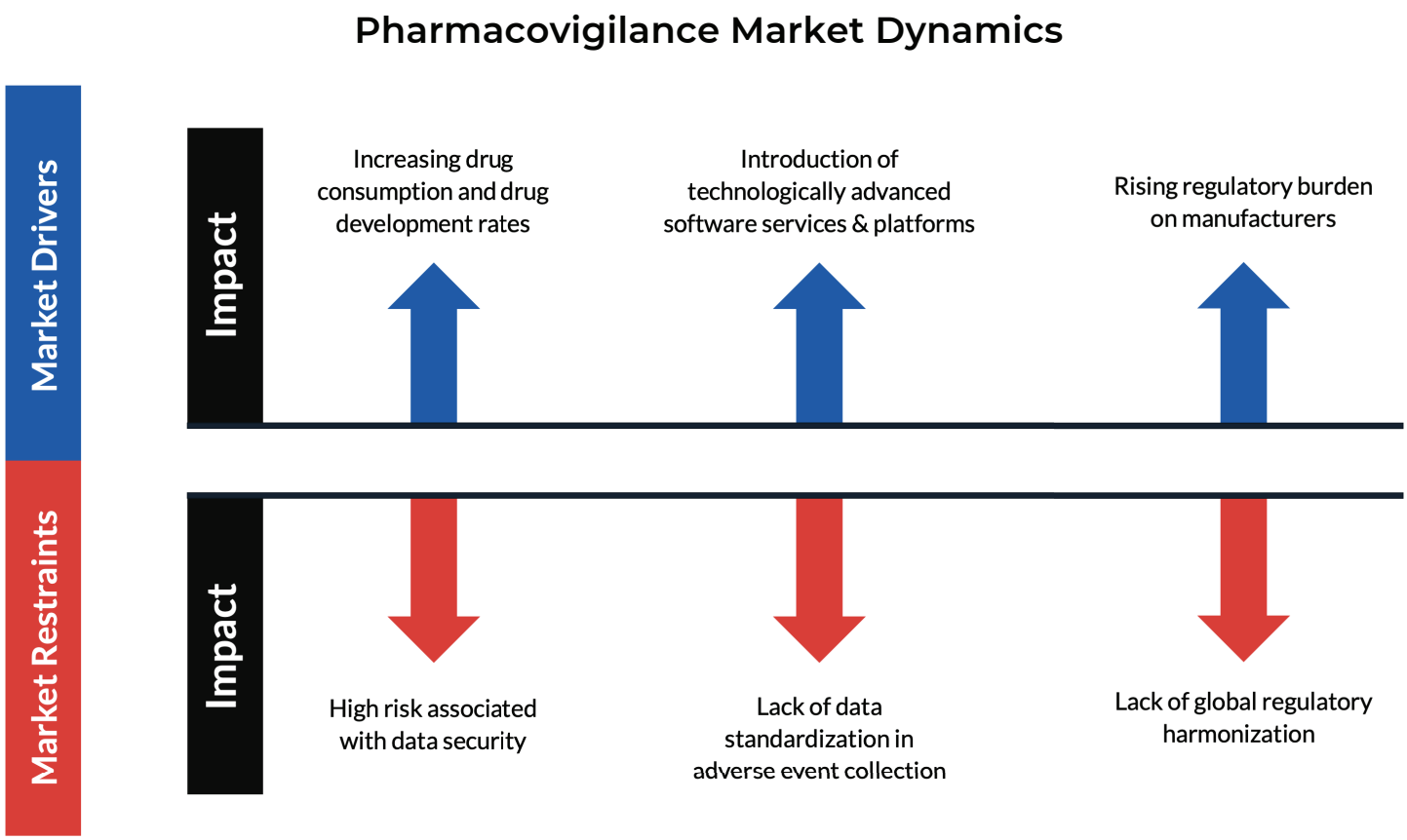
Globally, it is estimated that approximately 10% of patients have been affected by at least one adverse event.

The economic cost of medical error in the US was estimated to be almost USD 1 trillion per year. Additional indirect costs include loss of productivity and reduced trust in healthcare.

Improving patient safety in US Medicare hospitals is estimated to have saved around US$ 28 billion between 2010 and 2015.

Industry drivers impacting traditional PV landscape

The advent of digitalization has brought in a radical shift in the traditional PV landscape. Emerging global healthcare trends are reshaping the pharmacovigilance function. While some of these trends exert a positive impact on the market, some act as restraints that wield caution. The key market drivers impacting the PV landscape are:



Increasing drug consumption and drug development rates

The increased incidence of lifestyle diseases, changing lifestyle patterns, and lack of physical activities have led to the growing consumption of drugs, which in turn brings in high demand for market surveillance and monitoring of adverse reactions. Further, the outbreak of COVID-19 has provided an impetus to the ongoing clinical trials in search of new improved and more effective drugs. These factors result in a growing incidence of adverse events and drug toxicity.

The emergence of technologically advanced platforms and solutions

Many advanced cloud-based adverse events monitoring software platforms have emerged in the market offering seamless connectivity to legacy safety applications and removing redundancies in the PV processes. Few forward-looking pharma companies have achieved success in leveraging intelligent automation and analytics solutions to reduce the manual effort and time taken for case processing and generate insights through big data analytics.

Rising regulatory burden on manufacturers

The existence of stringent regulations for reporting adverse events further increases the need for adverse event monitoring. The regulatory guidelines warrant accurate reporting of adverse events immediately when they are detected and failure to do so would result in serious consequences such as penalties, drug withdrawals from the market, and damage to brand reputation.

High risk associated with data security

The collection and storage of adverse event data require adherence to constantly evolving stringent regulatory guidelines. Adopting innovation in PV case processing by leveraging digital solutions becomes challenging due to the high risk involved in lapses to adverse event data security and the associated direct and indirect costs.

Lack of data standardization in adverse event collection

The adverse events data comes from multi-channel sources such as email, text, phone, chat, social media, etc. The formats of the incoming source documents vary depending on the reported case types. The huge variations in templates of incoming source documents make it difficult to standardize the PV case processing workflows. This results in the huge manual effort involved in collecting, sorting, and processing the adverse event data to be entered into the safety databases. Leveraging intelligent automation becomes crucial in such scenarios to convert the data into a structured format and standardize the downstream process steps.

Lack of global regulatory harmonization

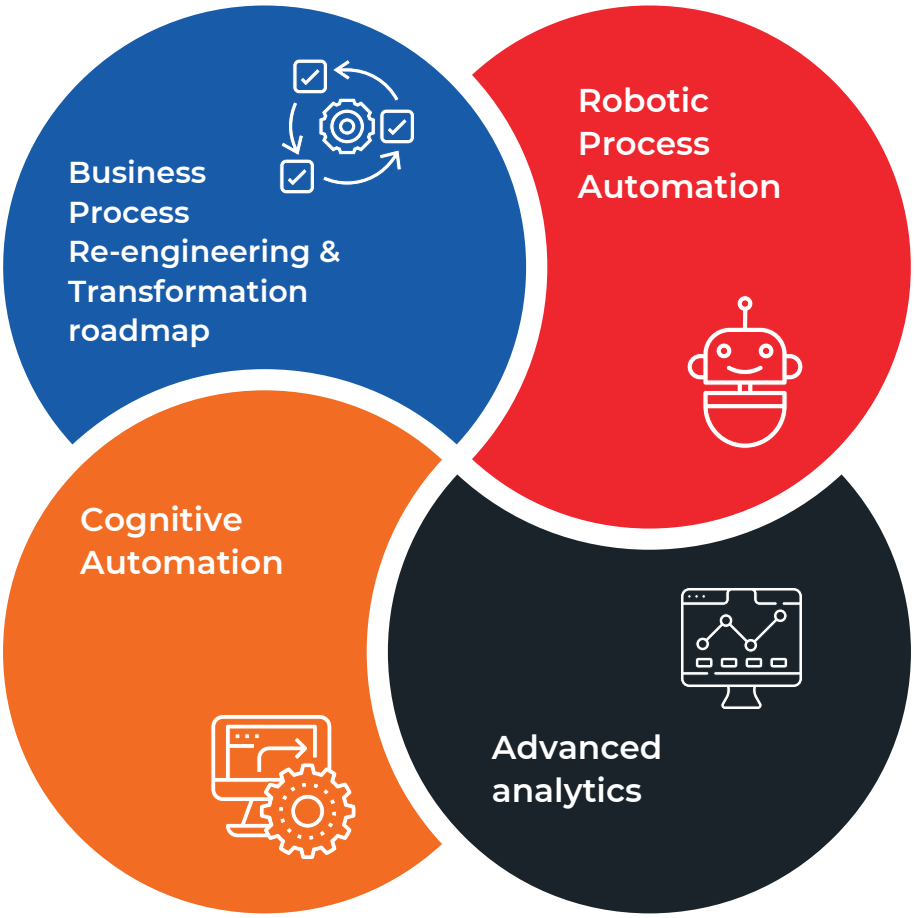
The global regulations around PV case processing and reporting vary broadly by countries and regions with occasionally unclear or ambiguous guidelines. Due to the lack of standardized PV regulatory requirements globally, the majority of pharmaceutical companies still struggle to comply with the regulatory obligations and find it difficult to develop process-efficient standard operating procedures in PV case processing.

Adopting a digital-first approach and leveraging partnership with firms providing next-generation technology solutions could help the pharmaceutical companies to rethink the PV case processing value chain and re-engineer the manual processes eliminating redundancies. Leveraging intelligent automation and analytics throughout the traditional case processing value chain could help in the early detection of potential adverse events by analyzing the existing data, improving the compliance to regulatory requirements, and reducing the need for corrective actions.

Transforming PV case processing through intelligent automation

The main business challenges with traditional pharmacovigilance processes are the huge volumes of incoming data and source documents to be processed, which vary in templates and formats. This results in manual errors, increased processing time, and the need for rigorous manual quality control to comply with the regulatory standards. To successfully overcome these challenges, we have looked at the key capabilities to be developed for next-generation intelligent pharmacovigilance case processing.

Transforming Pharmacovigilance - Key capabilities



Process re-engineering through a digital-first approach

Organizations could maximize the business benefits of adopting intelligent automation by redesigning their pharmacovigilance processes, eliminating redundant tasks, and standardizing them before automation. Due to the highly regulated nature of the PV processes, organizations are generally reluctant to change the old ways of working and redesigning the processes. It is critical to overcome these barriers and re-engineer the PV processes for a successful PV transformation. This would enable seamless transition of processes between bots and humans in the post-automation scenario and increase the overall process efficiency. The pharmacovigilance leaders should also conduct the technology maturity analysis of their PV processes, identify gaps, and develop a roadmap for the transformation journey using intelligent automation solutions.

Intelligent PV case processing

Intelligent automation solutions include a combination of Robotic Process Automation (RPA) and cognitive solutions that leverage AI technologies such as intelligent OCR (Optical Character Recognition), Machine Learning (ML), Natural Language Processing (NLP), and Natural Language Generation (NLG). The transformation efforts should involve investigation of the entire pharmacovigilance case processing value chain and identification of use cases where the intelligent automation solutions could be implemented. This approach will help the PV leaders to achieve end-to-end process automation with minimized human intervention for PV case types such as E2B and non-serious cases that involve lesser process complexity. Some of the key applications of the intelligent automation solutions in the PV case processing value chain are highlighted below:

Automate repetitive manual processes using Robotic Process Automation

Organizations can adopt RPA to automate standardized PV processes that are less complex and require low human judgment. Some of the use cases where RPA is suitable in the case processing workflow are automated case intake, especially for E2B and non-serious cases, duplicate check during triage, acknowledgment response sent to case reporter, data entry for structured E2B case types, logging case into a safety system, auto-locking and archival of cases. In addition, the generation of pre-configured standardized reports for regulatory submission could be enabled through RPA. Automating such rule-based processes could provide quick wins, dramatically reduce operational costs, and improve accuracy.

Leverage cognitive solutions to maximize the business impact

Cognitive solutions that leverage AI technologies should be explored for the most time-consuming and critical phases of the PV case processing, such as triage, data entry, and quality control. Intelligent OCR solutions with AI/ML capabilities can review the incoming source documents, extract, and convert the information present in source documents into structured data and perform document redaction. The extracted information, which is converted into a structured format could be an input for the RPA bots to complete the data entry into the safety database. This approach of combining RPA and cognitive solutions would help the enterprises to achieve increased automation rates and reduce human intervention to a great extent. Further, it also frees up time for safety associates to focus on more complex value add activities.

As an example of intelligent automation adoption in PV, Hexaware recently conducted an assessment for a large global clinical research organization. The objective was to automatically process semi-structured source documents that varied in templates into structured data and enter the extracted data into the safety database. A combined solution with intelligent OCR, machine learning, and RPA is developed that could process 10,000+ cases with 80-85% accuracy. With increased use, the solution continuously updates knowledge base through user correction during quality control. and increases the process efficiency.

The NLP solutions assist in reading and interpreting the data present in source documents and extracting key attributes required with greater accuracy. These solutions could facilitate standardized adverse event monitoring across multiple sites, hospitals, and regions. Further, text analytics solutions that leverage NLP could also mine data from social media, news articles, literature reports, and medical records and identify adverse events along with drug associations. An ML-based approach would be scalable for social media mining that could use large volumes of training data sets to facilitate drug safety signal detection by efficiently separating adverse events and non-adverse events from the informal text present in social media.

In addition, the NLG solutions could be deployed in use cases such as narrative generation for different case types based on standard templates and configurations, outgoing queries to case reporters for any missing information, and sending standardized follow-up emails to the case reporters. The NLG solution could generate case narratives with defined sections and paragraphs extracting the required information from a structured database. Other use cases where the NLG solution could be implemented are the generation of aggregate reports from individual case reports and signal detection.

Adopt advanced analytics to enable proactive adverse event monitoring

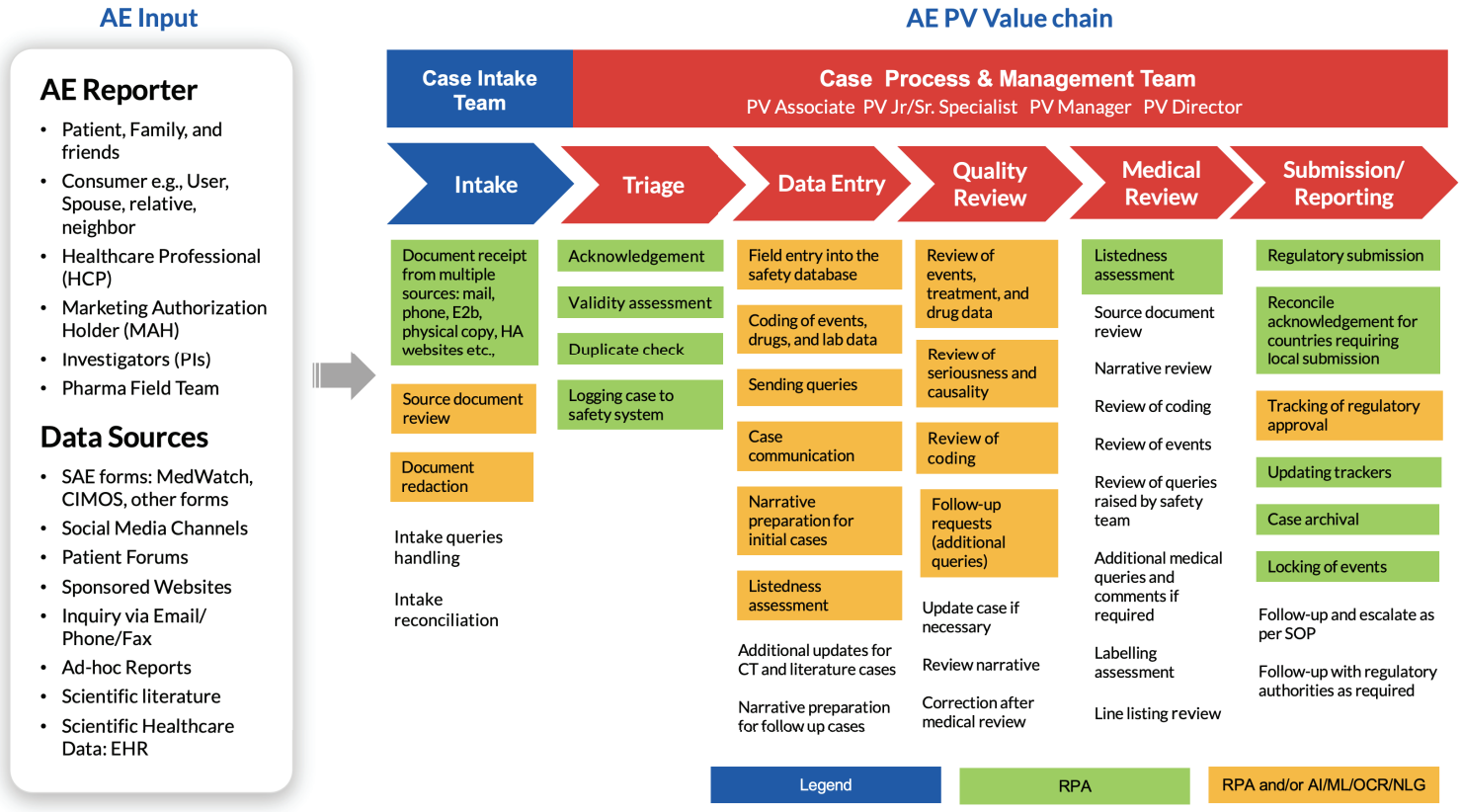
Data mining with predictive analytics solutions on aggregated large volumes of safety data could identify new patterns, correlations, trends, patient preferences and generate real-time actionable insights. Such solutions could analyse the collected data from the safety databases and predict patient-related risk factors (such as demographic characteristics, concomitant disorders.), drug-drug interaction, possible association between drugs and adverse events, and calculating risk at population level for clinical and regulatory purposes. These insights could augment safety managers and pharma companies to transform the PV function from reactive to proactive adverse event monitoring and drive competitive advantage.

Envisioning the Pharmacovigilance of the future

A successful transformation of the PV function would involve evaluating the entire value chain from intake to regulatory reporting, identifying, standardizing and re-engineering the processes, and implementing appropriate automation technologies. This approach would empower the safety associates and PV managers to focus on more value-added tasks that drive proactive adverse event monitoring.

An example of a transformed pharmacovigilance value chain with intelligent automation is illustrated below. It demonstrates how the use cases from each phase of PV case processing, such as intake, triage, data entry, quality control, medical review, and regulatory reporting could be identified for automation. Simple, standardized processes that involve lesser human judgment could be automated with RPA. For more complex processes that involve semi-structured and unstructured data, a combination of RPA and intelligent OCR/ML or NLP/NLG solutions could be explored.

Future State - Transformed & Automated PV Process



Intelligent PV case processing

Automation Impact Across the Value Chain

Total Average Manual hours (Before Automation)	190 – 290 mins	Total Average Manual hours (After Automation)	130 – 195 mins	% Avg Manual Effort Reduction	24-33%

Value chain element	Current average time invested per case (mins) Before Automation	Updated average time invested per case (mins) After Automation	% Effort Reduction	Automation Areas	Level of impact
Case Intake	20-30	15-20	20-30%	• Automated data collection & ingestion • Automated scan of social medical channels to identify adverse events	■ ■ □ □
Case Triage	10-20	5-10	40-50%	• Assign case priority log • AI-OCR to read scan documents. • ML & NLP to classify data and perform duplicate checks	■ ■ ■ □
Data Entry	60-90	35-50	40-50%	• Automatic data entry/processing and analyzing from logs/reports into safety DB	■ ■ ■ □
Quality Review	60-90	45-70	20-30%	• AI-NLG for narrative writing and aggregation of information • Follow ups on missing info & draft queries	■ ■ □ □
Medical Review	20-30	15-25	5-10%	• Assist reviewer by using NLP to identify drug event pairs as per MeDRA coding and drug coding • Automated Listedness assessment	■ □ □ □
Case Submission	20-30	15-20	20-30%	• Generation of safety reports & distribution	■ ■ □ □

Adopting intelligent automation can reduce the manual effort across all phases of the PV case processing value chain. This could result in an overall effort reduction of approximately 30%. The transformed PV of the future would enable the safety case associates and PV managers to become more proactive and focus on preventing safety issues, augment clinical research with actionable real-time insights, and improve patient outcomes.

Critical success factors to enable intelligent PV of the future

Organizations need to evaluate their current PV function, identify quick wins and opportunities that deliver high business impact. Ensuring the following critical success factors outlined below would help the PV leaders and managers to accelerate the transformation of their PV function through intelligent automation.

Key considerations for enterprises to successfully transform their pharmacovigilance

Transformation strategies	• Develop PV transformation roadmap and align internal drivers such as vision, mission, and organizational goals • Develop effective project management with defined plan, identify automation champions and stakeholders for successful execution • Define metrics to assess the project effectiveness and benefits realized • Develop strategic partnerships with leading intelligent automation technology vendors
Automation-led operational model for PV	• Develop simplified, standardized, and efficient PV processes removing redundancies • Make appropriate changes to organizational structure and job-profiles • Conduct regular governance and review of program roadmap
Communication and training strategies	• Change management and obtain buy-in from executive leadership for automation initiatives • Open communication, engagement and collaboration with all stakeholders • Upskill safety associates, PV leaders, and managers to work harmoniously in the post-automated PV function

Moving forward

The pharmacovigilance function is being reshaped by the dynamically evolving industry landscape, emergence of new and innovative AI-based technology solutions, and growing focus on patient-centricity to improve safety. Early adopters of intelligent automation solutions in the PV function have successfully enabled proactive pharmacovigilance and realized broader business impact ranging from more productive research and development, post-market surveillance, and improved sales and marketing outreach. Hence, adopting intelligent automation solutions is no longer optional but a necessity for pharmaceutical firms to thrive in the digital-first world. Organizations must embrace this change and initiate their PV transformation journey with the following key questions:

- What is the current state automation maturity of the PV function? How does the desired future state PV operations model look?
- What are the organizational gaps and measures to be taken to reach the desired future state?
- How can we evaluate and identify quick wins to demonstrate confidence in leadership about the success of automation initiatives?
- What are the long-term scalable automation initiatives that could be identified with achievable roadmap and timelines?
- How can we develop sustainable strategic technology partnerships with leading automation vendors and system integrators based on the current PV technology maturity and needs?

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