Moving to Patient-Centric Pharmacovigilance

Advanced Technologies are Harnessing Patient Information to Drive Better Safety

Data on patient experiences with new drugs and therapies promises to play a prominent role in drug reviews and approval.[1] Analysis of this information could help identify and address adverse drug reactions and safety problems before they occur. Currently, these problems cost the industry nearly $30 billion per year.[2]

The increase in patient-reported safety data has led to growth in pharmacovigilance workloads. Safety leaders have more data sources and values to analyse, making identifying true safety signals and trends harder. The lack of data standardisation within the industry[3] brings additional complexity and requires more time and resources to aggregate information for analysis.

The industry is looking for better ways to leverage patient safety data effectively and efficiently. Modern pharmacovigilance solutions bring together information while streamlining scientific and regulatory processes. These new tools are helping safety leaders to drive patient focus, use new sources of data, and improve collaboration with stakeholders.

Modernizing Pharmacovigilance to Increase Patient Focus

Growing case volumes and new data sources are leading to an increase in outsourcing of safety to contract research organisations (CROs) generally low risk, high volume functions such as processing non-serious cases. By 2026, demand for outsourced pharmacovigilance services is expected to reach $10.6 billion,[4] increasing the need for solutions that improve collaboration, provide greater visibility into safety data, aid analysis, and make compliance easier.

"Many of the systems used for pharmacovigilance dated back to the 1990s," said Martijn van de Leur, head of global pharmacovigilance for Biomapas, a CRO that offers clinical trial, regulatory, and pharmacovigilance services. "Given the strict regulations affecting pharma, many have been afraid of adopting new technologies. There is a shift happening as more companies openly embrace change because they see the larger benefits to help meet compliance standards and reduce cost without affecting quality."

Cloud-based systems play a significant part in bringing together stakeholders and supporting end-to-end processes. They also help drive standardisation of data and reporting to aid the monitoring, analysis, and sharing of safety information. In the end, if leaders have the tools to streamline pharmacovigilance processes and easily collaborate with partners, they can enable a greater focus on patient safety.

Leveraging New Data Sources

Artificial intelligence (AI) can be used to sift through terabytes of data and automate manual, error-prone processes. Streamlining the analysis of information leads to faster determinations of risk levels and drug safety signals. The use of AI, including machine learning and natural language processing, promises to enable predictive pharmacovigilance by automating the identification of adverse event trends and potential signals.

AI can leverage real-world data from patients' electronic health records and insurance bills to improve drug safety monitoring. Exploring AI to mine other data sources, such as social media, online patient communities, and call centre data can provide further insights into adverse events. AI also allows users to perform more extensive literature searches, improving their ability to identify or predict drug safety trends.

Automating Case Safety Reports

Automating administrative work, particularly the intake, data entry, and processing of individual case safety reports (ICSRs), is a major potential benefit of AI. Today, many companies still rely on manual processes and paper to handle these crucial functions, increasing the risk of non-compliance and errors and preventing them from keeping up with rising caseloads.

According to the FDA, the number of adverse events found in the US tripled from 2010 to 2019, leading to a sharp increase in pharmacovigilance team workloads. By 2017, one study found that a normal large biotech's pharmacovigilance team was processing more than 200,000 ICSRs, up from 84,960 in 2007.[5] Using AI to process these volumes of ICSRs can significantly streamline safety reporting and analysis and allow teams to focus on more severe cases.

Deciding which steps to automate first requires an understanding of risks balanced with the time and effort needed to complete a task. A study by the non-profit group TransCelerate found the ICSR to be the most labour-intensive and crucial step in safety because it feeds subsequent processes such as reporting, signal detection, benefit-risk analysis, and risk management. Breaking the process down, researchers found the top priorities for automation to be language translation, case verification, in-line quality control, and case prioritisation and triage.[6]

Improving Collaboration Through Better Data Access

Given the state of the safety data landscape, true cloud-based multitenant solutions are needed to bring together data and content and support end-to-end processes. These solutions should be designed for ease of use and feature interactive dashboards, intelligent automation, and notification prompts. They should also streamline the electronic submission of ICSRs to regulatory authorities and license partners, with workflows that help with routing, escalation, and task completion.

NAMSA has found that its cloud safety solution is more intuitive and has simplified training, data access, and report generation, allowing them to deliver a higher level of service.

"We can easily set up new studies, add or modify workflows and fields, and create or run reports to support our clients as they move from pre-clinical to commercial," said Jennifer Kratz, senior product development strategist for pharmacovigilance at NAMSA. "We're delivering a better level of service because we can align with their processes and provide greater transparency."

For Biomapas, the solution is enabling greater collaboration with clients by providing different levels of data access, depending on needs and preferences. "Some customers want to outsource pharmacovigilance functions entirely and have little to no

involvement in day-to-day activities, while others want to be informed regularly or closely involved. Our cloud safety solution gives us options to meet customer requirements, such as granting read-only access to data," says van de Leur.

In the future, van de Leur expects to see better connections between safety, clinical, regulatory, and quality, which are important in supporting pharmacovigilance processes and understanding drug safety from different perspectives. "Connectivity between pharmacovigilance and other cross-functional systems is becoming a key requirement," he notes.

Using Technology to Cut Through the Noise

Even though the industry is studying AI and applying it to existing operations,[7] we are years away from routine use of predictive pharmacovigilance tools. Efforts today focus on automation, aiding processing, better data access and management, and earlier signal detection to protect patients and improve their quality of life.

As the science and practice of pharmacovigilance continue to evolve, cloud-based applications will play a crucial role in helping more companies to improve patient safety and reduce risk. "Drug safety has historically been a labour-intensive field. The cloud will change the scope of case processing so that pharmacovigilance departments can focus on higher value-add activities rather than filling out paperwork," says van de Leur.

Keeping Up with Safety Regulatory Change

The past decade has brought increasingly stringent requirements designed to protect patients. One of the firsts is the EU's Product Safety Master Files (PSMFs), which are now required by many countries and by local regulatory authorities within the EU. Cloud-based systems are helping pharmacovigilance teams to standardise data and processes and keep a closer watch on revisions and updates to documents that must be sent to QPPVs and filed with regulatory authorities.

Standardisation is essential because changing regulations, particularly on the local level, have led to an explosion in the amount of drug safety data that companies must monitor and process from different regions and languages.

"This data comes in different formats (e.g., Microsoft Excel and ASCII), so companies must expend more effort to deal with the noise surrounding it," said Peter Kohut, formerly director of drug safety at the Dublin-based pharmacovigilance services firm Arriello, s.r.o. "Avoiding duplicate reports and data is especially important when companies have multiple markets in the pharmacovigilance system and various authorisations across the same territory."

Business changes (including mergers and acquisitions) and a lack of proper change management can also affect pharmacovigilance systems and departments.

A Need for Seamless Processes Between Safety and Quality

An increasingly complex regulatory picture also mandates stronger connections between pharmacovigilance and quality management systems for improved operational efficiencies and compliance. These connections, which cloud-based systems can help enable, offer greater visibility into SOPs, CAPAs, change control, and training and allow more reliable tracking of key performance indicators.

"Pharmacovigilance and quality must go hand in hand, and strong quality management systems must be in place to maintain multinational oversight and compliance, along with tracking key performance metrics," Kohut says.

Pharma companies will need to automate QMS systems to manage the updates coming in from local regulators more effectively and to exchange drug safety information more efficiently, Kohut adds. There may be challenges based on the level of automation at CRO and other contract partners.

"Some CROs and CDMOs may have fully automated systems, while others won't," he adds. Using technologies that allow data to be summarised, shared, and reported via dashboards, a hallmark of cloud-based systems will make it easier for companies to meet requirements.

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