

Buyer's Guide: PV Reporting AI and Automation

Considerations for selecting modern pharmacovigilance and safety solutions that improve adverse event detection, assessment, understanding and prevention.

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THE PV AND SAFETY LANDSCAPE

Global pharmacovigilance (PV) has never been more complex for life sciences organizations. Evolving global regulations, rising safety case volumes, heightened expectations, restricted budgets, and continuously expanding datasets add complexity to an already intricate product development journey. Sponsors face enormous pressure to meet both internal and external timelines, reducing safety case routing and reporting timelines while also mitigating risk. Effective PV and safety programs that leverage advancements in technology, automation, and data analytics offer valuable advantages.

Learn how to identify powerful PV and safety solutions in this buyer's guide.

Included in this Guide:

- Business value of AI and automation in PV and safety
- AI and automation features and advantages
- Essential automation solutions for PV and safety
- Vendor evaluation resources

THE ROLE OF AUTOMATION IN PV AND SAFETY

“Not meeting timelines, either with regulatory bodies externally or with various divisions internally, is a major concern for PV and safety teams. Additionally, we want to ensure we don’t miss any AEs or SAEs.”

PV and safety teams are responsible for capturing every adverse event (AE) and serious adverse event (SAEs), ensuring total compliance on PV reports to global regulatory bodies, enforcing corrective actions, and communicating the risks and benefits of drugs at all stages of development and post-market. On top of that, any non-English language documents may need to be translated for global reporting purposes. Traditional event reporting struggles to meet the demands of the evolving PV and safety landscape. With the surge in safety case volume, up 30-50% according to the International Data Corporation (IDC)¹, coupled with ever-changing global regulations, ensuring timely reporting amidst this influx of data and changing standards is a significant hurdle for organizations. PV and safety teams are under pressure to re-evaluate their PV and safety workflows, and invest in automation and AI to refine their processes.

¹ <https://www.idc.com/getdoc.jsp?containerId=US48061622>





Some applications of AI and automation include:

- Automated case triage, analysis, and reporting
- Centralized team communication
- Expedited AI translation and redaction
- Local literature monitoring
- Media monitoring

The rise of AI and automation in healthcare has revolutionized case management and communication processes. Automated workflows, powered by AI technologies like optical character recognition (OCR) and natural language processing, enable real-time notifications and efficient triage of cases. These systems can convert unstructured content, prioritize cases by severity, and significantly reduce case processing times. Furthermore, automation has replaced manual safety case monitoring, with the capability to identify and translate relevant articles, reducing identification times by up to 85%. Centralized databases enhance team communication, offering clear insights into safety processes and ensuring timely notifications. Additionally, the integration of AI-driven translation tools expedites regulatory submissions, offering advanced content handling, real-time translations, and automated literature tracking.

While PV and safety reporting remain complex and demanding tasks for life sciences organizations, the integration of AI and automation offers solutions to enhance both the speed and accuracy of these processes. By leveraging these technologies, organizations can achieve the efficiency and precision they aim for in monitoring and reporting adverse events.

HOW AI AND AUTOMATION MAKES PV REPORTING FASTER AND REDUCES LEGAL LIABILITY

AI enablement and automation in PV processes facilitate high volumes of data processing to reduce manual burdens. Teams can accelerate their reporting timelines by up to 50%, reducing the manual effort required for efficient and compliant case processing.

By adequately collecting data and promptly reporting potentially harmful events in clinical trials, sponsors advance toward the primary objective of PV ensuring patient safety. However, when performed manually, this process involves reading, understanding, and translating incoming cases and physically entering the data into the PV and safety workflows. Not only is this process time consuming, putting reporting deadlines at risk, but it is also prone to human error. **On the other hand, AI and automation increases efficiency in detection, streamlines assessment and understanding, enhances prevention measures, and reduces legal liability.**



Efficiency in Adverse Event Detection

The integration of AI in PV has revolutionized the way adverse events are detected. With the power of real-time monitoring, AI algorithms monitor data, offering immediate insights into any adverse events that may arise. This is complemented by real-time reporting and alerts made possible by machine learning (ML) algorithms, ensuring that safety data is consistently under surveillance. Additionally, the automation of routine tasks ensures that traditionally manual tasks like data entry and the initial sorting of reports are handled swiftly and accurately, freeing up professionals to focus on more complex tasks.

Streamlined Assessment and Understanding

Understanding and assessing the vast amounts of data in PV is made simpler with AI. Natural language processing not only streamlines the extraction of data but also aids in comprehending the context surrounding adverse events. Meanwhile, optical character recognition is a game-changer, converting unstructured content into structured data. This ensures that cases are prioritized based on their severity and relevance, making the assessment process more efficient.

Enhanced Prevention Measures

AI doesn't just detect and assess; it also plays a pivotal role in prevention. Proactive risk management is now a reality, with AI fostering a forward-thinking approach to risk management throughout the PV life cycle. Moreover, the importance of data quality and compliance cannot be overstated. AI tools assist in maintaining pristine data sets and guarantee that all operations are in line with regulatory requirements, ensuring that patient safety is always at the forefront.

Reduced Legal Liability

Legal liabilities can arise from inaccuracies, delays, or non-compliance in reporting adverse events. AI and automation play a crucial role in mitigating these risks. By streamlining data collection, ensuring real-time monitoring, and automating complex processes, these technologies drastically reduce the margin for human error. Furthermore, AI-powered predictive analytics can foresee potential issues, allowing for proactive measures rather than reactive responses. This timely and accurate reporting not only ensures adherence to regulatory standards but also significantly diminishes the potential for legal repercussions, safeguarding organizations from costly litigations and reputational damage.

ESSENTIAL AUTOMATION SOLUTIONS FOR PV & SAFETY TEAMS

As mentioned above, automation solutions offer companies many advantages—from improving adverse event reporting times to reducing legal liability. The next challenge is identifying the right technologies to optimize unique PV and safety workflows. There are a few technologies companies looking to be at the forefront of PV excellence should consider when evaluating vendors:

- **Artificial Intelligence/Machine Learning:** Companies should consider the vendor's AI/ML capabilities due to its ability to unlock substantial value in the pharma industry, particularly in PV. AI/ML offers rapid data analysis, data extraction, signal detection, and automated case triage capabilities, with the potential to revolutionize processes while leveraging human expertise in the right places to mitigate risk and build strong AI
- **Multilingual Case Processing:** A vendor's multilingual case processing technology can enhance global PV operations by meeting reporting requirements in multiple languages and improving signal detection, reducing risk during expansion into new regions.





- **Global Submission Platforms:** Companies should consider vendors with global submission platforms to automate and streamline safety data submissions worldwide, reducing non-compliance risks and potential penalties while ensuring timely and compliant reporting to regulatory agencies.
- **Automated Data Collation:** Vendors offering automated data collation solutions for safety reporting should be a top choice for companies, as they enhance accuracy and efficiency in processing safety data, ensuring timely reporting and upholding regulatory standards with minimal risk of human errors.

Read more about the importance of these solutions in our whitepaper, [The Imperative of Automation in Pharmacovigilance and Patient Safety](#).

EVALUATING PV AND SAFETY VENDORS

“There are many restrictions around SAEs, like tight timelines for reporting, and we want to have the capabilities to handle any language for someone to call in to report an event.”

A vendor’s purpose is to reduce strain on your team, enable you to scale as needed, maintain and expedite timelines, and mitigate risk. When evaluating PV and safety vendors, it is important to ask the right questions and select a partner who understands your organization, supports your goals and objectives, and provides modern PV and safety solutions that meet the demands of your PV processes.

If you are looking for a new PV and safety system, but do not know where to start, the eight considerations below can help you identify a best-in-class system:

1. Experience and Expertise
2. Support and Training
3. Investment in Automation
4. Scalability
5. Product Configuration
6. Interoperability
7. Security
8. Regulatory Compliance





Experience and Expertise

What is the vendor's reputation in the PV and safety sector?

When researching PV and safety software and solutions, sponsors should assess the organizations' technological capacity. These teams work closely with their vendors, so it is important to identify a partner with experience and one who is capable of scaling and adapting according to fluctuating PV reporting requirements.

Companies with a long history of PV and safety experience have an intimate understanding of complex and nuanced workflows. These vendors can help you identify and apply the right technology to streamline PV processes.

Here are some considerations for evaluating vendors for experience and expertise:

- Look for vendors with a **proven track record in PV and safety** by understanding audit experience and capabilities.
- Read **case studies that demonstrate the solution's effectiveness** in real-world PV scenarios.
- Consider **testimonials and reviews to gauge customer satisfaction** and the vendor's commitment to their clientele.
- Ask for a product roadmap, history of releases, customer involvement, innovation initiatives to **determine their dedication for ongoing development**.



Support and Training

Does the vendor provide in-house training, customer service, and technology support?

Training is an essential aspect of effective PV operations. The PV vendor should provide comprehensive training to sponsors to ensure the team is well-acquainted with system implementation, adoption, compliance, protocols, user roles, and more. In-house training cultivates knowledgeable and efficient end users and administrators, primed to optimize and automate their workflows. Beyond training services, post-implementation support is vital for addressing any challenges that arise.

Here are some considerations for evaluating vendors for customer support and training:

- Ask if the vendor provides resources like **user guides, manuals, video tutorials, and hands-on training** sessions.
- Determine the **vendor's tailored approach to compliance and business process training** on crucial topics such as data integrity, informed consent management, adverse event reporting, regulatory documentation, and audit trail requirements.
- Look for vendors who provide **24/7 support to address any issues that might emerge**, ensuring uninterrupted PV operations.
- Gain insights on the **frequency of software updates and the management of the update** process.
- Clearly detail the **avenues to reach customer support** and outline the range of support services available.



Investment in Automation

Has the vendor made an adequate investment in automation capabilities?

Automation is a pivotal component for streamlining intricate PV and drug safety processes. When selecting a pharmacovigilance solution, it's essential to identify vendors with a proven track record of substantial investment in automation. The best providers are those who recognized the potential of automation early on and have consistently invested in it, leveraging their experience and technological advancements to craft superior automation tools tailored for the industry.

The ideal vendor integrates automation at the core of their platform instead of appending third-party automation solutions. These integrations often indicate that automation was an afterthought, leading to platforms that may struggle with the unique and complex processes inherent to drug safety.

The most suitable providers not only offer automation but possess the expertise to discern which tasks are prime candidates for automation. They utilize the most appropriate technologies to execute those tasks and integrate this automation flawlessly within a dedicated safety solution. This holistic approach ensures that the platform remains agile, efficient, and industry-specific, providing users with a truly optimized PV experience.

Here are some considerations for evaluating vendors for automation:

- Look for vendors who have **invested in automation** by determining how long they've integrated AI and automation into PV and safety solutions.
- Determine whether the **vendor's automation solutions are pre-validated** to provide nearly out-of-the-box compliance by ensuring their solutions will not require additional validations during implementation.
- Seek PV and safety solutions that provide **end-to-end automation, allowing processes to run independently**, eliminating the need for manual intervention after every single task.

Scalability

Does the vendor listen to and adapt the technology based on your business needs?

Not all PV vendors possess the resources and expertise to adapt to the complex needs of sponsors. Depending on the volume and intricacy of their safety data, sponsors require a PV and safety solutions that can expand with their organization. It's essential to ensure that the PV system can manage growing data volumes and the increasing complexity of safety reporting as their operations develop.

Here are some factors to consider when evaluating PV vendors. The PV system should:

- Accommodate a rising volume of safety reports and adverse events. A **scalable PV system will feature** real-time monitoring capabilities for the proactive assessment and identification of safety cases, which can be easily integrated for seamless interoperability with other clinical systems, such as a Clinical Trial Management System (CTMS).
- Manage an increasing amount of data over time. **All safety data – old and new – should be easy to reference** without the system slowing or users experiencing performance issues.

Product Configuration

Can you configure the vendor's technology to suit your organization's unique processes?

Every pharmacovigilance process has its distinct requirements. Sponsors should ensure the technology they select aligns with their team's safety workflows. When assessing vendors, gauge the extent to which the product can be tailored right from the start.

Here are some considerations for evaluating vendors for product configuration:

- Request a consultation session with the vendor to **ensure their technology aligns with your pre-existing workflows and business processes** or can be customized.
- Look for a vendor who **values your feedback through a well-established feedback mechanism**, utilizing it to refine the PV system based on evolving business needs.



Interoperability

Does the vendor's technology seamlessly connect to your other clinical research systems?

PV system interoperability refers to the capability of the PV system to exchange data and integrate seamlessly with other systems or applications involved in product development. An interoperable PV system ensures different platforms can collaborate, share information, and communicate effectively. Such interoperability in PV systems promotes efficient data exchange, minimizes manual data entry and redundancy, and enhances overall data quality and integrity.

Achieving interoperability can be facilitated through various means, including Application Programming Interfaces (APIs) that allow systems to interact and share data in a consistent and structured manner.

Here are some factors to consider when evaluating interoperable PV solutions. The PV system should:

- Provide APIs that **enable integration and migration with external systems** with available product specifications, developer resources, or API documentation.
- Interoperate with other systems used in your organization including CTMS, Electronic Data Capture (EDC), Drug Safety Databases, and Regulatory Information Management (RIM) Systems.
- Exchange and use data from other systems **without compromising data integrity** in accordance with industry standards.



Security

Does the vendor provide the security controls necessary to keep your safety data safe?

Given the confidential nature of PV data and the severe implications of data breaches, security remains paramount. It's vital to choose a vendor that implements rigorous security controls, encompassing encryption, user access controls, and secure PV audit processes.

It is crucial that vendors offer options that limit identification risk, such as using redaction services, audit trails, or data encryption. These controls should comply with HIPAA and GDPR regulations, safeguarding personally identifiable information (PII) and personal health information (PHI). In addition, good PV solutions often comply with regulations such as, 21 CFR PART 11 and ICH E6 (R2) Good Clinical Practice (GCP).

The repercussions of insufficient data security in PV aren't merely ethical and legal but also financial. For instance, mishandling sensitive data can lead to substantial fines and even threaten a company's reputation and market standing.

Consider these factors when evaluating secure PV solutions:

- ❑ Confirm that the solution uses strong encryption methods by identifying their data management practices, and any certifications they may have, such as ISO 27001, or HITRUST.
- ❑ Make sure the vendor complies with data protection laws, such as HIPAA and GDPR.

Regulatory Compliance

Does the vendor's technology support compliance with the most common regulatory standards?

Compliance with regulatory standards is crucial in clinical research. It helps to ensure patient safety, data integrity, ethical conduct, legal due diligence, reputation and trust, and product approval. For PV, timely and accurate reporting to the appropriate regulatory bodies is essential. There are various types of safety reports, including Individual Case Safety Reports (ICSRs), Periodic Safety Update Reports (PSURs), and Development Safety Update Reports (DSURs). Each of these reports has its own specific format, content requirements, and submission timelines. ICSRs, for instance, focus on individual adverse event cases, while PSURs provide an overview of safety information for a medicinal product over a specific period. DSURs, on the other hand, are used during clinical development to summarize the safety profile of a drug.

Failure to submit these reports accurately and within the stipulated timelines can lead to severe consequences. Regulatory agencies may impose hefty fines, issue warning letters, or even halt clinical trials. In extreme cases, non-compliance can result in the withdrawal of a product from the market, which can have significant financial implications and damage a company's reputation. Therefore, it's vital to choose a vendor whose technology is equipped to support and streamline the process of generating and submitting these diverse safety reports, ensuring full compliance with regulatory standards.

Consider these factors when evaluating regulatory compliance in PV vendors:

- Look for a **global company that has experience with international regulatory bodies** and their specific requirements. Given the global nature of clinical trials, working with a vendor with offices around the world can support timeliness and accuracy of safety reporting.
- Seek out vendors with **regulatory expertise by determining their understanding of the complex regulatory landscape**, including the latest guidelines and requirements of safety reporting.
- Handle **various types of safety reports**, such as individual case safety reports (ICSRs), adverse event (AE) and serious adverse event (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSAR).
- Ask for the **vendor's record with timeliness** and their track record of submitting reports within the stipulated timelines to avoid potential penalties.

THERE'S A BETTER WAY TO STREAMLINE PV AND SAFETY REPORTING AND MEET REGULATORY TIMELINES WITH EASE.

Achieve 100% compliance with drug safety reporting timelines while reducing localization costs by 30% with TransPerfect Life Sciences.

TransPerfect helps PV and drug safety teams accelerate safety reporting through a blend of AI and technology. With solutions such as a global call center support, a translation management solution that incorporates AI, redaction services, media monitoring, TransPerfect streamlines the collection, processing, tracking, and reporting of cases.

High-level advantages include:

- **AI-Driven Reporting:** Seamlessly blend AI and technology to streamline the collection, processing, tracking, and reporting of cases, ensuring top-tier patient safety.
- **Global Support:** Our global call center, staffed with licensed healthcare professionals, ensures efficient case intake and processing.
- **Advanced Translation:** Utilize safety-specific AI engines and human post-editors, alongside terminology glossaries, product information, and translation memories (TMs) to drive consistency across materials, cut translation timelines by half, ensuring timely regulatory submissions.
- **Efficient Redaction:** AI technology paired with professional redaction specialists slashes redaction time by over 75%.
- **Media Monitoring:** Advanced technology to monitor digital media outlets in any language, providing insightful reporting on patient feedback and real-world drug usage.
- **Compliance & Efficiency:** Achieve 100% compliance with drug safety reporting timelines and reduce localization costs by 30%.

TransPerfect provides content and technology solutions to help clients ensure the safety of their patients by accelerating the time to report safety cases to regulatory agencies. Through AI and automation, our solutions drastically reduce the time to report multilingual cases, while ensuring security and quality of cases reported, enhance compliance to good PV practices, and improve patients' real-world usage and feedback.



Take the Next Step

Learn more about our AI and automation
pharmacovigilance and safety solutions

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