

# Multivigilance in the Cloud

How Cloud Technology Makes Patient Safety Less Expensive and More Efficient

One of the biggest responsibilities of a biopharmaceutical or medical device company is to ensure their products are safe as well as effective. A significant part of the clinical trial process before approval involves examining the safety profile of a new medicine to understand any potential risks to patients. The need to ensure the safety of an innovative treatment doesn't stop the day regulators approve it for sale, however. Manufacturers must monitor how each product they sell performs with real patients as they use it outside the carefully controlled conditions of a clinical study. This process of multivigilance – the management of safety information for different kinds of medicinal products such as drugs, vaccines, medical devices, and combination products – is required throughout the entire product lifecycle.

## Challenges in Multivigilance Today

Multivigilance involves the tracking of enormous amounts of adverse event data from a wide range of sources. Reports from healthcare professionals, literature articles, direct patient communication, and even social media postings can create the need for a company to record and assess a potential problem. If it's significant enough, a safety issue may also require reporting to regulators and/or the initiation of risk mitigation or minimization activities. As the complexity of new medicinal products has increased along with greater regulatory scrutiny,




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Bruce Palsulich is responsible for the strategic direction of the Oracle Health Sciences Safety Cloud – an integrated suite of the market-leading safety case management solution (Oracle Argus), and the market-leading safety signal management solution (Oracle Health Sciences Empirica), delivering unified end-to-end multivigilance throughout the entire lifecycle of medicinal products.

Regulatory compliance, costs and efficiencies, extending capabilities, and reducing complexity are key drivers for the shift from on-premise deployments to the cloud.



Up to  
**50%**  
annual growth  
in adverse event  
cases



**58%**  
have or plan to have  
their safety solutions  
in the cloud

the sheer volume of cases being handled by safety departments is zooming higher, growing by up to 50% in some cases.

### Lessons from the Clinical Cloud

The good news is that the same cloud-based platform that helped a company get that medicine through the clinical trial process efficiently also offers those benefits to the people and applications managing safety throughout a product's lifespan. Unfortunately, because many companies have siloed data operations, the technology platform adopted in the clinical trial phase often isn't used by safety departments. That can mean a disconnect between the safety reviews of a product in clinical trials and the ongoing multivigilance post-approval. Worse, some safety organizations are reluctant to adopt a cloud-based platform, despite those advantages.

### Choosing the Right Cloud Solution

According to [a recent survey of safety professionals\\*](#), the biggest deterrents to leveraging the cloud are concerns about data security and data privacy, highlighting the huge importance of these two factors when choosing a safety cloud platform. The right solution, however, can address these issues by delivering more robust security and privacy than self-hosting, hosting through small providers, or utilizing large infrastructure-only providers, significantly reducing risk for companies at a time of constant news reports about computer viruses and malicious hackers. Enter the [Oracle Health Sciences Safety Cloud](#).

### Drivers for Moving to the Cloud

The survey shows that 58% of respondents already have some or all of their safety solutions in the cloud, or are planning to move there within the next two years. The four main reasons for this shift away from traditional on-premise deployments are: regulatory compliance, costs and efficiencies, extending capabilities, and reducing complexity.

### Regulatory Compliance

Companies need to ensure compliance with the latest regulations from FDA, EMA, PMDA, and other health authorities around the world. These regulations and new standards are becoming more stringent, they're different in every region, and the pace

The cloud provides powerful infrastructure that underpins Oracle's artificial intelligence platform.

of change has dramatically increased. In order to keep up, safety software requires frequent upgrading – according to the survey, 63% of companies now upgrade at least every three years. The Oracle Health Sciences Safety Cloud makes upgrades – and thus regulatory compliance – easier, faster, and less costly.

### Costs and Efficiencies

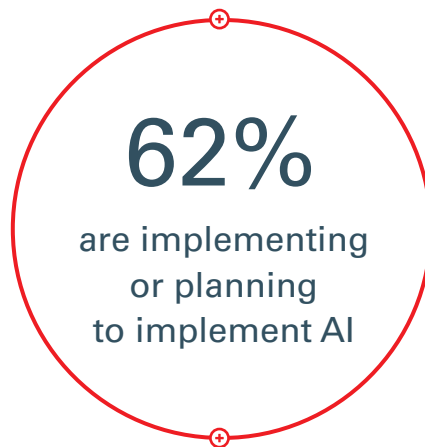
Case volume increases along with flat budgets mean new efficiencies must be gained without sacrificing quality, security, or data privacy. Many safety departments have already outsourced as much case processing as they can. Reducing costs in other ways, such as moving to the cloud, is therefore a priority. Adopting the Oracle Health Sciences Safety Cloud, coupled with standardization and automation, lowers the total cost of ownership and increases productivity, with comparisons projecting savings of 30-50% over three to five years for some companies.

### Extending Capabilities

As life science companies grow, their safety needs grow too. The move to the cloud is an ideal time to extend safety analytics capabilities by adopting Oracle Argus Enterprise Edition, enhance signaling capabilities by integrating Argus with Oracle Health Sciences Empirica Signal, and increase operational efficiencies by integrating Argus with Oracle Health Sciences InForm. Oracle offers these integrations out of the box rather than as customizations. The cloud also provides the powerful infrastructure that underpins Oracle's artificial intelligence (AI) platform. That's important because the survey reveals that 62% of companies are actively implementing or planning to implement AI for case processing.

### Reducing Complexity

As the only true Software as a Service (SaaS) offering for the integrated Argus and Empirica product suites, Oracle Health Sciences Safety Cloud goes beyond mere hosting by including a complete set of services above and beyond just the software applications. SaaS frees up safety organizations from worrying



Oracle Health Sciences Safety Cloud streamlines the manual work in safety case management and safety signal management, from clinical studies through post-marketing surveillance.

about things like patching the tech stack, keeping components compatible with each other, scaling up servers and memory, executing installation qualifications (IQs), and testing disaster recovery. Safety professionals want to focus on benefit-risk analysis rather than IT issues.

### A Unified Cloud Solution for Argus and Empirica

The Oracle Health Sciences Safety Cloud was created to streamline the manual work in safety case management and safety signal management, from clinical studies through post-marketing surveillance, while simultaneously improving regulatory compliance, data security, and data privacy. As a SaaS solution, it's faster and less costly to implement than on-premise deployments. It was built for the market and by the market, leveraging standard industry best practices and automation, allowing companies to detect risks early and respond quickly, and flexibly scaling up to support growing data sources and volumes. By recognizing how the cloud can deliver value not only to your safety organization, but through a tighter connection to the rest of your enterprise, you can confidently begin the transition to the Oracle Health Sciences Safety Cloud.

#### \*Research Report: Addressing the Data Challenges of Pharmacovigilance

A research survey conducted by Informa Engage, commissioned by Oracle, and distributed globally to safety and pharmacovigilance industry professionals reveals users' attitudes, expectations, and concerns around embracing new technologies in their efforts to detect safety issues early, reduce costs, and maintain compliance, while safeguarding patients' health. Download the research report at <https://go.oracle.com/LP=67881>.

Learn more about Oracle Health Sciences Safety Cloud at [oracle.com/goto/pharmacovigilance](http://oracle.com/goto/pharmacovigilance)

## DRIVING INNOVATION AND UNIFYING SAFETY IN THE CLOUD

30-50%

savings projected over three to five years






*"We rely on technologies like Oracle Argus Cloud to help ensure that we are making safety decisions, reduce risk and help ensure global compliance, so that we can focus on delivering therapies that will improve the quality of life of patients."*

**MICHELLE KIM**  
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### LEARN MORE

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