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Review Article

# Harnessing Artificial Intelligence for Enhanced Pharmacovigilance: A Comprehensive Review

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**ABSTRACT**

Pharmacovigilance (PV) plays a crucial role in ensuring drug safety by monitoring and assessing Adverse Drug Reactions (ADRs). However, the traditional methods of PV are often labor-intensive, time-consuming and limited by human capacity for data processing and analysis. Recent advancements in Artificial Intelligence (AI) present new opportunities to enhance PV activities, enabling more efficient and accurate detection, assessment and prevention of ADRs. This comprehensive review explores the integration of AI technologies, such as machine learning, natural language processing and data mining, into PV systems. It examines the potential of AI to automate the collection, analysis and interpretation of vast amounts of data from diverse sources, including electronic health records, social media and scientific literature. Furthermore, the review discusses the challenges and ethical considerations associated with AI implementation in PV, such as data privacy, algorithmic bias and the need for regulatory frameworks. By synthesizing current research and case studies, this review highlights the transformative potential of AI in PV and provides recommendations for future research and practice in this critical field.

**Keywords:** Pharmacovigilance, Artificial Intelligence, Adverse drug reactions.

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## INTRODUCTION

Pharmacovigilance (PV), originating from the terms "Pharmakon" and "vigilia," is a vital scientific discipline focused on monitoring medicinal products both before and after they reach the market. Its goal is to detect, evaluate and prevent adverse effects, medication errors and drug interactions, thereby ensuring safe drug usage. This field involves identifying previously unknown harms, understanding dose-response relationships and disseminating important information to healthcare professionals and the public. Pharmacovigilance is essential for public health initiatives, effective drug regulation and clinical practice. It enables the rapid identification of pharmacological risks, defends products from unjustified withdrawals and oversees the global safety of pharmaceuticals. Despite challenges like underreporting adverse drug reactions, pharmacovigilance strives to enhance drug safety, improve reporting rates and reduce adverse drug reactions. Ultimately, it contributes to assessing the benefit-risk profile of drugs, ensuring better patient safety and efficacy.[1,2]

Traditional methods of pharmacovigilance primarily involve Spontaneous Reporting Systems (SRS), literature reviews and case reports. Spontaneous reporting is the most widely used method, where healthcare professionals, patients, or manufacturers voluntarily submit reports of Adverse Drug Reactions (ADRs) to national or international databases like the FDA's FAERS or WHO's VigiBase. These reports are then analysed to detect safety signals. Literature reviews involve the systematic monitoring of scientific publications for new information on ADRs, which is critical for maintaining up-to-date drug safety profiles. However, these methods face challenges, such as underreporting, data duplication and the difficulty of processing large volumes of unstructured data, which can lead to delays in detecting potential safety issues.[3,4]

Artificial Intelligence (AI) encompasses a range of technologies aimed at mimicking human intelligence, including machine learning, natural language processing, neural networks, computer vision and robotics. Machine Learning (ML) focuses on analysing data to allow systems to learn from it, identify patterns and make decisions with minimal human intervention. Natural Language Processing (NLP) allows computers to understand, interpret and communicate in human languages. Neural networks, modeled after the human brain, utilise interconnected nodes to process information and recognize complex patterns. Computer vision employs pattern recognition and deep learning to analyse images and videos. Robotics focuses on creating and using robots, with AI empowering them to carry out tasks that require human-like intelligence.[5]

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The need for AI in pharmacovigilance arises due to the significant limitations of traditional methods, such as manual data processing, underreporting of ADRs and delays in detecting safety signals. Current pharmacovigilance systems often struggle with large amounts of unstructured data, leading to inefficiencies and missed safety alerts. In India, for example, underreporting of ADRs is a significant challenge, with the Pharmacovigilance Programme of India (PvPI) working to create a more dynamic network to overcome these shortcomings. AI can address these challenges by automating data processing, enhancing the accuracy of signal detection and speeding up ADR reporting. Studies by Soussi Tanani *et al*. demonstrate that AI-based systems can significantly enhance the reporting of ADRs. For instance, after AI was integrated into a pharmacovigilance program in Morocco, the average monthly number of spontaneous reports surged from 3.6 to 37.4 cases.[6]

This comprehensive review aims to explore the current and emerging applications of AI in pharmacovigilance, highlighting the opportunities, challenges and future directions in this rapidly evolving field.

## APPLICATIONS OF AI IN PHARMACOVIGILANCE

### Adverse Event Detection and Reporting

Manually reporting Adverse Events (AEs) is often a slow process, resulting in significant delays in detecting potential safety issues. The vast amount of data from sources like electronic health records, social media and scientific literature can be overwhelming, resulting in under-reporting or missed cases. This data overload hinders the timely detection and reporting of crucial safety issues, underscoring the need for more efficient approaches. Research by Ruchika Sharma indicates that underreporting of ADRs is a significant issue, with traditional systems capturing only about 10% of actual ADRs.[4] Integrating automated systems like AI, especially NLP, is crucial for extracting adverse event information from various sources. For instance, NLP techniques analyse social media data, such as tweets, to identify and classify ADEs. By processing large volumes of text data, NLP algorithms can detect mentions of drug names and associated adverse effects, often hidden in casual or non-standard language. This capability allows for the real-time monitoring of drug safety from social media platforms, providing a rich and timely source of information. Additionally, NLP helps in understanding patient sentiment and detecting emerging trends in drug safety, which might not be reported through traditional channels. Alfred Sorbello *et al*., introduced the SPINEL prototype, an AI-enabled software designed to enhance opioid pharmacovigilance by identifying ADEs from discharge summaries in Electronic Health Records (EHRs). This prototype aims to improve opioid drug safety and research activities at the FDA. SPINEL demonstrated high accuracy in detecting known opioid-related ADEs and garnered positive feedback from FDA participants. The software employs keyword and trigger-phrase searching to extract potential ADEs associated with specific opioid drugs.[7]

## SIGNAL DETECTION AND MANAGEMENT

Manual signal detection can be a lengthy process, often taking several months to identify new safety signals, which can result in delays in taking necessary actions. For instance, a study by Ruchika Sharma found that confirming a new signal using traditional methods could take between 6 to 12 months.[4] Traditional signal detection methods often depend on disproportionality analysis, which may overlook emerging trends or subtle patterns in data. This reliance can result in missed signals that could indicate new or rare adverse drug reactions. Additionally, the manual nature of this analysis is highly time-consuming, leading to delays in recognizing new safety concerns. These limitations underscore the necessity for more advanced methods, like AI technologies, including machine learning and data mining, which have significantly improved the efficiency and accuracy of signal detection in pharmacovigilance. These technologies enable the identification of potential adverse drug reactions and emerging safety signals by analyzing both structured data (such as clinical trial results and electronic health records) and unstructured data (like social media posts and patient forums). Machine learning models can detect complex patterns and correlations within these datasets, often identifying signals earlier than conventional approaches. Additionally, AI-driven tools can continuously monitor and update safety profiles, providing real-time insights and facilitating prompt regulatory actions. This comprehensive approach improves drug safety and patient outcomes by ensuring timely detection and management of potential risks.[8] According to J Praveen in 'Empowering Pharmacovigilance,' generative AI shows promise in enhancing drug safety monitoring by automating the creation of case reports, identifying adverse events and prioritising safety signals. It can analyse diverse data sources, including adverse event reports and electronic health records, to detect potential safety issues. However, human oversight and validation are crucial for interpreting and acting upon the insights generated. Integrating generative AI with traditional pharmacovigilance methods can improve signal detection, data analysis and risk assessment, leading to improved patient outcomes. Addressing challenges related to data quality, interpretability and model validation is essential to fully leverage generative AI in pharmacovigilance responsibly and ethically.[9]

## RISK ASSESSMENT AND MITIGATION

Research by ClinChoice indicates that nearly 90% of pharmacovigilance activities are centered on post-market surveillance rather than on proactive risk assessment. This reactive strategy often results in delays when addressing emerging safety issues.[10] Predicting adverse outcomes is particularly challenging due to the complex interplay of various factors, including patient demographics, drug interactions and underlying health

conditions, resulting in traditional models often achieving accuracy rates of less than 70%. This low level of accuracy underscores the difficulty in foreseeing adverse outcomes before they happen.[4] AI-powered risk prediction models and tools are essential in drug safety assessment and mitigation. By utilizing machine learning algorithms, AI can analyze large datasets from clinical trials, medical records and post-market surveillance to identify patterns and signals that may suggest potential safety concerns. This analytical capability allows for the early detection of adverse events, enabling timely interventions and mitigating risks before they escalate. For example, AI-driven models have demonstrated the ability to predict patient-specific risks of adverse events with an accuracy of up to 85%, significantly surpassing traditional methods. A notable application of this technology is by AstraZeneca, which has integrated AI-based models into their clinical trials.[11] This implementation has not only reduced patient risk but also enhanced overall trial safety, showcasing the potential of AI in transforming healthcare practices.

## CASE PROCESSING AND TRIAGE

Manual case processing often results in considerable inefficiencies due to the time-consuming nature of tasks like data review, entry and analysis. Delays in triaging and prioritising cases create bottlenecks, further slowing down workflow. The absence of standardized reporting formats and frequent instances of incomplete data complicate case management, making it difficult to maintain consistency and accuracy. These inefficiencies can severely affect decision-making, leading to longer case resolution times. Implementing AI in case processing and triage streamlines these tasks, greatly improving efficiency and accuracy. AI technologies can automate the handling of individual case safety reports, significantly boosting performance compared to manual processing. For instance, the proposed design for case processing in the Pharmacovigilance Department of Indonesian vaccine companies has demonstrated a remarkable 219% increase in performance value when utilising AI technology.[12] This increase in efficiency is due to AI's capability to quickly analyze large volumes of data, detect patterns and accurately flag potential safety issues. Moreover, AI reduces human error, ensures consistency in evaluations and frees up valuable human resources for more complex decision-making tasks. Consequently, the adoption of AI in pharmacovigilance not only improves operational productivity but also enhances the overall quality and reliability of safety monitoring processes.

## POST-MARKET SURVEILLANCE

Monitoring the long-term safety of drugs post-market is challenging because of the extensive data produced from diverse sources like electronic health records, patient registries and spontaneous reporting systems. The diversity and volume of this information make it difficult to detect rare or long-term adverse effects using traditional surveillance methods. These methods often lack the sensitivity needed to identify uncommon or delayed side effects, potentially leading to underreporting and a delay in recognizing safety signals, which could compromise patient safety. AI's role in post-market surveillance is pivotal, offering tools and techniques to continuously monitor the safety of pharmaceutical products. AI can process real-time data from multiple sources, including electronic health records, social media and spontaneous reporting systems, to identify emerging safety issues and deliver prompt alerts. This continuous surveillance helps ensure that any potential risks associated with marketed drugs are promptly identified and managed.[13] By utilizing advanced machine learning algorithms, AI can rapidly analyze extensive datasets to detect adverse drug reactions and trends that traditional methods might overlook. Furthermore, AI-driven systems can prioritize alerts according to severity, helping regulatory agencies and healthcare providers make prompt and informed decisions. Integrating AI into post-market surveillance not only boosts the efficiency of monitoring processes but also greatly enhances patient safety and public health outcomes.

## SPONTANEOUS REPORTING SYSTEMS

Spontaneous reporting systems like the FDA Adverse Event Reporting System (FAERS) are vital in pharmacovigilance, as they gather and analyze data on adverse drug reactions. AI methods automate the handling of Individual Case Safety Reports (ICSRs), substantially decreasing the manual effort needed for data entry and analysis. This automation enhances the speed and accuracy of detecting potential safety issues, allowing for quicker regulatory responses. Additionally, AI-driven data quality improvements ensure more reliable insights into drug safety. Robert Dal Pan *et al*., highlighted the increasing interest in utilising AI in PV, especially for processing and assessing ICSRs. Although AI algorithms have demonstrated potential in enhancing efficiency and scientific value, they are not yet suitable for complete automation. Implementing AI in PV necessitates a sociotechnical framework that encompasses technology, evaluation, people, workflows and organisational policies. Full automation is unlikely to be achieved soon and a "human-in-the-loop" approach will probably remain essential for the foreseeable future. Figure 1 shows the application of AI in Pharmacovigilance.[14]

## CASE STUDIES AND REAL-WORLD EXAMPLES

### AI-Based Optimization from Social Media

AI techniques have been increasingly applied to analyse user behaviour indicators on social media platforms to detect ADEs. A notable study conducted by Roche *et al*. employed NLP in combination with a Word Cloud Convolutional Neural Network (WC-CNN) to classify and identify potential ADEs. The innovative method showed an impressive accuracy rate of 75% in detecting new safety signals, highlighting the potential of AI and machine learning models to improve pharmacovigilance

efforts. By monitoring social media interactions, these techniques can provide timely and valuable insights into drug safety, supplementing traditional reporting systems.[15]

### COVID-19 Related Pharmacovigilance

During the COVID-19 pandemic, adaptive signal detection approaches leveraging AI were employed to identify pulmonary Adverse Drug Events (pADEs) linked to hypertension medications. The study, conducted by Xu *et al*., utilised a range of sophisticated methods such as penalised regression, Graphical LASSO (GLASSO) clustering and the Generalised Propensity Score (GPS) method. These techniques were applied to analyse associations between drugs, drug interactions and drug-related ADEs. The comprehensive analysis revealed significant variations in pADE profiles among different drugs within the same class. This nuanced understanding highlighted that even medications within the same therapeutic category can exhibit distinct safety profiles, particularly in the context of acute respiratory illnesses like COVID-19. The findings from this study have the potential to enhance drug safety surveillance and inform clinical decision-making during health crises.[16]

Table 1 compares traditional pharmacovigilance with AI-enhanced pharmacovigilance across several aspects. Traditional methods are prone to significant errors in data entry and inconsistencies in adverse event classification, with delays in signal detection and challenges managing large data volumes. AI-enhanced systems improve accuracy by automating data extraction and using validation algorithms for real-time cross-checking. They enable immediate signal detection, scalable data processing and automated case triage. Additionally, AI enhances report quality with standardised templates, ensures regulatory compliance through automated documentation and provides real-time monitoring with continuous surveillance and up-to-date dashboards.

## CHALLENGES AND LIMITATIONS

### Data Quality and Availability

A major challenge in applying AI to pharmacovigilance is securing high-quality and accessible data. For training effective machine learning models, diverse and reliable data are essential, but acquiring such data can be challenging. Incomplete datasets, due to underreporting or missing information and biased datasets, reflecting reporting biases, can compromise the effectiveness of AI systems. These issues hinder the ability of AI to accurately identify ADRs and ensure drug safety. Therefore, addressing data quality and diversity is essential for the successful implementation of AI in pharmacovigilance.[17]


**Figure 1:** Applications of AI in Pharmacovigilance.

**Table 1: Comparative analysis of AI-driven vs traditional pharmacovigilance methods.**

| Aspect | Traditional Pharmacovigilance | AI-Enhanced Pharmacovigilance |
|---|---|---|
| Data Entry Errors | Error Rates: Up to 20% errors in manual data entry.<br>Inconsistencies: 30% variability in adverse event classification. | Automated Data Extraction: Reduces errors with OCR and NLP.<br>Validation Algorithms: Real-time cross-checking. |
| Signal Detection | Delayed Detection: 6-12 months delay in identifying safety signals.[4]<br>Detection Rate: Only 10-20% of ADRs detected. | Real-Time Analysis: Immediate signal detection through continuous monitoring.<br>Predictive Analytics: Early identification of potential issues. |
| Data Volume Management | Data Overload: 60% of organizations report difficulties.<br>Resource Allocation: 40% spend over 50% of resources on manual tasks. | Scalable Processing: AI handles large volumes efficiently.<br>Automated Case Triage: Prioritises and categorises cases effectively. |
| Report Quality | Incomplete Data: 25-30% of reports lack essential information.<br>Quality Variability: 15% variability in report quality. | Standardized Collection: Ensures completeness with predefined templates.<br>Quality Control: AI reviews for consistency. |
| Regulatory Compliance | Compliance Costs: Up to 20% of the budget.<br>Audit Failures: 10% of organisations face compliance issues. | Regulatory Intelligence: Keeps track of evolving requirements.<br>Automated Documentation: Simplifies audit trails. |
| Real-Time Monitoring | Reporting Lag: Up to 4 weeks delay in processing serious ADRs.<br>Data Gaps: 30% report challenges in real-time data. | Continuous Surveillance: AI enables real-time monitoring.<br>Real-Time Dashboards: Provides up-to-date insights. |

## Algorithm Bias and Interpretability

Algorithmic bias represents another major challenge in applying AI to pharmacovigilance. AI systems can unintentionally reinforce biases present in the training data, leading to distorted results and potentially harmful outcomes. For instance, if certain populations are underrepresented in the data, the AI might not detect adverse drug reactions specific to those groups. Additionally, the interpretability of AI models is vital for obtaining regulatory approval and gaining trust from the scientific and medical communities. However, many AI models function as "black boxes," making their decision-making processes difficult to understand. This lack of transparency can impede the adoption of AI technologies in pharmacovigilance, as stakeholders may be hesitant to rely on systems they cannot fully grasp.[18]

## Ethical Considerations

The implementation of AI in pharmacovigilance raises several ethical concerns. Data privacy is a major issue, as sensitive patient information must be protected. There is also the potential for AI to displace human jobs, leading to workforce disruptions. Transparency in AI operations is crucial to ensure that decisions are fair and understandable. Ethical and responsible use of AI is paramount to maintaining public trust and ensuring compliance with regulatory standards. Addressing these concerns is essential for the successful integration of AI in pharmacovigilance.[19]

## Integration with Existing Pharmacovigilance Systems

Integrating AI with existing pharmacovigilance systems presents both technical and organisational challenges. Many current systems are not equipped to handle the volume and complexity of data that AI systems require, necessitating significant upgrades and adjustments. Additionally, resistance from stakeholders accustomed to traditional pharmacovigilance methods can be a major hurdle. Overcoming this resistance requires careful change management, clear communication of AI benefits and comprehensive training programs. Ensuring a smooth transition is crucial for the successful implementation of AI in pharmacovigilance.[20]

## Human-AI Collaboration

Effective human-AI collaboration is essential for maximising the benefits of AI in pharmacovigilance. AI systems should be designed to complement and enhance human decision-making. This involves developing user-friendly AI tools that seamlessly integrate into existing workflows. Adequate training for healthcare professionals is crucial so they can effectively interact

with and leverage AI systems. Adopting a human-centred design approach ensures that AI systems are intuitive and meet the needs of users. This collaborative dynamic can significantly improve the accuracy and efficiency of pharmacovigilance efforts Figure 2 shows the challenges and limitation of AI in PV.[21]

## AI TECHNOLOGY USE IN COLLECTING AND MONITORING ADRS BY AGENCIES

### Uppsala Monitoring Centre (UMC)-WHO Collaborating Centre for International Drug Monitoring

The Uppsala Monitoring Centre (UMC), which maintains VigiBase, the world's largest database of Individual Case Safety Reports (ICSRs), is at the forefront of AI use in pharmacovigilance. UMC has developed several AI-based tools to enhance ADR detection:

### VigiRank

UMC's VigiRank uses a machine learning algorithm to prioritise ICSRs based on various criteria, including report completeness, clinical relevance and geographic origin. By combining these factors, VigiRank ranks ADR reports in a way that emphasises serious and unexpected reactions, allowing for more focused signal detection. This AI-powered ranking system improves efficiency in global drug safety surveillance by filtering out less relevant data, reducing false positives and speeding up the identification of significant ADRs.

### VigiLyze

This AI-enabled tool facilitates visual data exploration of VigiBase records, allowing pharmacovigilance professionals to detect trends and emerging safety concerns in real time. By combining Natural Language Processing (NLP) and machine learning, VigiLyze assists in identifying clusters of ADRs from global reports.[22]

### U.S. Food and Drug Administration (FDA)

The FDA has been pioneering the use of AI in pharmacovigilance, particularly through the integration of AI tools within two major initiatives:

### Sentinel Initiative

Launched in 2008, the Sentinel Initiative uses AI and machine learning algorithms to analyze Real-World Evidence (RWE) from Electronic Health Records (EHRs), insurance claims and other healthcare data sources. AI is utilized to identify potential ADRs by processing vast datasets from millions of patients in real time, allowing for quicker detection of safety issues, especially for rare and serious reactions that might not be captured during clinical trials.

### FDA Adverse Event Reporting System (FAERS)

The FAERS database collects spontaneous reports of adverse events submitted by healthcare professionals, consumers and manufacturers. The FDA has integrated NLP techniques into FAERS to analyse unstructured text from patient narratives and case reports, enabling more effective and automated detection of safety signals. NLP helps extract meaningful insights from large

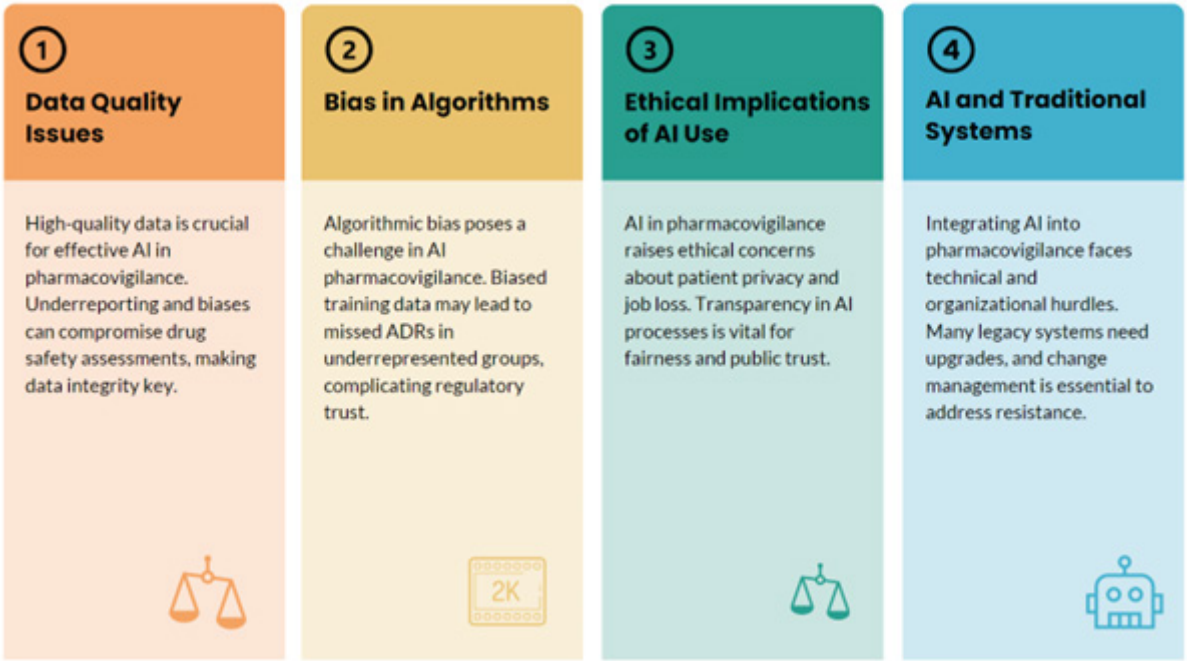


**Figure 2:** Challenges and Limitations in Pharmacovigilance.

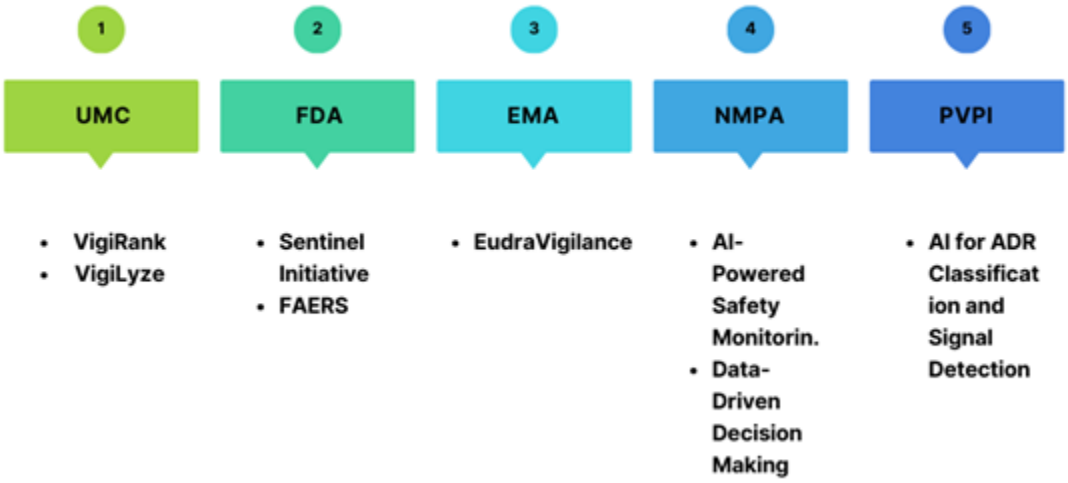


**Figure 3:** Agencies use AI Technology.

quantities of free-text information, which are often difficult to process with traditional statistical methods.[23]

## European Medicines Agency (EMA)

The European Medicines Agency (EMA) has been actively using AI technology to improve its pharmacovigilance system, particularly within the EudraVigilance database, which collects and manages reports of suspected ADRs from across Europe.

## AI in EudraVigilance

EudraVigilance leverages AI for enhanced signal detection, enabling the EMA to detect safety signals earlier by analyzing spontaneous reports from European Union (EU) member states. AI models within EudraVigilance can identify patterns of drug safety concerns from diverse datasets, helping regulators better assess the benefits and risks of medicines. AI tools have allowed EMA to automate data processing and prioritise high-risk cases, reducing manual workload while maintaining accuracy in safety assessments.

## Collaboration with Academia and Industry

EMA has partnered with research institutions and pharmaceutical companies to explore innovative AI models for predicting ADRs, assessing drug interactions and improving post-market surveillance. These collaborations are pushing forward AI adoption across Europe for more robust drug safety monitoring.[24]

## National Medical Products Administration (NMPA)-China

The National Medical Products Administration (NMPA), China's regulatory authority, has been modernizing its pharmacovigilance system by integrating AI to enhance ADR monitoring.

## AI-Powered Safety Monitoring

The NMPA has implemented AI algorithms that analyze spontaneous ADR reports, clinical trial data and electronic health records to detect potential safety signals. By applying machine learning models, NMPA can identify unexpected patterns of adverse reactions; classify severity levels and alert health authorities to emerging drug safety concerns.

## Data-Driven Decision Making

NMPA's use of AI is not limited to signal detection but extends to decision-making processes regarding drug approvals and post-market safety assessments. AI tools provide insights from real-world data, helping to predict drug interactions and potential ADRs more accurately.

## Medicines and Healthcare products Regulatory Agency (MHRA)-UK

The Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom has embraced AI technologies in its efforts to monitor ADRs through the Yellow Card Scheme.

## AI in the Yellow Card Scheme

The MHRA uses AI-enhanced systems to analyse reports submitted to the Yellow Card Scheme, a national system for reporting suspected side effects or safety concerns for medicines and medical devices. AI helps prioritize serious reports and accelerates the detection of ADRs, allowing MHRA to take timely regulatory actions. By combining patient reports with EHR data, the AI system helps identify risk factors that could predispose individuals to ADRs.[25]

### Pharmacovigilance Program of India (PvPI)

The Pharmacovigilance Program of India (PvPI), under the Indian Pharmacopoeia Commission, has also integrated AI into its ADR monitoring framework.

### AI for ADR Classification and Signal Detection

PvPI is working with global pharmacovigilance experts to implement AI-based tools for automated classification of ADRs and detection of serious adverse events. The AI models help prioritise safety reports based on severity, ensuring faster identification of significant safety signals. PvPI is focusing on using AI to automate reporting workflows and minimise manual intervention, thereby improving reporting accuracy and timeliness.

### Health Canada-Canada Vigilance Program

Health Canada utilises AI in its Canada Vigilance Program to enhance the monitoring of ADRs. AI models are used to detect safety signals from various sources, including spontaneous reports, clinical trial data and electronic health records.

### AI for Signal Prioritization

The AI algorithms used by Health Canada prioritise reports based on seriousness, geographic factors and frequency, enabling the agency to identify emerging safety concerns more efficiently. By utilising machine learning for continuous data analysis, Health Canada can quickly spot patterns of potential harm and initiate appropriate regulatory actions Figure 3 shows agencies use AI technology.[26,27]

## FUTURE DIRECTIONS AND OPPORTUNITIES

Pharmacovigilance is evolving rapidly, with future directions focusing on integrating advanced technologies like AI and machine learning to enhance drug safety monitoring. Big data analytics and Real-World Evidence (RWE) are becoming crucial for identifying adverse drug reactions more effectively. Personalised medicine, driven by genomics, is expected to tailor pharmacovigilance strategies to individual patient profiles. Additionally, increased regulatory emphasis on global collaboration and harmonisation presents opportunities for more consistent and comprehensive safety surveillance across borders. Emerging therapies, such as biologics and gene therapies, also require specialised pharmacovigilance approaches, creating new areas for expertise development.[28]

The integration of AI into pharmacovigilance holds transformative potential to enhance the detection, monitoring and management of ADRs. AI-driven techniques like natural language processing, machine learning and deep learning can analyse vast datasets, including electronic health records, social media posts and patient narratives, to identify ADR signals more accurately and in real-time. Such capabilities help address traditional challenges in pharmacovigilance, such as underreporting and delayed ADR detection, by automating data analysis and uncovering complex patterns that human analysis may miss. Moreover, AI can facilitate personalised risk assessment and early identification of high-risk patients, ultimately improving patient safety and optimising regulatory responses. With ongoing advancements in AI, the future of pharmacovigilance could see increasingly proactive safety monitoring systems, enabling faster responses to emerging drug safety concerns on a global scale.

## CONCLUSION

In conclusion, harnessing AI for enhanced pharmacovigilance presents significant opportunities to improve drug safety monitoring. AI-driven systems can efficiently analyse vast datasets, identify adverse drug reactions earlier and reduce human error. However, successful integration requires addressing challenges like data quality, algorithm transparency and regulatory compliance. Overall, AI holds great promise in transforming pharmacovigilance into a more proactive and accurate process.

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## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## ABBREVIATIONS

**PV:** Pharmacovigilance; **ADRs:** Adverse drug reactions; **AI:** Artificial Intelligence; **SRS:** Spontaneous reporting systems; **ML:** Machine learning; **NLP:** Natural language processing; **PvPI:** Pharmacovigilance Programme of India; **AEs:** Adverse events; **EHRs:** Electronic health records; **FAERS:** FDA Adverse Event Reporting System; **ICSRs:** Individual Case Safety Reports; **WC-CNN:** Word Cloud Convolutional Neural Network; **pADEs:** Pulmonary adverse drug events; **GPS:** Generalised Propensity Score; **UMC:** Uppsala Monitoring Centre; **RWE:** Real-world evidence; **EMA:** European Medicines Agency; **NMPA:** National Medical Products Administration.

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