Key Considerations for Evaluating Modern Safety Solutions to Easily Scale Pharmacovigilance

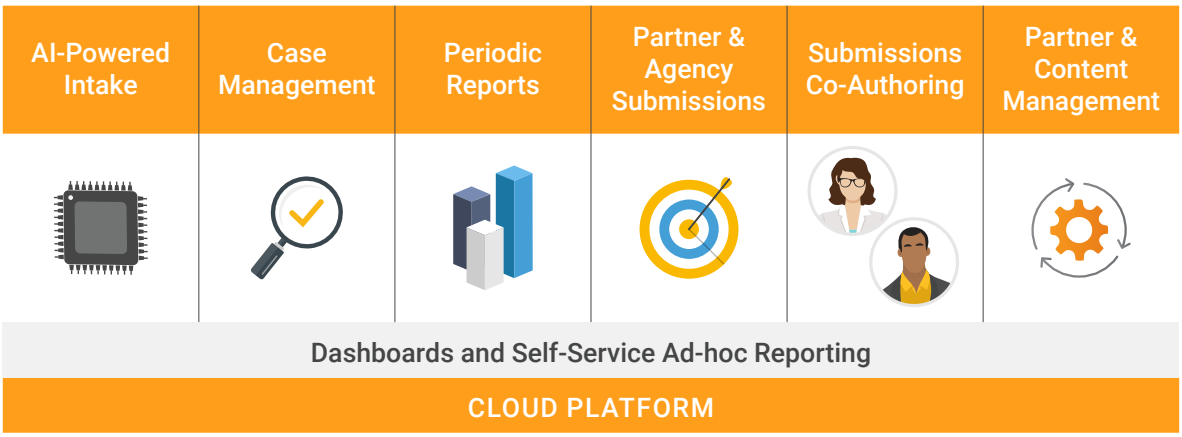
Pharmacovigilance organizations are facing growing adverse event volumes, increasing disease complexity, and challenging global regulations. There is also rising pressure for safety teams to demonstrate greater value with tighter budgets. Leveraging innovative technologies can provide cost and process efficiencies and make it easier for pharmacovigilance teams to scale with growing data volumes, changing regulations, and expand into new markets. Many companies are adopting modern applications or upgrading their internal systems to reduce overhead and get more from their investments. As pharmacovigilance teams evaluate new safety solutions, they need to consider the following:

1. Complexity of Safety Solution Landscape

Pharmacovigilance organizations usually have multiple point solutions – for each stage in the case processing lifecycle – that often do not work well together and can be even more difficult to manage if there are multiple vendors involved. A lot of resources are spent developing and maintaining integrations, assuring compliance, and carrying out manual activities, including moving or copying data and content between systems. Data reconciliation and other non-value-added work become core activities to ensure information is accurate for reporting and decision-making. With complex processes, there are opportunities for errors, tasks not being completed in a timely manner, and other compliance risks.

Simplifying Safety with a Unified Solution

Modern pharmacovigilance applications are built on a single cloud platform, operating as a unified solution to enable seamless processes, reduce or eliminate manual activities, and provide a single source of safety data and content including reference materials and documents. With case intake, case processing, operational reporting and analytics, aggregate reporting, coding, content management, and submissions in one solution, it is much easier to track and complete activities, process adverse events from intake to submissions, and analyze data for potential signals.



2. Level of Effort to Keep Current with New Software Releases

Legacy safety systems require significant resources and cost to upgrade to new releases. Small companies with resource constrained IT teams are often forced to outsource the safety database to a CRO or other service provider.

Easily Upgrade to New Releases

Modern pharmacovigilance applications leverage the cloud, enabling access to new capabilities through automatic updates, several times a year. Some cloud vendors also reduce the validation burden for customers by performing and documenting all elements of infrastructure qualification (IQ) and operational qualification (OQ) for each major version.
They also provide sandbox and test environments, and user acceptance testing (UAT) scripts that can be leveraged for performance qualification (PQ). Customers can choose when to enable specific features – minimizing impact and providing control to each company.
The pharmacovigilance solution evolves with the industry, ensuring customers are always current with regulatory requirements.

3. Ease of Alignment with New or Changing Business Processes

Many pharmacovigilance applications are complex and often customized. Whether on premise, or hosted and managed by a vendor, modifying processes require significant effort and risk. Companies are slow to make changes or introduce manual steps to address new business requirements. Over time, the growing gap between what the business needs, and the application delivers, creates a lot of inefficiencies and risk.

Greater Agility with Process Configuration – Not Coding

Designed for the life sciences industry, cloud-based pharmacovigilance solutions are enabling companies of any size to adopt enterprise-level safety applications. Business workflows are created and modified with configuration – not coding – reducing the administration burden and enabling safety organizations to be more agile in meeting new business and regulatory requirements.

4. End User Adoption

One of the most important areas that impact user adoption is ease of use. Solutions that are intuitive from multiple perspectives – case processor, reporting team, occasional user such as senior management who wants to look at an individual case safety report (ICSR), CROs, and other service providers increases user productivity not only adoption. Safety systems that are challenging to navigate require more upfront, and recurring, training. It can also put a strain on support teams and increase risk as information is not entered correctly or in a timely manner. Occasional users and stakeholders can independently find information instead of waiting for data from a staff member before a critical decision can be made.

Easily Onboard and Train Users

Built with a consumer web experience, cloud-based safety solutions require less training. End users can effortlessly navigate through the application to find information or complete tasks and business administrators can quickly add users or modify security or application settings. With an intuitive interface and a simplified environment – one unified safety solution – there are less errors, and pharmacovigilance teams are more productive.

Test environment can also be easily set up to allow users to login and get feedback on the application, workflows, and changes. You cannot easily do that with on premise systems as they require hardware and IT resources. Having different user types involved during evaluation helps promote user adoption, and if moving from another system, reduces challenges from change management.

5. Real-time Data Access When Outsourcing

Many emerging pharma companies outsource the safety database to CROs / service providers and may not have direct access to the system – limiting visibility and control over the data. They rely on reports from CROs / service providers that can impact decision-making if the data is delayed or incomplete. Partners play critical roles and safety systems need to align with today's business models.

Direct Data Access by All Parties

Pharmacovigilance organizations can easily access their data in cloud-based safety solutions – anytime, anywhere for oversight. Data becomes more accurate and up-to-date when all parties are using the same safety solution. With real-time visibility into the outsourced work, such as capturing a new adverse event or case processing status, there is greater transparency and safety teams can improve oversight.

6. Supporting Business Process Outsourcing Flexibility

As companies grow, they change CROs / service providers to better align with evolving business needs. Usually, there are challenges migrating the data in the safety database to a new partner's system such as incorrect mapping of fields that impact report generation and incomplete data sets.

Change Service Providers Without the Burden of Data Migration

Cloud technology has lowered the barrier to owning a safety system, providing a viable option to bring it in-house. Pharmacovigilance organizations can easily add or remove CROs / service providers, while the data continues to reside in their cloud-based safety system. With flexibility to change service providers without the burden of data migrations, pharmacovigilance organizations are more agile.

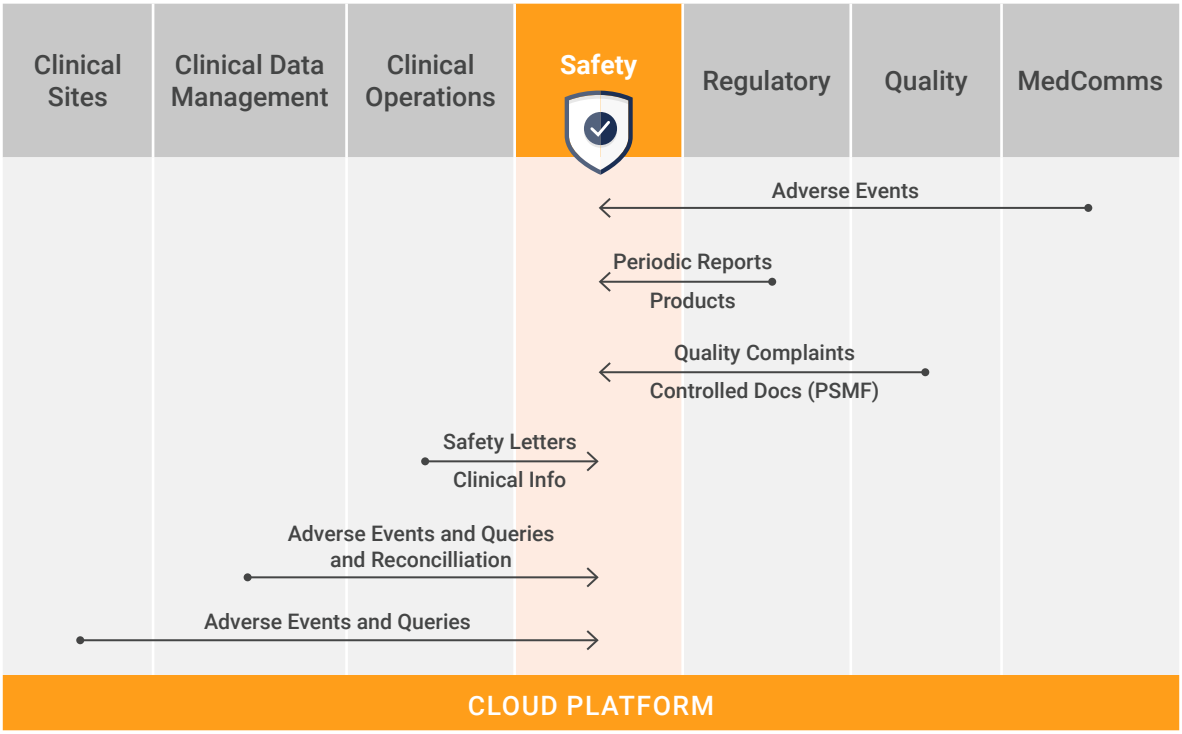
Multiple CROs / service providers can also access the same safety system, while performing similar or different tasks. With granular security and flexible workflows, pharmacovigilance teams can control what each partner can see and do in the system. For example, some service providers can process and review cases, while others can only view them without changing the record. Cloud safety solutions are designed to bring together different parties, supporting partner-defined workflows while keeping administration simple.

7. Integration Across Functional Areas

Pharmacovigilance processes may span into other areas such as quality, clinical, or regulatory. Often, manual overhead is needed to support processes between organizations creating inefficiencies and high risk of error.

Seamless Cross-functional Processes for Greater Efficiency

With applications built on the same cloud platform, companies can more easily integrate and streamline end-to-end processes and provide a single source of pharmacovigilance data and content across the company. Providing a consistent user experience across each area and centralizing security administration, also simplifies application management and reduces end-user training. Seamless, cross-functional workflows minimize or eliminates manual tasks such as reconciliation of serious adverse events (SAE) or quality system product complaints with non-adverse events (NAEs), data queries, and re-entering of clinical data into safety applications. With an accessible and strong data foundation across the company, each organization can quickly complete tasks and make better and more informed decisions.



8. Ease of Scalability

Pharmacovigilance solutions need to scale as companies evolve from clinical stage to product commercialization requiring global drug surveillance in multiple markets and regions. Traditional on premise safety systems are typically designed for larger, enterprise companies that process many cases and are cost prohibitive for smaller companies. Dedicated IT teams are also required to ensure adequate application infrastructure application and business continuity plans are robust.

Automatically Scale to Companies of Any Size

Cloud safety solutions are delivered as a service. Pharma companies do not need to worry about hardware, storage, or disaster recovery and the environment is continually monitored to ensure expected performance. With a single unified solution, safety teams can meet the global pharmacovigilance demands. Built-in gateways, including U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), China National Medical Products Administration (NMPA), and Japan Pharmaceuticals and Medical Devices Agency (PMDA), support regional submissions and innovative technologies such as artificial intelligence makes it easier to scale processes.

9. Speed of Innovation and Ability to Meet New Regulatory Requirements

Legacy software vendors maintain multiple versions of safety solutions as customers are often several releases behind. For each version, the software vendor must spend resources fixing bugs as well as building, testing, and deploying security patches and integrations. With an ever-increasing portion of the development budget spent on maintenance, legacy software is slow to innovate and incorporate technology advancements, such as automation and artificial intelligence.

Enabling Rapid Innovation

A true cloud solution only runs one software version for all customers, enabling more resources to focus on innovation and delivering new capabilities. They are also more robust as issues found by one customer are fixed for everyone. With industry-driven best practices and functionality rolled into new releases, cloud applications lead to better pharmacovigilance solutions with superior quality and stability.

When evaluating safety applications, having a holistic perspective that encompasses current and future business requirements will reduce long-term risk. Additionally, total cost of ownership comparisons needs to include costs for hardware, software, training, and ongoing resources for upgrades, validation of new releases, and maintenance.

Legacy safety systems require significant overhead whether managed in-house, outsourced to a service provider, or hosted by a software vendor that is sometimes marketed as 'cloud.' Difficult to manage and make changes, these systems hinder business agility and are slow to innovate.

Designed to scale and with a consumer web experience, true cloud safety solutions are easy to upgrade, maintain, and align with new business processes and regulations. They enable biopharma companies of any size to own an enterprise-level safety application, or support collaboration with CROs / service providers when outsourced. All parties directly access a unified safety solution of pharmacovigilance data and content for faster and more informed decisions. With rapid innovation, pharmacovigilance teams gain a solution that is always improving and increasing in value.