Accelerating Pharmacovigilance Innovation with Cloud Solutions

Drug safety has reached a critical point with industry complexity, stagnant legacy systems, and growing expectations for pharmacovigilance organizations. Cloud-based solutions are streamlining operations to allow allocation of more resources to safety science – providing greater impact to patient outcomes.

Leaders need to make safety decisions quickly with the most available data. However, this is increasingly difficult with expanding case volumes, complexity of biologics, new regulatory requirements, greater focus on combination therapies, and convoluted partner agreements.

Pharmacovigilance systems have also not kept pace with growing business demands. Legacy, on premise applications are costly, inflexible, and siloed - ultimately restricting growth, innovation, and the ability to optimize business processes. As a result, drug safety has not evolved into a strategic enabler for the biopharma industry.

Cloud-based solutions have transformed many areas of drug development including clinical, regulatory and quality. Here are five ways cloud can accelerate pharmacovigilance innovation:

Innovation Enabler – Same Software Version for Everyone

Traditional software providers spend an ever-increasing portion of their development effort on fixing and supporting multiple versions of software that are running on premise at a customer or in hosted environments – rather than investing in the future.

Organizations often claim applications managed offsite in a hosted environment as "cloud." However, they have many of the same challenges as on premise systems. For each version of the application, the software vendor must spend resources on fixing bugs, supporting, building, testing, and deploying security patches as well as ensure each software version runs as expected. With integrations between

applications, exponential amount of resources is consumed maintaining systems as vendors need to test and support multiple combination of software versions.

A true cloud solution only runs one software version, simplifying the maintenance landscape. Issues are fixed once for all customers and the vast majority of resources is invested in delivering innovation and new functionality. With a single version of the application, customers of a true cloud application also realize the benefits of best practices and new capabilities driven across the industry. True cloud solutions innovate faster and lead to better, more stable, tailored safety software.

Always Current and Compliant

Cloud makes upgrades easier. As regulations are announced or updated, or there are technological innovations, the application is automatically improved to support new requirements or take advantage of new capabilities.

Upgrades for on premise safety applications are extremely expensive. For each release, customers perform a cost-benefit analysis to determine what the new upgrade will provide versus how much time and resources it will take to update the application. With new regulatory requirements, companies may need to upgrade by a specific date to be compliant . Forcing upgrades with each regulatory change is expensive and disruptive to the business.

The cloud offers a much better solution with seamless upgrades as new functionality becomes available in a validated and compliant state. Customers can choose when to enable specific features in each release – minimizing impact and providing control to the customer. The pharmacovigilance solution evolves with the industry, future proofing customers against unforeseen regulatory changes.

Greater Data Access

Accessing and controlling your data should be easy in today's modern world. Consumer applications have changed user's expectations for software and cloud solutions are enabling companies to deliver the same ease-of-use and access.

Security is complex with on premise software, requiring firewalls and security protocols. It is difficult to grant access to external partners and collaborators as well as internal individuals that are in different organizations or geographical locations. Companies never realize the full value of the safety data with barriers to information access.

With cloud, security and data access are maintained as part of the service. Simple point and click administration replaces the heavy burden of managing and maintaining the network, infrastructure, and firewalls. Companies can provide self-service access to internal or external individuals, collaborators, and other organizations – anywhere, anytime, on any device. Partner processes are no longer complex, enabling greater operational efficiency and faster response times. By having safety data more easily shared and analyzed across internal and external organizations, it increases information intelligence and impact.

Integrations Made Easy

Data is more valuable if it is shared with appropriate individuals as well as other systems in a timely manner. With true cloud solutions, information can be moved "in" or "out" of the application.

Traditional pharmacovigilance solutions require manual export of data to third party solutions for reporting and integration, or transferring of data between systems with error-prone and resource intensive user data entry. The lack of APIs and simple integration tools for on premise applications – whether hosted onsite or in a multi-version "cloud" solution – creates significant challenges for drug safety. Inefficiencies are compounded when you consider the entire drug development lifecycle, as safety is the hub with many spokes connecting to clinical, quality, regulatory, and medical affairs.

Integrations are easier with cloud applications and data is managed in a highly scalable way. Combination of tools simplify how data is inserted, imported, or exported from the application, such as robust public APIs, ad hoc and self-service reporting, and data loading or exporting utilities. Cloud applications also have intuitive user interfaces for ease of navigation to export data on demand.

Dependencies on connections between safety and other functional areas, such as accessing adverse events (AEs) from the EDC application or notifying clinical of a safety letter distribution (SLD), impacts the overall efficiency of the organization. Simplifying integrations and enabling greater data access will improve process efficiencies, reduce overall compliance risk, and allow information to have a greater business impact.

Embedding Artificial Intelligence

Many companies outsource drug safety activities creating a barrier between pharmacovigilance (PV) organizations and their data. Cloud technology brings data from behind the firewall and makes it easily accessible to innovative technologies like artificial intelligence (AI).

AI-powered cloud solutions significantly reduce the overhead of manual activities, such as data entry during case intake and processing. Using natural language processing (NLP), AI solutions automatically identify, extract, and convert text from both structured and unstructured data sources into the required fields for a drug safety case. Machine learning can also help determine if a report is a duplicate versus a follow up, linked to an existing case, or is a new report, enabling safety teams to be more efficient in case processing.

Learnings from across the industry – not just for a single company – are fed back to the AI engine, making it continually smarter. Cloud-based safety applications have comprehensive APIs, easily integrating with other information sources. The more data, the better refinement of existing, or development of new data models including identifying trends and relationships and enabling predictive analytics. With a foundation for aggregating learnings across the industry, safety organizations will realize the greatest value from their data.

Summary

Moving from siloed, on premise applications to the cloud is key to accelerating pharmacovigilance innovation. Cloud solutions are easy to upgrade as well as access and share data. Pharmacovigilance cloud applications stay up-to-date with regulations and continually improve with new capabilities or performance enhancements.

Minimizing the effort to manage and maintain systems allows more resources to focus on analyzing safety data and leveraging technology advancements. With valuable insights and greater access to data, safety teams can provide more comprehensive benefit-risk analysis – effectively balancing therapeutic efficacy and safety risks.

Innovating quickly, cloud-based pharmacovigilance applications will further streamlining safety operations and enable the next wave of innovation in big data, advanced analytics, and artificial intelligence (AI).