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The AI Revolution in Multivigilance

Advanced technology helps protect patients and billions in R&D investment

BUSINESS BRIEF

The life science industry is undergoing dynamic change thanks to advances in science and engineering. Companies are developing, testing, and marketing medicines based on new technologies that promise to treat everything from cancer to rare genetic conditions more effectively than ever. At the same time, the costs of R&D have exploded. Bringing a therapy from the lab through approvals takes more than a decade, on average, at an overall investment of more than $2.6 billion, according to industry estimates.

During that whole process from clinical trials through postmarketing surveillance, companies carry out multivigilance—the monitoring and reporting of safety risks in new and existing life science products such as drugs, biologics, vaccines, medical devices, and combination products. Multivigilance is vital because it protects patients, fulfills regulatory obligations, and shields companies' huge R&D investments by helping to avoid recalls, financial penalties, and negative media about unsafe products.

Given the enormous resources devoted to developing new medicinal products while ensuring the well-being of patients, managing the exceedingly complex responsibility of multivigilance has become a crucial challenge for every company, from single-drug biotechs to global market leaders. In today's environment of changing regulations and a surge in the volume of data, safety departments are facing steeply increased demands.

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.

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New regulations, patient support programs, and consumer reporting channels have led to a significant increase in the number of incoming adverse event cases, while the detection and management of signals has seen a whole slew of additional data sources to monitor.

But just as new technologies are helping to create innovative new medicines, they're also revolutionizing safety. In particular, artificial intelligence (AI) can now replace manual processes and allow safety organizations to effectively handle the huge amount of data—and noise—they deal with every day.

Facing an overload

There are two main activities within multivigilance: safety case management and safety signal management, and both of these areas are dealing with data deluges. The number of incoming adverse event cases has increased significantly in recent years due to a combination of new regulations, patient support programs, and consumer reporting channels. IDC reports a 30-50% annual increase in the caseload being processed. Many of these new cases turn out to be noise that don't actually add any new information to a product's safety profile, but they have to be processed (or at least reviewed) anyway.

The other major area—detecting and managing signals—has traditionally relied on mining databases of spontaneous reactions, but today a whole slew of additional data sources is available, including clinical trial data, electronic healthcare records, administrative claims, social media, and many others. This raises both the hope of finding new safety insights as well as uncertainty about how to analyze all that data properly without opening the floodgates of new workloads that can overwhelm the organization.

Until now, both case and signal management have required significant manual efforts as safety specialists review the constant stream of data in order to separate the meaningful information from the noise. But that's proving almost impossible to sustain given the increased workload—not only is the cost enormous, but there are also too few human experts to perform the review.

30-50%

annual growth in adverse event cases

SOURCE:
IDC MARKETSCAPE: WORLDWIDE LIFE SCIENCE DRUG SAFETY SERVICES 2019–2020 VENDOR ASSESSMENT — BUILDING FOR INNOVATION

BIG DATA

New big data sources for signal detection include clinical trial data, electronic healthcare records, administrative claims, and social media.

AI processes the mass of data and filters out the noise, allowing safety staff to concentrate their valuable time on the most important cases and signals.

Automating the process with AI

Artificial intelligence can make this overloaded system much more efficient by automating manual workflows, processing large amounts of data at high speed, and identifying cases and signals that merit additional analysis by expert resources. In effect, AI processes the mass of data and filters out the noise, allowing safety staff to concentrate their valuable time on the most important information.

Although robotic process automation tools have been available for years, AI represents a fundamental transformation of that technology. Deep learning algorithms learn and improve over time, meaning that the value of AI keeps increasing. Natural language processing techniques extract adverse event information from unstructured free text narratives, circumventing the colossal time needed for manual data entry. And image processing algorithms figure out which checkboxes on a form have been ticked, for example. It's dozens of these algorithms working in unity, each one specialized at performing a very specific task, that comprises a well-working solution. There's no general AI tool that can simply be pointed towards a safety problem and expected to produce accurate results. It requires a high level of expertise in both AI and safety to select and finely tune techniques for multivigilance purposes.

Intelligent case intake

One of the most resource-intensive tasks within case processing is intake and manual data entry, thus making it a prime candidate to be automated using AI. Many AE reports do not arrive in E2B format, which means they have to be entered manually. This can take hours and represents a significant cost to the organization. Free-text narratives take the most time, requiring a manual sift through every sentence to find relevant information and then enter it into the correct field. Even forms can introduce manual effort and human error when the fields on the form do not follow the same order as the system.

Oracle Life Sciences Safety One Intake is powered by AI that can make these challenges a thing of the past. Proofs of concept have demonstrated that Safety One Intake can dramatically reduce overall case processing time by 50%. The cost per case goes down while the quality and consistency go up, as manual data entry issues are avoided. Faster case handling translates into better compliance as ICSRs to health authorities are expedited sooner. Safety One Intake is a revolutionary solution that is transforming today's safety case management into next-generation multivigilance.

62% of survey respondents are implementing or planning to

SOURCE:
ADDRESSING THE DATA CHALLENGES OF PHARMACOVIGILANCE, INFORMA BUSINESS INTELLIGENCE RESEARCH REPORT

TAILORING AI FOR SAFETY

A well-designed safety AI solution uses dozens of algorithms working in unity, each one fine-tuned by safety experts to perform a very specific task.

Safety One Intake can reduce case processing time by 50%

Oracle Life Sciences Safety One Intake saves time and money by leveraging AI to automatically turn paper AE reports into E2B files and reducing manual data entry.

Oracle Life Sciences and Oracle Labs

Oracle is one of the only software developers in the world that brings together decades of experience in both AI and safety. Dr. Rave Harpaz, Senior Director of Safety Research and Data Science, with a PhD in Computer Science specializing in Machine Learning, leads the efforts of researchers at Oracle Life Sciences and the Machine Learning Research Group at Oracle Labs to enhance and expand the AI features in our multivigilance applications. They have published the results of their research in peer-reviewed scientific journals, including articles on predicting side effects using machine learning, mining text for adverse events, and extracting attributes from noisy text. And their work demonstrates how AI is revolutionizing case management and signal management by allowing safety departments to focus on high-value multivigilance, protecting both patients and life science companies with high efficiency and low cost.

ORACLE EXPERTISE

Oracle is one of the only software developers in the world that brings together decades of experience in both safety and AI.

Learn more about Safety One Intake at
oracle.com/safety-one-intake

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