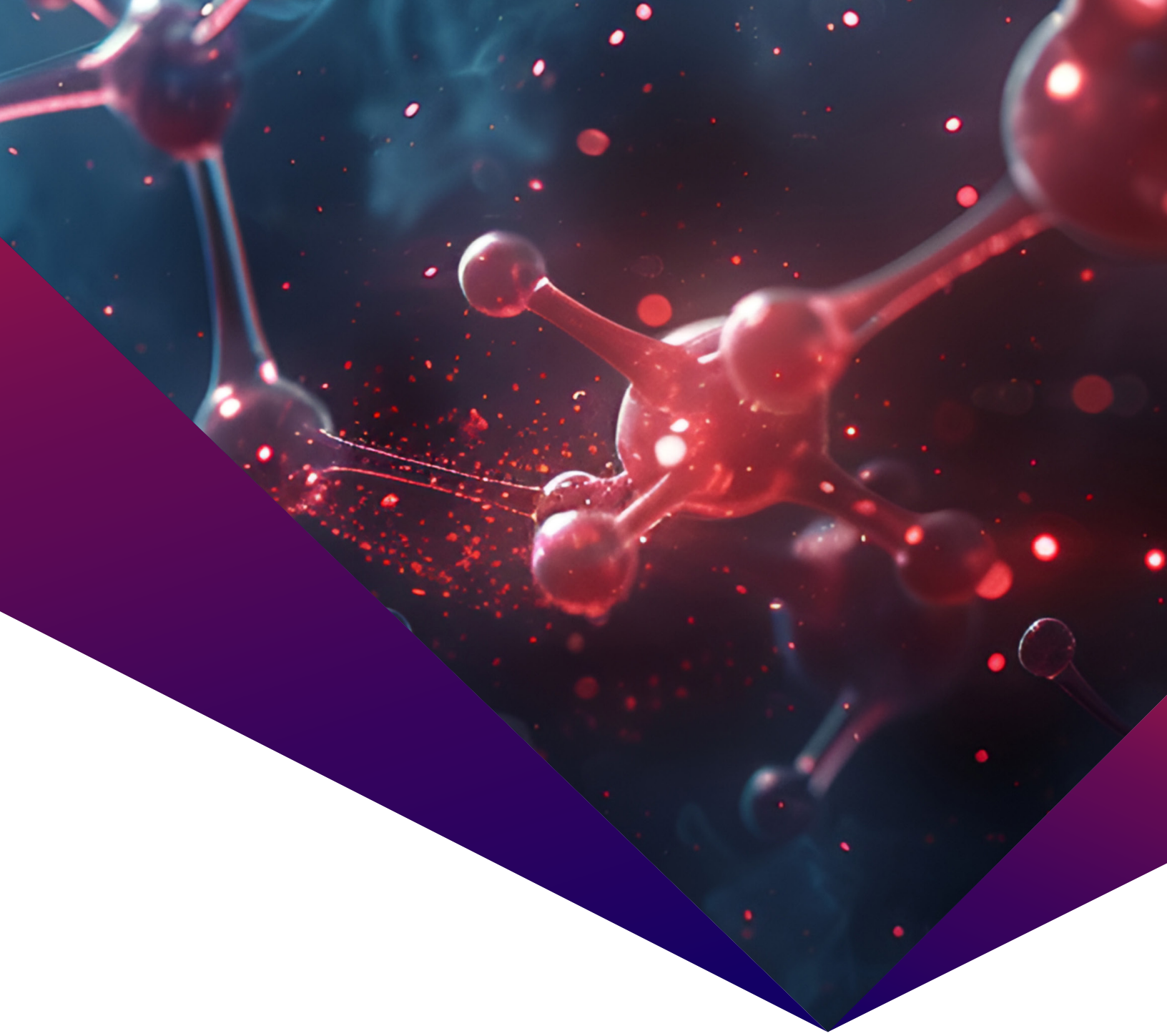

The evolution of technology for safety notifications

How a global platform is scaling safety while enabling international growth

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Clinical trials are becoming more intricate and complex in nature, while also incorporating a wider array of patient populations. With more patients enrolling in studies, multiple drugs being tested, and increasing numbers of countries hosting trials, the stakes for reporting, maintaining and communicating safety information has never been greater.

To address the challenge, recent years have seen a dramatic development of solutions driven by robotic process automation (RPA), artificial intelligence (AI) and machine learning (ML). This has enabled sponsors to simplify and expedite almost every step in the pharmacovigilance (PV) process, from case intake and processing to medical review, (signal) surveillance and reporting (e.g., periodic review and update). Natural language processing (NLP) and generative AI have brought scalability and significant effort reduction and process efficiency gains across all steps of the pharmacovigilance process.

Challenges, however, still persist. Investigators sometimes struggle with this inundation of safety information and how to ensure the effective and efficient translation of safety information to the patient. Further, in keeping with the strictest of safety standards, regulatory agencies mandate that sponsors promptly notify their principal investigators (PIs) of adverse events related to investigative drugs in clinical research. With an 84% increase in adverse events (AE) cases **reported to the US FDA** from 2014–2020, having the right safety parameters and notifications in place is crucial to ensuring that study sites are well equipped to handle safety events quickly and effectively.

Meanwhile, clinical trials are expanding to new regions around the world, particularly in emerging markets like Latin America, Southeast Asia and Eastern Europe. These regions are seeing an influx of clinical trials due to the availability of diverse patient populations. This presents an opportunity but also a challenge. The need for standardization, scalability and safety around the notification process becomes more critical as trials go more global.

For many years, safety notifications were mailed, emailed or delivered via overnight couriers. Though reliable, these delivery methods have proven to be time-consuming and costly, while involving significant risk of error and administrative burden to sites and sponsors. A more streamlined, standardized and digital approach to disseminating safety notification information is desperately needed, particularly as trials have grown exponentially around the world.

The need for streamlined and efficient safety protocols is especially acute in the Latin American region. Nations such as Argentina, Brazil, Mexico, Chile, Peru and Colombia are seeing a meteoric rise in the establishment of clinical sites and research institutions. The increase and demographic variety of populations, along with lowered operational expenses, makes this region ideal for clinical trial investigations. Additionally, progressive enhancements in healthcare frameworks and additional investments in medicine are helping make Latin America an epicenter for worldwide clinical research.

"Latin America and Argentina have seen sustained growth in clinical studies since the 1990s to align with ICH standards," said Dr. Jorge Velasco Zamora, site manager, at the **CER Institute**. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) brings together regulatory and pharmaceutical authorities to standardize drug development around safety and quality control.

A new platform for a digital age

Because of the added complexities surrounding safety notifications for clinical trials that are now being conducted throughout regions like Latin America, the flow of safety information must be in real time, accurate and efficient.

Cognizant's **Shared Investigator Platform (SIP) Safety Exchange Module** has emerged as the strategic solution to expedite safety notification processes for both CROs and sponsors. SIP addresses safety notification challenges by enabling electronic dissemination of information based on compound-driven, country-specific distribution rules. The preconfigured safety distribution rules ensure accuracy, while reducing manual effort and improving operational efficiency. This innovation assures quick and easy access to safety developments, while allowing clinical sites to focus more on patient care.

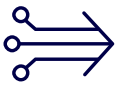
SIP has not only optimized the operational dimensions of clinical trials but has also instilled a robust framework for patient safety. Its impact on clinical research around the world is profound, marking a significant stride in the field and setting a precedent for future innovations in global clinical trial management.

"Over the past three years, the CER Institute has transitioned to platforms such as SIP. This shift has facilitated access to studies from big pharmaceutical companies, the centralization of Suspected Unexpected Serious Adverse Reactions (SUSARs), training processes and the management of essential regulatory documents," said Zamora. "The B2B relationship between sites and sponsors in global clinical trials is complex, but platforms like the SIP provide an excellent opportunity for both parties to connect and share needs."

In the LATAM region, there are currently more than 640 active studies across all sponsors on the SIP platform at more than 1,400 clinical research locations (a majority are in Brazil, Argentina and Mexico) representing over 8,400 study sites and receiving more than 11 million safety notifications in real time. Globally, with over 2,400 active studies involving over 70,000 sites, more than 1.1 million safety notifications have been distributed to 550 million recipients worldwide via SIP, averaging over 1,000 document uploads and 4,000 distributions per day. Here are just some of the ways in which SIP is transforming global safety notification in clinical trial operations:

Reducing redundant notifications and over-reporting

By using a single portal to send all notifications, sponsors streamline the process by automatically and directly distributing safety notifications only to specified site staff and their delegates. This enables them to prioritize based on urgency.



Streamlining review and acknowledgment of safety notifications

With SIP, safety notifications are delivered through a unified system that simplifies the acknowledgment process, without having to juggle multiple communication channels. Investigators and clinical site staff can delegate tasks or specify how notifications should be delivered to different team members. The system also enables automated multiletter acknowledgment, allowing sites to confirm receipt of multiple notifications across different studies with just one action.

Enhanced tracking and reporting

Sponsors can generate reports that track site safety notification acknowledgment status, making it easier to manage communication and follow-up in real time. Sites can quickly search for and locate relevant safety documents using filters specific to the study or sponsor. Sponsors also benefit from real-time distribution reporting and monitoring across regions.

Faster, more compliant safety reporting

Compared to manual or even email-driven distribution, SIP could dramatically reduce the time and effort required to distribute and acknowledge safety notifications. Investigators no longer need to worry about receiving physical documents, dealing with mail delays, or searching through overflowing email inboxes to find critical information. SIP also provides an audit trail that tracks every action taken on safety notifications, from receipt to acknowledgment.

Greater scalability and standardization

The platform's ability to accommodate country-specific safety distribution rules, and adapt to different local regulatory environments, is a game changer for sponsors conducting global trials. It allows the scaling of operations in emerging markets without sacrificing efficiency or patient safety.

"Responsibility for safety has grown with the increasing volume and complexity of clinical studies. Managing these demands efficiently is essential, especially with safety reports arriving daily from various sources, making evaluation tedious," said Zamora. "SIP centralizes these reports on a single platform, allowing for easy filtering and management. The integration of AI promises to further streamline processes, optimize time and enhance site efficiency."

And as more pharmaceutical companies and CROs adopt a digital approach, the process of safety notification will become more streamlined and accessible, regardless of location. SIP also provides investigators and sites with quick and easy access to all relevant safety developments and enables clinical sites to allocate greater focus to patient care, treatment and support while reducing the likelihood of errors.

The future of safety notifications in clinical trials

The future of clinical trials—and safety notification protocols—lies in digital transformation. We have come full circle, from AE capture to safety notification distribution and reporting. There are opportunities for greater efficiency at every step, ensuring compliance and, most importantly, patient safety.

With tools like **Cognizant's AI-enabled Neuro®** PV and the SIP Safety Exchange Module, and APIs enabling system integration, the industry is moving toward a more efficient, standardized and cost-effective path to manage safety data and notifications. By integrating safety management (SIP has integrations with Oracle Argus, Veeva Vault Safety and a proprietary system) and safety distribution systems, and automating and streamlining the processes, sponsors and CROs can reduce the administrative burden on clinical sites, allowing investigators to focus on patient care while still maintaining the highest standards of safety.

For sponsors, this means faster trial execution, lower cost and better patient outcomes. For clinical sites, it means a more manageable workload, improved compliance and enhanced ability to respond to safety concerns. Ultimately, the digitization of safety notification processes not only mitigates risk but also improves the overall quality of global clinical trials. This will pave the way for more successful outcomes in the development of new drug therapies.

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