Multivigilance in the Cloud

How cloud technology makes patient safety less expensive and more efficient

BUSINESS BRIEF

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, biologics, vaccines, medical devices, and combination products—is required throughout the entire product lifecycle.

Bruce Palsulich is responsible for the strategic direction of Safety One—an integrated suite of market-leading safety solutions including Argus, Empirica, and Safety One Intake—that delivers unified end-to-end multivigilance throughout the entire lifecycle of medicinal products.

BRUCE PALSULICH
VICE PRESIDENT
PRODUCT STRATEGY
ORACLE LIFE SCIENCES

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, the sheer volume of cases being handled by safety departments is zooming higher, growing by 30-50% annually according to IDC.
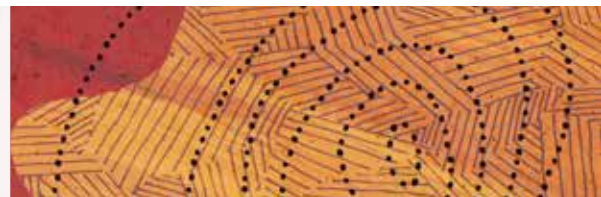
Lessons from the clinical cloud

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, using technologies such as always-on encryption, continuous monitoring, isolated network virtualization, strict separation of duties, and threat mitigation. Such security-first design principles significantly reduce risk for companies at a time of constant news reports about computer viruses and malicious hackers. Enter Safety One (Oracle Life Sciences Safety One Cloud Service).

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 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. Safety One makes makes upgrades—and thus regulatory compliance—easier, faster, and less costly.
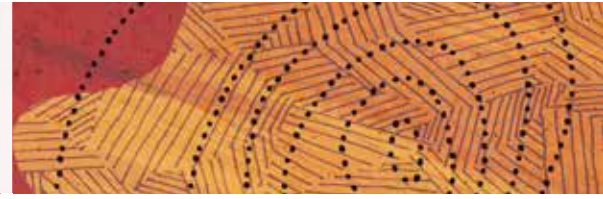
Up to
30-50%
annual growth in adverse event cases

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

Costs and efficiencies

Annual case volume increases of 30-50% 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 Safety One, coupled with standardization, automation, and artificial intelligence (AI), lowers the total cost of ownership and increases productivity, with a reduction of manual work and overall case processing time by up to 50%.

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 Argus Enterprise Edition and integrating it with Safety One Intake to automatically process incoming AE reports using AI, with Empirica to enhance signaling capabilities, and with InForm to increase study SAE operational efficiencies. Oracle offers these integrations out of the box rather than as customizations. The cloud also provides the powerful infrastructure that underpins Oracle's 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, Empirica, and Safety One Intake solutions, Safety One goes much further than mere hosting by including a complete set of services above and beyond just the software applications. SaaS frees up safety organizations from worrying 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.

63% upgrade at least every three years

50% reduction in case processing time

62% are implementing or planning to implement AI

Safety One streamlines the manual work in case intake, case management, and signal management, from clinical studies through post-marketing surveillance.
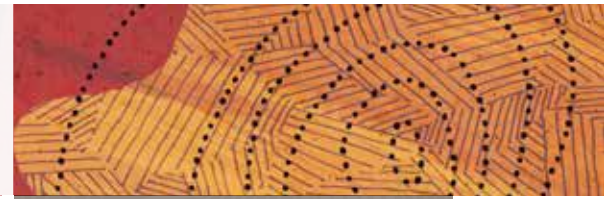
A unified cloud solution

Safety One was created to streamline the manual work in case intake, case management, and 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 to your organization, you can confidently begin the transition to Safety One.

"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
GEMVAX & KAEL GROUP

*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 oracle.com/goto/pvresearch.

Learn more about Safety One at
oracle.com/multivigilance

CONTACT

+1 800 633 0643

healthsciences_ww_grp@oracle.co

m oracle.com/lifesciences

CONNECT

blogs.oracle.com/life-sciences

facebook.com/oraclelifesciences

linkedin.com/showcase/oracle-life-sciences

About Oracle Life Sciences

Oracle Life Sciences is a leader in cloud technology, pharmaceutical research, and consulting, trusted globally by professionals in both large and emerging companies engaged in clinical research and pharmacovigilance, throughout the therapeutic development lifecycle, including pre- and post-drug launch activities. With more than 20 years' experience, Oracle Life Sciences is committed to supporting clinical development and leveraging real-world evidence to deliver innovation and accelerate advancements – empowering the Life Sciences industry to improve patient outcomes. Learn more at oracle.com/lifesciences