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Pharmacovigilance and Safety aren't just about identifying serious risks, but also honing suitability

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In conversation with Bruce Palsulich, Vice President, Product Strategy, Oracle Health Sciences



Life science organisations in APAC and around the world are increasingly realising the real-world benefits that artificial intelligence (AI) can bring to their operations. Along with providing speed, efficiency, and accuracy to safety programmes, AI can also help practitioners in evaluating the safety and effectiveness of their medicinal products. **Bruce Palsulich, vice president of product strategy at Oracle Health Sciences**, shares insights towards enabling predictive signal detection and reducing pharmacovigilance costs while implementing automation and AI in the Asian drug, vaccine, and medical device arena. Edited excerpts;

- **Can automation and AI leverage an effective Pharmacovigilance by tackling the consequences of adverse events (AEs)? What is Asia's perspective on post-marketing surveillance of AE?**

Determining a medicinal product's efficacy, i.e. analysing its side effects versus how effective it is at treating a disease, is the role of pharmacovigilance (PV) and multi vigilance. PV teams are under pressure from regulators seeking improved patient and product safety to comply with regulations, analyse more data sooner, monitor risks more broadly, and accurately report consumers' and patients' adverse events (AEs), globally.

As APAC life science organisations try to gather and analyse the explosion of new data related to adverse reactions, converting such massive and multiple data sets into meaningful information has become more complicated. Identifying a safety signal (new data about a known or unknown adverse reaction) based on the degree of priority is critical, aggregate data

gives a more holistic safety picture than any single adverse reaction case and is the basis for signal detection (mining the data for signals).

The secret weapon in this data battle is AI, which provides useful insights that help enable safety evaluators to make more informed observations, including using new techniques such as neural signal detection, multimodal signal detection, and predictive signal detection. AI can assist these observations by integrating disparate big data sources, which could include traditionally collected post-marketing AE reports such as the Japanese Adverse Drug Event Report (JADER) database, combined with electronic health records (EHRs), journal articles, and information on chemical structures, pharmacodynamics, pharmacokinetics, and genomics. As capabilities improve over time, a phased approach of introducing AI into the signaling process can pay significant dividends.

Such insights will help specialists make more informed benefit-risk evaluations, cross-check patterns of data to better understand the safety profiles of their products, and extend the boundaries of scientific research. PV and safety are not just about identifying serious risks, but also honing suitability. Leveraging the analytical capabilities of AI allows experts to decide which patient populations (cohorts) respond well to certain medications and which ones don't. This helps pharmaceutical companies avoid a market recall when the therapies could continue to benefit the lives of patients that do not experience adverse reactions.

- **How well can organisations reduce their pharmacovigilance costs by deploying AI and implementing automation?**

Before and after new drugs, vaccines, and medical devices become commercially available, it is a regulatory requirement for sponsors and manufacturers to address and guarantee their safety. This includes the tracking of AEs related to their usage. Ernst & Young estimates that large pharma companies deal with an average of 700,000 AE cases annually. According to International Data Corporation (IDC) market intelligence, the number is rising, with caseloads surging by 30-50 per cent annually. And with the proliferation of COVID-19 vaccines and therapies across the global markets, this number is expected to reach more than one million a year for some organisations.

Despite this huge increase in AE reports every year, APAC companies can't just continue to commit more resources to address the rising volume. At Oracle, we've helped dozens of organisations use the built-in automations in our safety case management application, using best-practice configurations.

Going beyond rule-based automation, some organisations have begun adopting AI for safety, usually starting with the case intake process because that is typically the longest step of the case management workflow. Using AI to automatically extract and structure data from safety source documents allows the safety team to skip manual data entry.

A well-designed, automated system using the right technologyâ€•a combination of rule-based and AI-based algorithmsâ€•can eliminate tedious and repetitive tasks, help reduce data entry errors, and significantly cut down on case management time, enabling better compliance as expedited reports go out the door faster. Finally, these business process automations allow for the reallocation of human resources from low-value tasks to high-value ones such as medical review and signal evaluation.

- **Can you describe Oracle's APAC life science business operations model in strengthening MedTech innovations, clinical management, and drug discovery in the region?**

In APAC, as well as around the globe, Oracle Health Sciences' goal is to provide a unified platform to life science organisations so they can deliver life-saving and enhancing treatments faster, safely, and with greater accuracy to patients in need.

AI and machine learning are changing the way these organisations can approach certain aspects of their clinical trials, making the management and various required reporting more automated. For example, with an AI-powered safety application, you can automatically extract AE case data from source documents, eliminating the need for so much manual work. There are areas in PV where AI, automation, and touchless case processing are having a significant and positive impact on managing patient safety.

Our Oracle-Informa study found that 97 per cent of organisations which implemented changes to their clinical trials approach during the pandemic indicated they would continue using at least one of the new methods or technologies like remote monitoring to video visits to phone visits, eConsent, and EHRs which are most likely approaches to continue.

- **How is Oracle delivering unified end-to-end multi vigilance around the lifecycle of medicinal products in APAC?**

Multi Vigilance involves the tracking of enormous amounts of AE 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 an organisation 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 minimisation activities. As the complexity of new medicinal products has increased along with greater regulatory scrutiny, so has the sheer volume of cases handled by safety departments.

The good news is that the same unified cloud-based platform that helped an organisation 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 multi vigilance post-approval.

APAC companies need to ensure compliance with the latest regulations from PMDA, NMPA, MFDS, TFDA, and other health authorities in the region. 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. Using a reliable cloud platform with an extensive application suite can help make upgrades and regulatory compliance easier, faster, and less costly.

Annual case volume increase of 30-50 per cent, 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 a cloud platform coupled with standardisation, automation, and AI can help lower the total cost of ownership and increase productivity, with a large reduction of manual work and overall case processing time.

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