# Pharmaceutical industry shifts focus from AI efficiency to enhancing human expertise in pharmacovigilance



As the pharmaceutical industry stands at the forefront of technological advancement, Artificial Intelligence (AI) has increasingly become integral to pharmacovigilance—the science of monitoring the safety of drugs. According to Updesh Dosanjh, practice leader for Pharmacovigilance Technology Solutions at IQVIA, AI enhances various operational aspects, from flagging adverse events to automating data entry and streamlining reporting timelines. However, a significant challenge persists: defining success in ways that encompass not only operational efficiency but also human outcomes.

The traditional metrics employed by many organisations, such as hours saved or improved processing speeds, provide only a superficial view of AI's impact. They fail to acknowledge the essential role that human expertise plays in this domain, particularly in an industry where patient safety and clinical judgement are paramount. Dosanjh argues that AI should not be perceived as a replacement for professionals but rather as a supportive tool that allows them to direct their efforts towards more complex and high-value tasks.

### Building Trust and Collaboration

Success in integrating AI into pharmacovigilance is contingent upon fostering a culture of trust. Adoption of AI tools often falters when these technologies are imposed from above without stakeholder involvement. A more collaborative approach involves creating cross-functional working groups that encompass pharmacovigilance and clinical stakeholders early in the process. This method not only helps tailor technology to actual workflows but also reduces the risk of costly rework later on.

Moreover, mentorship is vital. Organizations are encouraged to supplement vendor-led training with guidance from internal "super users" who understand both the technology and its application within the business context. These champions can effectively bridge the gap, demonstrating how AI can enhance, rather than compete with, human roles. Survey data from 2025 indicates that 58% of employees using AI experienced reduced stress, while 82% noted an improvement in the quality of their work. Such outcomes suggest that genuine engagement with AI tools can enhance workplace trust and motivation.

### The Imperative of a Broader Perspective

As the deployment of generative AI accelerates, many organisations report noteworthy time savings in tasks like drafting adverse event narratives. However, the true value lies beyond mere efficiency; it enables skilled professionals to focus on complex clinical assessments. The critical question for organizations should shift from "How many hours were saved?" to "What higher-value activities did this enable?" According to a recent Deloitte report, the internal rate of return on pharmaceutical AI projects witnessed a substantial increase from 1.2% in 2022 to 4.1% in 2023, attributed to more focused use and alignment with business objectives. Companies that evaluated downstream impacts—such as regulatory accuracy and improved staff allocation—achieved the most meaningful advancements.

### Constructing a Comprehensive Metrics Framework

To truly understand the benefits of AI, organisations must adopt a multifaceted metrics framework that includes operational optimisation, resource reallocation, analytical quality, and workforce engagement. This approach necessitates distinct methods of measurement for each dimension.

Operational optimisation is crucial, especially as traditional workflows often lack efficiency. Automating processes such as data handling and report generation not only enhances operational efficiency but also ensures regulatory compliance. AI's role in improving data quality is similarly significant. With data being processed by more professionals, the risk for human error increases; AI can mitigate this risk by establishing standardised procedures, strengthening patient protection through more reliable adverse event identification.

Refocusing expert capacity is another key area where AI proves beneficial. By automating routine tasks such as data entry, clinical and safety experts are liberated to engage in more meaningful pursuits, including signal evaluation and regulatory analysis. This shift has the potential to boost productivity and foster greater job satisfaction among teams.

### Regulatory Challenges and Opportunities

In the eyes of regulatory bodies such as the European Medicines Agency, ensuring consistency, traceability, and timely reporting is non-negotiable. AI solutions must meet these rigorous standards while also being transparent about how decisions are made. Effective governance of AI systems requires comprehensive documentation of decision processes, user overrides, and audit trails. This could involve integrating explanatory features into AI dashboards that clarify how inputs influence outputs. Additionally, incorporating regulatory affairs teams early in AI development ensures compliance with Good Pharmacovigilance Practices.

### A Future Aligned with Purpose

At its core, the pharmaceutical industry is dedicated to enhancing lives, and every tool employed—including AI—should be evaluated for its contribution to this mission. The primary measure of AI's success is its capacity to elevate human performance, protect patient safety, and empower professionals to make complex decisions.

As AI technology continues to mature, the pressing question remains whether the metrics for assessing its impact are evolving at a comparable pace. The industry must grapple with not only how to implement AI effectively but also how to measure its success in terms that truly matter for patient health and safety.

## Reference Map:

* Paragraph 1 – [[1]](https://pharmaceuticalmanufacturer.media/pharmaceutical-industry-insights/latest-pharmaceutical-manufacturing-industry-insights/reframing-ai%E2%80%99s-value-in-pharmacovigilance/), [[4]](https://www.quantzig.com/blog/role-artificial-intelligence-improving-pharmacovigilance/)
* Paragraph 2 – [[1]](https://pharmaceuticalmanufacturer.media/pharmaceutical-industry-insights/latest-pharmaceutical-manufacturing-industry-insights/reframing-ai%E2%80%99s-value-in-pharmacovigilance/), [[2]](https://www.datacreds.com/post/how-ai-and-ml-are-evolving-pharmacovigilance-systems), [[3]](https://careerinpharma.com/impact-of-ai-in-pharma-industry-revolutionizing-pharmacovigilance/)
* Paragraph 3 – [[5]](https://globalforum.diaglobal.org/issue/may-2025/artificial-intelligence-and-machine-learning-in-pharmacovigilance/), [[6]](https://us.pharmafocusasia.com/research-development/enhancing-pharmacovigilance-through-scope-artificial-intelligence)
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## Bibliography

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2. <https://www.datacreds.com/post/how-ai-and-ml-are-evolving-pharmacovigilance-systems> - This article discusses the integration of Artificial Intelligence (AI) and Machine Learning (ML) into pharmacovigilance systems, highlighting their potential to enhance drug safety monitoring by automating adverse drug reaction (ADR) detection from diverse data sources. It also addresses challenges such as data quality, regulatory compliance, and integration with existing systems, emphasizing the need for high-quality data and robust AI models to effectively implement these technologies in pharmacovigilance.
3. <https://careerinpharma.com/impact-of-ai-in-pharma-industry-revolutionizing-pharmacovigilance/> - This piece explores the transformative impact of AI on the pharmaceutical industry, particularly in pharmacovigilance. It highlights how AI-powered automation tools, like the FDA’s Sentinel System and IBM Watson, are revolutionising the identification, reporting, and management of adverse drug reactions (ADRs). The article also discusses challenges such as data integration, regulatory compliance, and the need for continuous learning and adaptation in AI systems within pharmacovigilance.
4. <https://www.quantzig.com/blog/role-artificial-intelligence-improving-pharmacovigilance/> - This blog post examines the role of Artificial Intelligence (AI) in enhancing pharmacovigilance, focusing on machine learning, natural language processing, and deep learning. It outlines the benefits of AI in improving efficiency, accuracy, and speed in adverse event detection and case processing. The article also addresses challenges such as data quality, interpretability, regulatory concerns, technical malfunctions, and the need for training drug safety professionals to effectively utilise AI technologies in pharmacovigilance.
5. <https://globalforum.diaglobal.org/issue/may-2025/artificial-intelligence-and-machine-learning-in-pharmacovigilance/> - This article delves into the integration of Artificial Intelligence (AI) and Machine Learning (ML) in pharmacovigilance, discussing their potential to revolutionise drug safety monitoring by automating adverse drug reaction (ADR) detection from diverse data sources. It highlights challenges such as data privacy, model bias, regulatory standards, and the need for human oversight. The piece concludes by emphasising the importance of combining technological innovation with human expertise to establish a patient-focused, data-driven pharmacovigilance system.
6. <https://us.pharmafocusasia.com/research-development/enhancing-pharmacovigilance-through-scope-artificial-intelligence> - This article explores the integration of Artificial Intelligence (AI) in pharmacovigilance, focusing on its potential to enhance drug safety monitoring. It discusses benefits such as improved efficiency, accuracy, and timely detection of adverse drug reactions (ADRs). The piece also addresses challenges including algorithm transparency, data quality, ethical considerations, and regulatory compliance. It underscores the importance of addressing these challenges to effectively implement AI in pharmacovigilance.
7. <https://www.pharmanow.live/ai-in-pharma/ai-in-pharma-safety-enhancing-pharmacovigilance-with-artificial-intelligence> - This article examines the role of Artificial Intelligence (AI) in enhancing pharmacovigilance, focusing on its potential to improve drug safety monitoring. It discusses challenges such as data quality, bias, regulatory compliance, and resource constraints in implementing AI-powered tools in pharmacovigilance. The piece highlights the need for high-quality data, addressing biases, and developing clear regulatory frameworks to effectively integrate AI into pharmacovigilance practices.