Can AI Improve Drug Safety Monitoring?

Rasit Dinc

Rasit Dinc Digital Health & AI Research

Published: July 4, 2022 | Drug Discovery and Pharmaceutical AI

DOI: 10.5281/zenodo.17998529

Abstract

The landscape of pharmacovigilance (PV) is undergoing a significant transformation, driven by the exponential growth of healthcare data and the advent of art...

Can AI Improve Drug Safety Monitoring?

Author: Rasit Dinc

Introduction

The landscape of pharmacovigilance (PV) is undergoing a significant transformation, driven by the exponential growth of healthcare data and the advent of artificial intelligence (AI). Traditionally, drug safety monitoring has relied on spontaneous reporting systems, which, while valuable, are often fraught with limitations such as under-reporting, data heterogeneity, and delays in signal detection. The increasing complexity of modern medicine, with polypharmacy and a growing number of biologic drugs, further strains these conventional methods. In this context, AI is emerging as a powerful ally, offering the potential to revolutionize how we monitor the safety of medicines and protect public health. This article explores the role of AI in improving drug safety monitoring, discussing its applications, challenges, and future prospects.

The Role of AI in Pharmacovigilance

AI, particularly machine learning (ML) and natural language processing (NLP), offers a suite of tools to enhance various aspects of pharmacovigilance. These technologies can analyze vast and diverse datasets, including electronic health records (EHRs), social media, and biomedical literature, to identify potential safety signals with greater speed and accuracy than ever before. The integration of AI into PV workflows can be categorized into several key areas:

Automated Case Processing

The sheer volume of adverse event reports is a major challenge for regulatory agencies and pharmaceutical companies. AI-powered systems can automate the intake, processing, and coding of these reports, significantly reducing the manual workload and improving efficiency. For instance, NLP algorithms can extract relevant information from unstructured narratives in adverse event reports, such as patient demographics, suspected drugs, and adverse drug reactions (ADRs), and map them to standardized terminologies like MedDRA. This automation not only accelerates the process but also enhances data quality and consistency [1].

Enhanced Signal Detection

One of the most promising applications of AI in PV is in the early detection of safety signals. Traditional signal detection methods often rely on disproportionality analysis of spontaneous reporting systems. While effective, these methods can be limited by the quality and completeness of the data. AI algorithms, on the other hand, can analyze large, real-world datasets, such as EHRs and insurance claims data, to identify potential drug-ADR associations that may not be apparent in spontaneous reports. For example, ML models can be trained to recognize patterns and predict the likelihood of an ADR based on a patient's clinical history, concomitant medications, and other risk factors. This proactive approach to signal detection can lead to earlier interventions and better patient outcomes [2].

Real-World Evidence Generation

The growing emphasis on real-world evidence (RWE) in regulatory decision-making has created a need for advanced analytical tools. AI can play a crucial role in generating RWE by analyzing large, longitudinal datasets to assess the long-term safety and effectiveness of drugs in real-world settings. This can provide valuable insights into the safety profiles of drugs in diverse patient populations, including those who are often underrepresented in clinical trials, such as pregnant women, children, and the elderly. AI-driven analysis of RWE can help to identify rare or long-term adverse events that may not be detected in pre-market clinical trials [3].

Challenges and Considerations

Despite the immense potential of AI in pharmacovigilance, several challenges need to be addressed to ensure its successful implementation. These include:

Data Quality and Accessibility: *The performance of AI models is highly dependent on the quality and accessibility of the data. Ensuring data privacy, security, and interoperability across different healthcare systems is a major hurdle.* **Algorithmic Transparency and Interpretability:** Many advanced AI models, such as deep learning models, are often referred to as "black boxes" due to their complex inner workings. Ensuring the transparency and interpretability of these models is crucial for building trust and facilitating regulatory acceptance. ***Bias and Fairness:*** *AI models can perpetuate and even amplify existing biases in the data. It is essential to develop and validate AI models that are fair and equitable, and that do not disadvantage certain patient populations.* **Regulatory Frameworks:** The regulatory landscape for AI in healthcare is still evolving. Clear guidance and standards are needed to ensure the safe and effective use of AI in pharmacovigilance.

The Future of AI in Drug Safety Monitoring

The future of drug safety monitoring will undoubtedly be shaped by the continued advancement of AI. We can expect to see more sophisticated AI models that can integrate multiple data sources, including genomics, proteomics, and wearable device data, to provide a more holistic view of drug safety. The development of federated learning models will allow for the training of AI models on decentralized data, addressing privacy concerns and facilitating collaboration across institutions. Furthermore, the integration of AI with other emerging technologies, such as blockchain and the Internet of Things (IoT), will create new opportunities for real-time drug safety surveillance.

Conclusion

AI has the potential to transform drug safety monitoring, moving the field from a reactive to a proactive and predictive paradigm. By leveraging the power of AI, we can enhance the efficiency and accuracy of adverse event detection, accelerate the generation of real-world evidence, and ultimately, improve patient safety. However, realizing the full potential of AI in pharmacovigilance will require a concerted effort from all stakeholders, including regulators, pharmaceutical companies, healthcare providers, and patients, to address the challenges and ensure the responsible and ethical use of this transformative technology.

References

[1] Nagar, A., Gobburu, J., & Chakravarty, A. (2025). Artificial intelligence in pharmacovigilance: advancing drug safety monitoring and regulatory integration. *Therapeutic Advances in Drug Safety*, *16*, 20420986251361435. https://doi.org/10.1177/20420986251361435

[2] Council for International Organizations of Medical Sciences (CIOMS). (2025). *Artificial intelligence in pharmacovigilance*. CIOMS. https://cioms.ch/wp-content/uploads/2022/05/CIOMS-WG-XIV_Draft-report-for-Public-Consultation_1May2025.pdf

[3] Shamim, M. A., & Arote, A. (2024). AI & Big Data for Pharmacovigilance & Patient Safety. *Drug Discovery and Development - New Advances*. IntechOpen.
https://www.sciencedirect.com/science/article/pii/S2949916X24000926
