Existing Functions of Pharmacovigilance System

windward studios

Index

Introduction

Increasing attention to drug safety has made the role of pharmacovigilance crucial in the pharmaceutical industry. Pharmacovigilance is defined by World Health Organization (WHO) as the science and activities relating to the ongoing detection, assessment, and understanding of adverse events (AEs) or adverse drug reactions (ADRs) to assess a product's risk profile. WHO began a Programme for International Drug Monitoring, in which 134 countries participate by providing country-level data to evaluate and ascertain the risk-benefit profile of drugs. (Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6267537/)

A common framework for a pharmacovigilance system at the national level comprises of a primary national regulatory body and many regional/national centers. As described by WHO, "National Centers (NCs) are WHO-approved pharmacovigilance (PV) centers in countries participating in the WHO Programme for International Drug Monitoring. NCs are usually a part of or closely linked to the national drug regulatory agency. Healthcare professionals and patients (in some countries) send individual case safety reports (ICSRs) to a regional PV center or an NC. The latter forwards the reports to the central WHO Global ICSR database, VigiBase, that is managed and maintained by the Uppsala Monitoring Centre (UMC)." (Source: https://www.who.int/medicines/areas/quality_safety/safety_efficacy/nat_centres/en/)

Estimates put that ICSR volume is increasing by about 15% every year. The growing data

volumes, as well as data complexity, is currently pushing the drug safety industry to search solutions that decrease case processing costs while staying compliant with continually evolving regulations across the world, as well as retaining or even enhancing the information quality contained in ICSRs. Meanwhile, the EU is continuing to ripen its framework around Article 57, in the chase of building a cross-member state database comprised of high-quality data for improved risk management and safety monitoring capabilities.

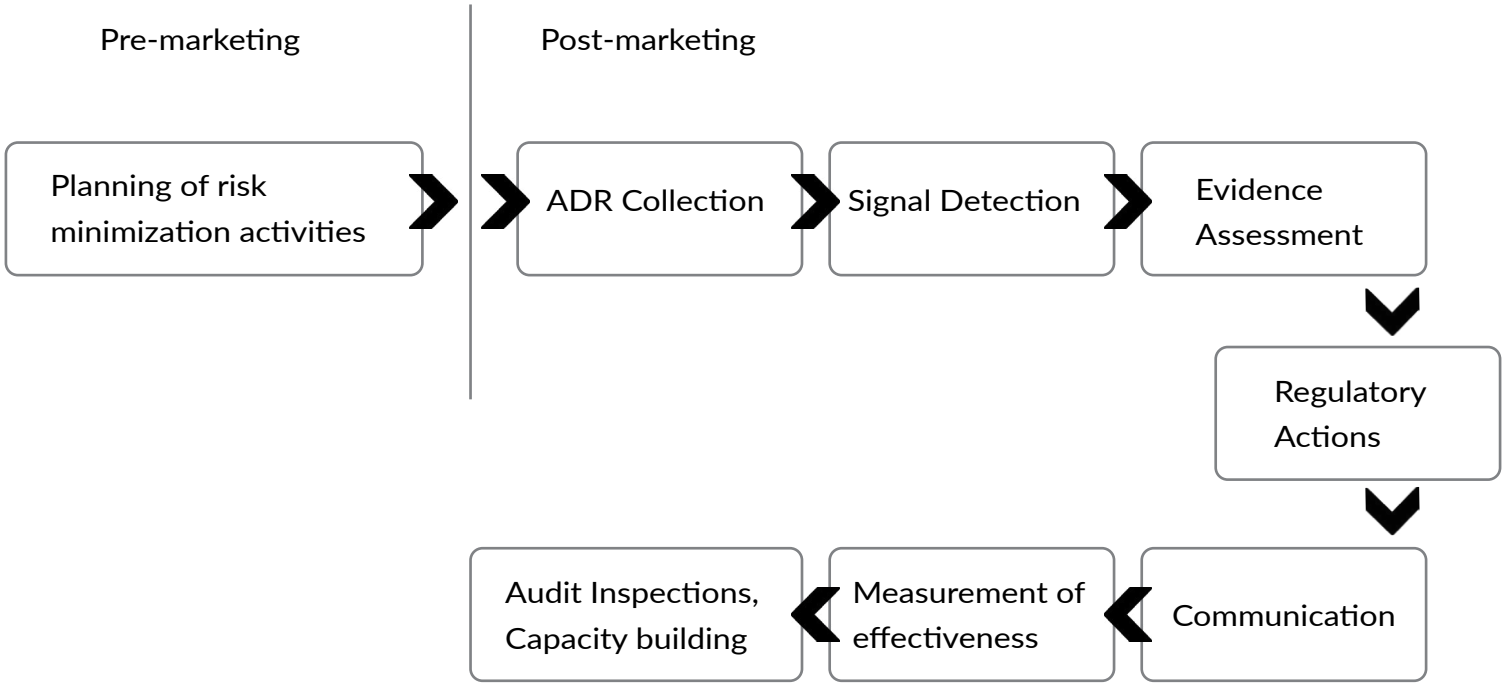
Concurrently, the amount of PV cases has observed a steady rise as regulatory bodies push doctors to report more incidences, and patients also share their adverse event stories

via chat groups and social media. Typically, any large pharma company seems to receive approximately 300,000 to 500,000 AEs a year; thus, raising the cost of pharmacovigilance tasks.

Pharmacovigilance processes, however, are traditionally highly manual and resource-intensive. Realizing that the constant headcount growth and steep cost increase is unsustainable; PV departments have started implementing several measures to control the growth challenge. This includes leveraging the benefits of outsourcing partners, which aids in managing workload pressures, and contain the headcount growth while delivering scalability. The industry has crossed the mark of 50% with the account of how much of PV is outsourced. Outsourcing comes with finite potential, but the processing still demands the same manual effort.

Existing Functions of Pharmacovigilance System

Pharmacovigilance is a post-marketing tool that ensures the safety of a medicinal product. It is concerned with the identification of ADRs and the reduction of associated risks. A well-structured PV system can help create safety data accurately with respect to different levels of the social healthcare environment. Having a pharmacovigilance system in place requires harmonization of different criteria and a well-thought plan that ensures perfect execution and corporeal advantages.



Ongoing Challenges in Pharmacovigilance

Though PV systems have made notable progress in the past decades, they still encounter several current challenges.

Challenge 1

Inconsistency in reporting Adverse Events

Adverse events not necessarily while paying a visit to the Healthcare Center. It can take place after several hours of dispensing the drug. Patients fail to remember minute information regarding the AEs, and many a time not able to report it accurately.

Circumstances, where a patient has not followed instructions given during medication or a patient had side effects caused by concomitant medicines taken along with the prescribed drugs, are reported as adverse events. Such wrong reporting can lead drug safety committees to incorrect conclusions, which in turn results in the suspension or withdrawal of drugs.

Studies show that

40%

of Health Care Personnel (HCP) have never reported an ADE

60%

of HCP's report has demonstrated difficulty in determining whether the drug has caused the ADE

Challenge 2

Continuously evolving regulations and business processes

Business growth into newer markets obliges that the PV systems scale efficiently and smoothly. Ensuring PV systems and processes continually evolve has become an essential requirement. The changing regulations influence PV operations at multiple stages – be it the underlying database, configurability, reporting capability, and system integration with data sources and other applications. Lack of support and consistently changing standards lead to regulatory non-compliance and associated penalties. Reporting in non-ICH (International Council for Harmonisation) regions is even more difficult as its demand varies more extensively.

Challenge 3

Signal Detection and Management

The continually rising volumes of AE data pose complications for the reviewers to depend solely on qualitative methods to monitor, detect, and manage all the possible emerging trends. As manual processes consume considerable time, the reviewer might require a few weeks to analyze a particular signal. On the contrary, the rapid shortening gap of the query and response cycles between regulators and life science companies compels the reviewers to interpret the signals speedily.

Reviewers require focusing on real-time issues while reducing the time and effort spent in determining the fake signals. Inept signal detection and management cause inefficiency in complying with regulatory reporting needs and thereby leads to penalties.

Challenge 4

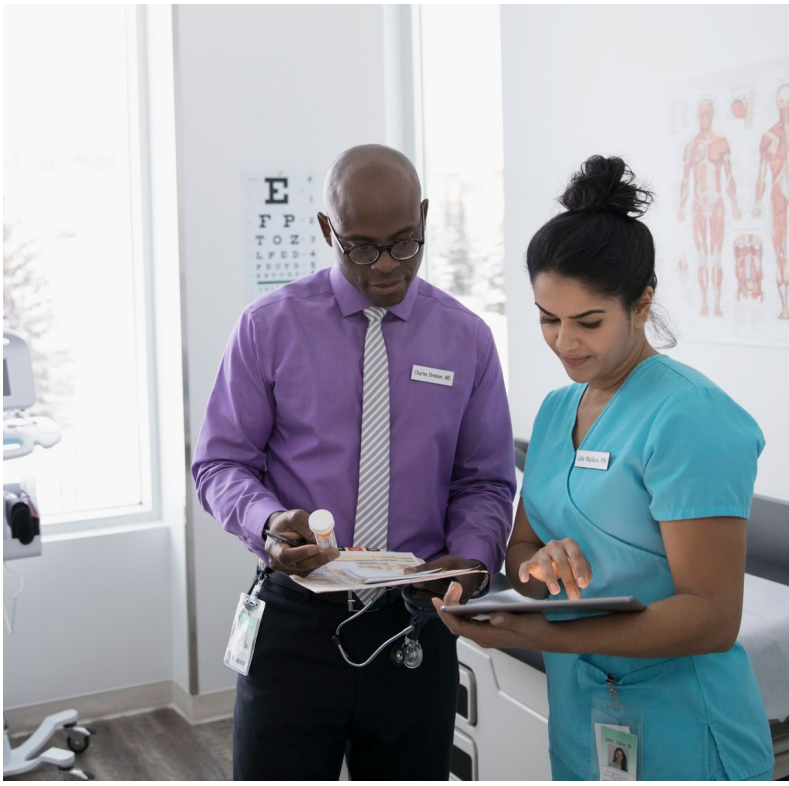
Efficient and Cost-effective operations

Sending and submitting cases across ICH regions poses a substantial challenge for an organization. Many companies prefer sending the data via Fax; some send it as a PDF file through email. These data are transmitted to subordinate companies. They re-type the data into local systems and create ICSR for the local regulatory authorities. Some organizations choose to send the submission data back to headquarters so that the central system remains updated. Hence, the lack of automation results in manual routing and keeping a tab of ICSRs. This causes obstructions in the process and leads to incompetent AE processing and reports.

Challenge 5

System Integration

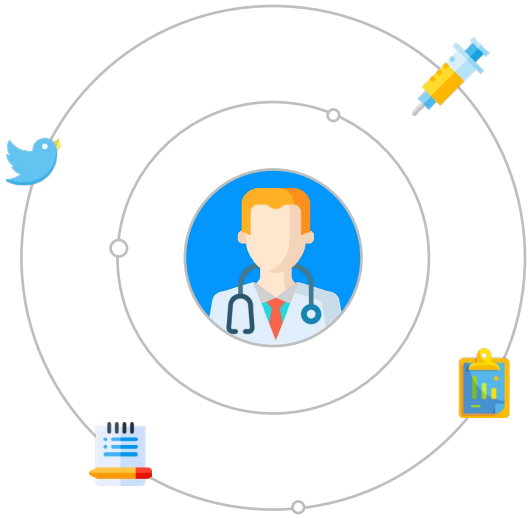
Existing PV systems face issues related to system integration, sharing data between disparate applications, and availability and scalability of systems. Due to inadequate scaling and fragile performance, it results in a system breakdown. This involves manual intervention that leads to data inconsistency. Thus, PV departments suffer from loss of productivity and decreased efficiency. Many of the legacy systems leveraged by companies are not up to date with the latest technologies and standards. This leads to potential privacy and data security issues.



Challenge 6

Processing increased data volume

The global PV industry is facing a significant challenge in processing the increasing amount of data being generated by the ecosystem. Varied sources like journals, articles, social media, patents, and a growing number of non-standardized data sources are contributing to an annual exponential rise in data volumes. Nevertheless, there are many organizations still using the legacy technology systems and manual processes for managing the information. This is prone to errors and hinders productivity.



Challenge 7

Assuring Data Quality

With the escalation in the volume and type of data collected during the life cycle of the product, there is an increase in the complexity and diversity of systems in which the data is captured and stored. For accurate reports and signal detection, it is vital to have certain data entry and data coding standards. Quality of newly entered or received data needs to be checked to maintain quality. These are specific requirements that a PV system should cater to in order to eliminate errors in aggregate reporting, recorded data, and signal detection.

Amidst the blended pressure of volume, cost, and increased demand for analytics, PV industries require weighing multiple facets as they chart their own roadmap. Thus, they are compelled to adopt advanced technology to uphold their pharmacovigilance operations.

Embracing technology to deduct manual data processing and eliminate double data entry in systems is a crucial part of pharmacovigilance today. The potential that lies here is more scalable with consideration of the recent advancement of technology for automation.

The Evolving Pharmacovigilance Landscape

With industries gearing to manage their PV activities efficiently, regulatory authorities have started utilizing modern technologies to collect, characterize, and analyze the AEs related to medicinal products.

The U.S. Food and Drug Administration (FDA) Amendments Act (FDAAA) of 2007 launched a Sentinel Initiative in 2008. The US FDA Sentinel System, an integrated electronic system, complements FDA Adverse Event Reporting System (FAERS) for its post-marketing monitoring capabilities. The Sentinel enables the FDA to access a significant amount of healthcare data rapidly and securely. This includes electronic health records (EHR), insurance claims, and more from multiple data sources.

European Medicines Agency (EMA) is another example that leverages advanced technology for PV activities. It continually monitors ADRs via EudraVigilance database, which is a comprehensive multi-component system facilitating data collection, management, and analysis.

Technological overlay in various forms – off-the-shelf, customized, and homegrown, has thus made pharmaceutical organizations capable of delivering successful PV programs that enrich innovation in meeting changing business needs.

Automation paves the way forward in Pharmacovigilance

Continually growing market and regulatory pressures have compelled the industries to re-evaluate their safety operations and how they affect operating costs, productivity, quality, audit, and compliance. For a pharma company to be successful, it is crucial to embed pharmacovigilance in its daily business operations. However, pharma companies can transform the complete PV process by unlocking the power of technology. The first step towards PV transformation is Automation.

Scope #1

Smart Document Capability

Conventional data sources such as National Spontaneous Reporting System, medical literature, and clinical trial outputs have been utilized as main data sources for obtaining patient safety information on medicinal products. But, none of these alone can serve as a golden standard by which a product's complete safety profile is established. Thus, it becomes crucial to enter into the world of big data and real-world evidence. It has led to an immense increase in data sources by including multiple social media channels, claims data, electronic health records, wearable platforms, and more. Though these new data sources provide valuable insights in identifying safety signals, it is very time-consuming to analyze the massive volume of information they render.

With a large volume of diverse, dynamic, distributed, structured, or unstructured data available for pharmacovigilance activities, it provides challenges in terms of its interpretation with respect to its complexity, content, and size. Since the volume of data is so large and complex, traditional methods are often inadequate for its processing because, without a structured generated document, no actions can be taken on the collected data.

A potential solution to this is the use of artificial intelligence technologies that offer smart document and reporting capabilities. Such systems can help PV experts design templates and streamline the content in such a way that it takes just seconds to fetch the required data when the need arises. With the ability to process multiple data sources simultaneously, it aids in generating the data-powered documents. As these systems possess the functionalities to work with the data sources directly, they decrease the manpower required to pull data each day. Creating templates tailored to specific data and needs help to analyze the information as and when required.

The FDA emphasizes the assessment and reporting of only the highest quality data. With AI platforms' smart document flexibility, PV experts can create reports targeted to a particular niche. They can choose to show or hide the data based on specific conditional logic incorporated right into the document template. This leads to a decrease in the time and cost required to generate targeted and segmented reports. Thus, the digital revolution introduced advanced computing capabilities that spurred the interest of regulatory authorities, pharmaceutical firms, and researchers in leveraging big data for monitoring drug safety and smart capabilities for building documents and reports.

Scope #2

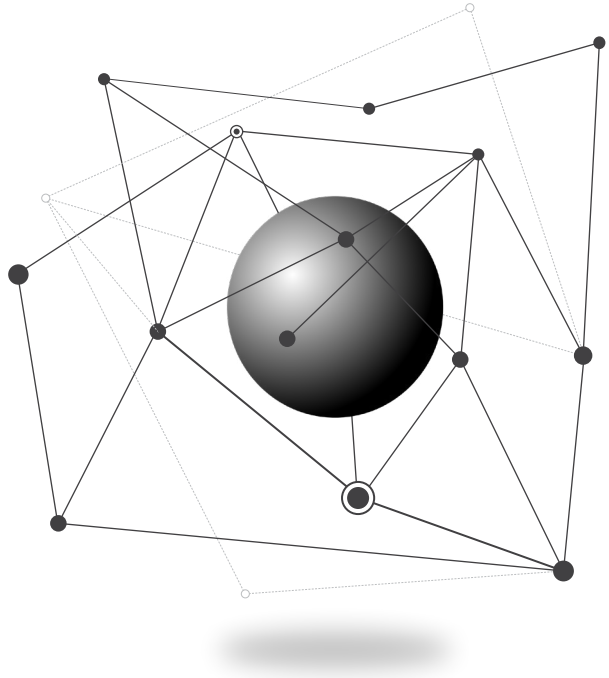
Document Automation in Pharmacovigilance

The benefits of automation in the PV arena begin with document automation. The WHO reports stats that adverse reaction of drugs is the 5th leading cause of death. Thus, modern patients look forward to gaining more information about medication safety and treatments, making pharmacovigilance extremely crucial.

Over the past few decades, PV has been instrumental in detecting, assessing, understanding, and preventing the AEs. Besides, drug manufacturing companies have deployed safety and PV systems to stay compliant with the Health Authority (HA) requirements. According to the new regulatory requirements implemented by HAs, companies require considering the information on AE from various data sources, including chatbots, public forums, social media, and other channels. With due diligence to this requirement, there has been extensive growth in the number of data channels, which has led to an inevitable surge in data volume.

With the gamut of adverse event data and the need to analyze, it has resulted in a complex PV process. Amid the data surge, segregating the cases of distress from false alarms consumes a lot of time. This leads to slow signal detection, which in turn spirals the adverse events out of control. At times, to design the documents, PV experts rely on programmers who don't understand what exactly they require and end up in creating a fuss. Thus, organizations need handling such a vast cluster of data efficiently, and the only possible way to deal with this is by leveraging document automation.

Harnessing the Power of Document Automation Pharmacovigilance



In addition to the pressure coming from the amount of data that the market produces, pharmaceutical organizations also need to meet the regulatory demand for integration and management of tremendous amounts of data that is utilized for the evaluation and processing of drug safety information. With the EMA's drive towards the ISO IDMP (Identification of Medicinal Products) standards to establish definitions and concepts and describe data

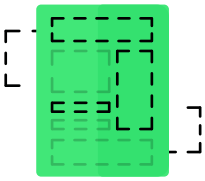
elements and their structural relationships, it demands significant adaptations of document automation systems for pharmaceutical industry stakeholders to meet these standards.

The document automation system not only automates the documentation process but also helps PV experts in generating visually dynamic documents that encapsulate all the data logic in the template itself. It takes a human an average of 15 minutes to process an ICSR. If an ICSR becomes an AE, the average processing time increases to hours. But with document automation systems, this time can be reduced by 70-80%.

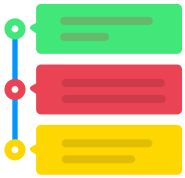
1. Simplified Document Generation
Some of the traditional document creation tools require specific technical knowledge. It poses difficulty in getting people with the same skills. Besides, such people are scarce in the market. Thus, implementing document automation tools in the PV industry can help generate stunning documents that incorporate relevant data quickly and seamlessly.

2. Visually Appealing Document Designs: CIOMS-I (Council for International Organizations of Medical Sciences) form is the widely accepted standard for reporting. It requires PV experts to incorporate certain necessary information or data elements in a tabular or narrative format. Moreover, the data must be accurate, in standard formats (other than predefined terms will be rejected), contain field controls (only specific values can be entered), and drop-down lists (for standard choices). This report is then sent to regulators and other official parties.

Accomplishing these tasks manually is impeding and consumes a lot of time. Moreover, this process is prone to human errors. But with a document automation system, PV experts can create documents that look precisely the way they want. They can create beautiful templates and use the same for future use. It also facilitates access to document design components that enable them to create tables, graphs, and other visuals to display the data more effectively. Thus, pharmacovigilance experts can create beautiful documents faster and easier.

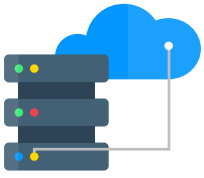


3. Smart Document Flexibility: Document automation system helps pharma companies tailor their data-driven documents for a specific niche. That means they can decrease the time and cost spent on creating targeted and segmented reports for different audiences. Moreover, they can customize the document content (i.e., show or hide the data) depending on specific conditional logic incorporated in the same document template. Hence, they can create documents tailored for any audience from a single template.



4. Enormous Time & Cost Savings: With document automation, template design, and production costs, pharmacovigilance experts can save between 50% and 90% in time and cost. It helps the experts work individually without relying on other departments' timelines. As document automation minimizes the burden on developers, template creation will be a task that can be accomplished in a fraction of time. Hence, it helps PV experts save time and money.

5. Time-saving Document Development: Sometimes, developers fail in understanding the exact requirement of document generation. Thus, PV experts do not get the desired document and send it for redevelopment. This entire process consumes a significant amount of time and causes a delay in submitting the data. The document automation system takes less time to create well-designed documents and helps developers meet internal demands on time.



6. Simple Integrations: The ever-expanding data can be challenging to manage when the business is growing rapidly. Integrating the new solutions to existing systems can reap the benefits of increased efficiency while reducing the disruption caused by having data at different places. Some document automation tools directly work with the data sources so that the documents are generated automatically. Moreover, these solutions can be integrated seamlessly with a company's new and existing applications to accommodate specific performance and security needs.

There are a lot of processes involved in pharmacovigilance from the collection of Adverse Events, processing, signal generation, and more. It takes up a lot of human resources, money, and skilled management. As pharmacovigilance must have minimum errors, quality workforce and management are crucial. Document automation in pharmacovigilance circumvents the need for human resources. As most of the tasks performed are repetitive, they can be automated. The document automation system thus enables pharma industries to automate the extraction of data and the process of reporting.

Scope #3 three

Artificial Intelligence in Adverse Event Processing

When it comes to automating PV tasks, adverse event processing is the foremost target. As it is a redundant process, pharmaceutical industries expend a lot of their resources, time, efforts, and money in performing it effectively.

"Over **60%** *of companies are either deploying or planning to implement AI-supported technologies for case processing in their organization."*

A large part of the case management process in PV has already been automated. This has led to an increase in the quality of submissions as compared to manual submission of forms. Besides, electronic submissions occur spontaneously and cause no delays in regulatory reporting timelines. Thus, the impact of AI applications in PV is further expected on the quality and speed of the work.

Automation in case processing depends on different aspects – it can be the complexity of case management processes, case volumes, case processing workflow steps, and more. This makes some of the manual steps obsolete. AI can be leveraged in further simplifying the case intakes. A blend of Natural Language Processing (NLP) and Machine Learning (ML) concepts can be utilized in this. Optical Character Recognition (OCR) technology enables self-reading of incoming source data and differentiating the information contained within it.

Though we will not see a complete elimination of human input into the case management process, particularly in the application of medical and scientific knowledge, we can expect a notable decrease in manual efforts laid on redundant PV activities. This can free pharmacovigilance experts to concentrate on strategic tasks, such as signal detection and benefit-risk assessment and management. It leads to an increase in efficiency while decreasing per-case-cost processing. Adapting AI applications enhances not only the quality of the PV process but also the speed of work.

Scope #4 four

Cloud Solutions for Pharmacovigilance

Large number of industries have benefitted by storing a considerable amount of data on the cloud. With an increasing number of data sources contributing to the knowledge of benefits and risks of medicinal products, the need to optimize the data intake, storing it, and then analyzing it has created a surge in the pharmaceutical industry.

58%

of respondents have some or all of their safety solutions in the cloud or are planning to move the data into the cloud within the next 2-3 years."

With the emergence of cloud technology, big data applications have come into play in Pharmacovigilance. For informed decision-making in PV, pharmaceutical industries will require tools that are efficient to handle the massive volume and multiple data sources around adverse drug reactions. Thus, the output of big data must be integrated and consolidated data that serves as a knowledgeable and useful source for regulators and marketing authorization holders. It can help them prevent serious and severe ADRs at an individual patient or public health level. The marketing authorization holders can protect the position of their drugs in the market with this big data.

Storing massive amounts of data in the cloud eliminates analyzing the data in dislocated fashion and frees firms from tedious uploading and downloading procedures. In order to make the most informed decisions about the benefit and risk profiles of medicinal products, the pharma companies and regulators will find the need to increasingly depend on the big data solutions in the near future.

Pharmacovigilance software providers are looking forward to offering highly specialized and robust packages that ensure data safety. Moving more and more of pharmacovigilance data to be analyzed into the cloud enables users to leverage signal detection and data mining methodologies seamlessly. Moreover, the aspect of always having access to the latest version of pharmacovigilance software without any necessity of in-house installation shall be a contributing factor for its wider adoption.

Conclusion

Document automation, Artificial Intelligence, and Cloud solutions have already transformed the way pharmacovigilance tasks are performed. And, every generation of tools will get smarter and more adaptive, extending applications to solve new pharma challenges in different ways. The pharmacovigilance industries, as well as the regulatory agencies, have picked up on the potentials of these technologies for PV.

Current technology systems and applications automate certain aspects of pharmacovigilance, such as case intake, case processing, and reporting activities. Companies can reduce the effort and spend required for individual case safety reports (ICSR); thus, allowing resources to focus on proactive identification, evaluation, and minimization of risks. Embracing technologies like document automation, AI, and cloud-based solutions can help pharmaceutical industries move towards end-to-end automation across the PV spectrum while ensuring compliance and quality.

Existing Functions of Pharmacovigilance System

windward studios