

# The AI Revolution in Multivigilance

Advanced Technology Helps Protect Patients and Billions in R&D Investment

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. These advances have also caused the costs of R&D to explode. 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 post-marketing surveillance, companies carry out multivigilance – the monitoring and reporting of safety risks in new and existing life science products such as drugs, 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.



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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.

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.



## BIG DATA

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

But just as new technologies are helping to create innovative new medicines, they're also poised to revolutionize safety. In particular, **artificial intelligence (AI)** has the potential to 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. For some, this has meant as much as a 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.

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 cases and signals.

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.

### Oracle Health 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 Health Sciences](#) and the [Machine Learning Research Group at Oracle Labs](#) to develop AI solutions in the multivigilance space. They have published the results of their research in peer-reviewed scientific journals, including articles on text mining for adverse events, attribute extraction from noisy text, and big data for adverse reaction detection. And their work demonstrates that AI will revolutionize case management and

### ORACLE EXPERTISE

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### TAILORING AI FOR SAFETY

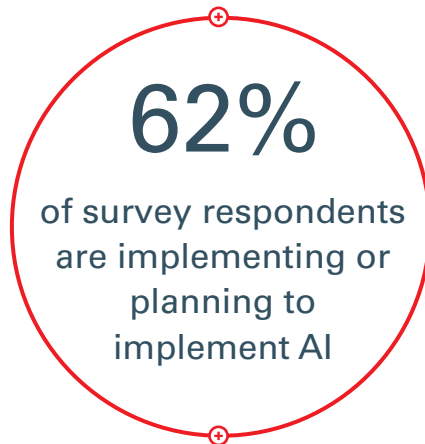
A well-designed safety AI solution uses dozens of algorithms working in unity, each one fine-tuned by safety experts to perform a very specific task.

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

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.

### 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 that 62% of respondents are actively implementing or planning to implement AI for case processing 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](https://oracle.com/goto/pvresearch).








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