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Review Article

# Revolutionizing Pharmacovigilance: The Role of Artificial Intelligence in Enhancing Patient Safety

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## A B S T R A C T

*Background:* Pharmacovigilance (PV) is responsible for monitoring drug safety, and Artificial Intelligence (AI) is a promising technology that has the potential to transform this field.

*Objective:* This article will investigate the role of AI in PV and its potential benefits for patient safety and healthcare providers.

*Methods:* A structured review of relevant literature was conducted to identify studies that demonstrate the applications of AI in PV. The identified studies were analysed to determine the specific roles of AI in PV and its potential benefits.

*Results:* The practice of AI in PV allows for the analysis of large datasets, adverse event reporting, the detection of safety signals, the prioritisation of safety issues, data mining, and predictive modelling. The benefits of AI in PV include improved efficiency, increased accuracy, enhanced patient safety, faster analysis of safety issues related to drugs, and reduced healthcare costs.

*Conclusion:* AI has enormous potential to improve PV by streamlining case processing and improving the identification of adverse events. However, there are also challenges that need to be addressed in implementing AI in PV. Overall, AI has significant promise for enhancing patient safety and reducing healthcare costs.

**Keywords:** Adverse Drug Reactions, Artificial Intelligence, Pharmacovigilance

## Introduction

Pharmacovigilance (PV) is the practice of monitoring and evaluating the safety of medicines and medical devices throughout their lifecycle. It involves collecting, analysing, and reporting adverse drug reactions (ADRs) and other drug-related problems to regulatory authorities, healthcare professionals, and patients. PV aims to identify and prevent potential harm to patients by detecting and assessing the risks associated with the use of medicines and medical devices.[1]

The importance of PV lies in several areas. Firstly, it protects patient safety by identifying and monitoring the ADRs of drugs and devices, preventing potential harm to patients. Secondly, it helps improve the quality of healthcare by

ensuring that medicines and medical devices are safe and effective.[2] Thirdly, it promotes public health by providing valuable information about the safety and effectiveness of drugs and devices to healthcare providers, regulatory authorities, and the public. Fourthly, it supports regulatory compliance by requiring pharmaceutical companies to conduct PV activities as a condition of marketing authorisation.[1] Finally, it facilitates continuous improvement by collecting and analysing data on ADRs, identifying areas for improvement, and fostering continuous learning and development.[1]

Artificial intelligence (AI) is a branch of computer science that deals with the development of algorithms and computer programs that can perform tasks that typically require human intelligence. AI is characterised by the ability to reason, learn, perceive, and adapt to changing circumstances. AI is rapidly transforming the healthcare industry in a variety of ways. Medical imaging, diagnosis, treatment, drug discovery, and personalised medicine are just a few examples of how AI is being used to improve patient outcomes and reduce costs.[3]

The current methods used in PV have limitations such as passive reporting, underreporting, data biases, and the impact of confounding factors and therefore can be time-consuming and resource-intensive. As the volume of data generated in PV increases, traditional methods of managing this data have become inadequate. This has led to an increased interest in the use of AI in PV.[4–6] AI has the potential to revolutionise healthcare by improving patient outcomes, reducing costs, and increasing efficiency. However, there are also challenges to overcome, such as ensuring the accuracy and ethical use of AI algorithms, protecting patient privacy, and addressing concerns about job displacement.[7]

In this review, we have discussed the role and benefits of using AI in PV, what the challenges are in implementing AI in the overall PV programme and what the prospect of the amalgamation of PV and AI.

## Background of AI

The use of AI in healthcare dates to the 1970s, when expert systems were explored for clinical decision-making.[8] However, it wasn't until the development of machine learning algorithms and large datasets that AI's potential in healthcare was realised. In the early 2000s, the use of AI gained momentum with the development of natural language processing and computer vision technologies.[9] Natural language processing enabled computers to interpret human language, which was crucial for extracting information from medical records. Today, AI is widely used in healthcare for various applications, including medical image analysis, clinical decision support, drug discovery, and patient monitoring.

## Types of AI

### Rule-based System

A rule-based system utilises a set of "if-then" rules to tackle intricate problems. These rules enable the system to make informed decisions or draw conclusions based on data input.[10] For example, a rule-based system could diagnose a medical condition based on a set of symptoms, using pre-defined rules that specify which symptoms indicate which conditions. Rule-based systems are most effective in specific domains with clear decision-making processes, such as medical diagnosis or fraud detection. However, they may struggle to handle situations outside of the predefined rules.

One benefit of rule-based systems is their transparency and ease of understanding, which is important in applications such as medical diagnosis. Moreover, rule-based systems can be developed rapidly and at a low cost, as they don't require large amounts of training data.

## Machine Learning

Machine learning (ML) is a rapidly evolving sub-discipline of AI that enables computers to learn from data and make predictions or decisions without explicit programming.[11] ML involves training algorithms on large datasets, and the algorithm learns to recognise patterns and make predictions based on that data. There are three main types of ML: supervised learning, unsupervised learning, and reinforcement learning.

- Supervised learning involves training the algorithm on a labelled dataset, where each data point is associated with a label or target variable.[12] The algorithm learns to recognise patterns in the input data and to make predictions based on those patterns. Supervised learning is commonly used for tasks such as image classification or speech recognition.
- Unsupervised learning involves training the algorithm on an unlabelled dataset, where there are no target variables. The algorithm learns to recognise patterns and structures in the data and to group similar data points. Unsupervised learning is commonly used for tasks such as clustering or anomaly detection.[12]
- Reinforcement learning involves algorithm learning to make decisions based on feedback from the environment. The algorithm receives a reward or penalty based on its actions, and it learns to make decisions that maximise its reward. Reinforcement learning is commonly used for tasks such as game playing or robotics.[13]

## Deep Learning

Deep learning is a type of supervised machine learning technique that employs neural networks to learn from

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data by recognising patterns in multiple layers of neurones inspired by the human brain's structure and function.[14] This method has achieved exceptional performance in image and speech recognition, natural language processing, and game playing. The healthcare industry has also leveraged deep learning to advance medical image analysis, drug discovery, and disease prediction.[15]

The ability of deep learning to automatically learn and extract features from raw data has proven valuable when it is challenging to manually design features. Moreover, training deep learning models with large datasets can improve their accuracy and generalisation performance. Nevertheless, deep learning models' challenges include their high computational expense and reliance on large amounts of training data. Moreover, they can be challenging to interpret and comprehend, particularly in medical diagnoses where understanding the reasoning behind a decision is crucial.[15]

## Bayesian Network

Bayesian networks are a type of probabilistic graphical model that represents a set of random variables and their conditional dependencies using a directed acyclic graph.[16] Bayesian networks can be used to model the relationship between ADRs and patient characteristics, such as age, sex, and medical history. By modelling the dependencies between these variables, a Bayesian network can help to identify patient subpopulations that are at increased risk of developing ADRs.[17]

## Decision Tree

A decision tree is a model that predicts by recursively splitting data based on informative features. Each split creates a new node, and each leaf node represents a prediction.[18] Decision trees identify ADRs that are associate with a drug based on patient characteristics and clinical features. They can help to identify the relevant risk factors for an ADR.

## Natural Language Processing (NLP)

NLP deals with the interaction between computers and human language. NLP algorithms can be used to perform tasks such as sentiment analysis, machine translation, and question answering. It can analyse unstructured data sources, such as social media posts and electronic health records, to identify potential ADRs and monitor drug safety in real-time. By analysing large volumes of text data, NLP algorithms can identify patterns and trends that may be missed by traditional PV methods.[19]

There is often a lack of clear demarcation between different techniques of AI, as researchers often use combinations of various AI approaches in healthcare research. The use of multiple techniques, including ML, deep learning, and NLP, can lead to improved performance and outcomes in healthcare applications.[20] However, the lack of a clear boundary between these techniques can make it challenging to understand the specific contribution of each approach in a given study. Ultimately, a better understanding of the strengths and limitations of different AI techniques can help to guide the development of more effective and efficient healthcare applications.

# Application of AI in PV

## ADRs Reporting

ADRs pose a significant public health challenge and contribute to hospitalisation and death rates in developed countries. Unfortunately, ADRs are commonly underreported, which undermines the effectiveness of spontaneous reporting. Healthcare professionals may be hesitant to report ADRs as it increases their workload. However, an alternative approach is to integrate an electronic health record (EHR) system that assists healthcare professionals in completing ADR reports. This method is efficient and may increase the ADR reporting rate, which ultimately improves patient safety.[21]

NLP algorithms can extract relevant information from unstructured text sources, such as medical records and social media posts, to identify potential ADRs. ML algorithms can analyze large datasets to identify potential safety signals and predict which patients are most at risk of developing ADRs. These techniques can help to develop targeted prevention strategies and improve patient outcomes Figure 1.[22]

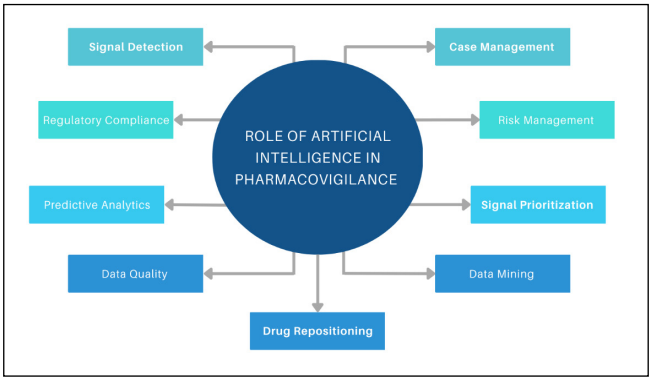


**Figure 1.Role of Artificial Intelligence in Pharmacovigilance**

## Signal Detection

Signal detection is a critical process in PV that involves identifying potential safety issues associated with medication use through the analysis of post-market surveillance data.[23] The Bayesian confidence propagation neural network (BCPNN) is a valuable tool that combines Bayesian statistics and neural network architecture to identify potential safety signals from large amounts of PV data. BCPNN has been shown to effectively detect

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safety signals early and avoid false positives, making it an important tool for improving PV and patient safety.[24] The FDA collects and stores numerous data sets related to post-market drugs and adverse events (AEs), including the FDA Adverse Event Reporting System (FAERS). However, the narratives contained in these reports need to be coded using standardised terminology to enable further review. A proof-of-concept ML approach has been used to automatically detect AEs in various textual regulatory data sets, which could help support post-market regulatory activities and improve patient safety.[25] These approaches demonstrate the potential of AI to automate and improve signal detection in PV.

## Signal Prioritization

Signal prioritisation is the process of determining which potential safety issues identified during signal detection should be investigated further. The growing number of ADR reports from patients and mass media-related sanitary crises have led to overwhelming PV networks. AI could assist PV experts by automatically coding reports and prioritising assessments. A recent study successfully trained and validated AI models to identify ADRs and assess their seriousness using unstructured text data from patient reports on the French national PV web portal. The study utilised gradient boosting and transformer-based approaches, both of which produced similar results in internal and external validation. This research suggests that AI has the potential to support PV networks during periods of high ADR reporting.[26]

## Case Processing

Effective PV requires efficient case processing, which involves collecting, managing, and evaluating individual case safety reports (ICSRs) related to ADRs. The process includes several steps, such as data entry, medical review, causality assessment, quality control, and reporting. Upon receipt of an ICSR, the information provided is verified, and the ADR experienced is evaluated to determine its seriousness and causality. This information is entered into a safety database, and a medical review is conducted to ensure its accuracy and completeness. Quality control checks are then performed to confirm the data's accuracy and completeness before submission to regulatory authorities.

The traditional method of case processing can be time-consuming and labour-intensive, involving a manual review of ICSRs submitted by healthcare professionals, patients, and other sources. However, the use of AI can help automate case processing, enabling faster and more efficient identification of AEs.

Recent studies have demonstrated the effectiveness of AI-based approaches in case processing. Wang et al. utilised the Medical Language Extraction and Encoding (MedLEE) algorithm, an NLP system, to extract information about seven drugs from unstructured data and convert it into structured representation to identify medication events and AEs.[27] Bostsis et al. used a rule-based classifier to classify cases of AE anaphylaxis after H1N1 vaccination, achieving over 93% accuracy.[28] Schmider et al. conducted a pilot study to evaluate case management using AI-based technology and observed case-level accuracy with the processing of approximately 33.3% of cases with not less than 80% completion.[29] These studies demonstrate the potential of AI to improve PV by streamlining case processing and improving the identification of AEs (Table 1).

**Table 1.Role of Artificial Intelligence in Pharmacovigilance**

| Role of Artificial Intelligence in Pharmacovigilance | Description |
|---|---|
| Signal Detection | AI can analyse large volumes of data from multiple sources, such as electronic health records (EHRs), social media, and other sources, to detect potential adverse drug reactions (ADRs) and signals. AI can also analyse data in real-time, allowing for the detection of ADRs in near real-time. |
| Data Mining | AI can analyse large amounts of data from clinical trials, EHRs, and other sources to identify patterns in adverse event reporting, drug utilisation, and patient outcomes. This can help identify previously unknown ADRs and enable better drug safety decision-making. |
| Risk Management | AI can help identify patient populations that may be at higher risk of adverse events and help optimise risk management strategies. AI can also help identify drug-drug interactions, contraindications, and other risk factors. |

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| | |
|---|---|
| Signal Prioritisation | AI can prioritise signals based on their clinical relevance and potential impact, allowing pharmacovigilance teams to focus on the most important signals first. |
| Case Management | AI can help streamline the case management process by automating the data entry process, identifying duplicate cases, and ensuring that all relevant information is captured. |
| Data Quality | AI can help improve the quality of pharmacovigilance data by identifying errors, inconsistencies, and missing information. |
| Predictive Analytics | AI can help predict the likelihood of future adverse events and drug interactions, enabling proactive risk management and improved patient safety. |
| Regulatory Compliance | AI can help ensure that pharmacovigilance activities comply with regulatory requirements, such as the reporting of adverse events to regulatory agencies. |
| Drug Repositioning | AI can help identify new therapeutic uses for existing drugs, enabling the repurposing of drugs for new indications. This can help accelerate drug development and improve patient outcomes. |

## Data Mining

In PV, data mining plays a crucial role in extracting useful patterns and insights from complex data sets. Advanced analytical methods, such as clustering, classification, association rule mining, and text mining, are used to discover hidden relationships and associations between drugs and ADRs and to identify potential safety signals that might otherwise go unnoticed. Data mining techniques can help identify patterns in data sets, such as drugs that are frequently associated with a particular AE or patients who are at a higher risk of experiencing a certain AE. This can enable regulatory authorities and pharmaceutical companies to quickly identify and evaluate potential safety concerns associated with marketed drugs, thereby improving patient safety and preventing AEs.

To further improve patient safety, it is essential to automatically extract drug-drug interactions (DDIs) from medical texts. A deep neural network model and a novel attention mechanism were proposed to enhance the discrimination of significant words for DDI extraction from medical texts.[30] In another study, a neural network-based predictive system (NNPS) was used to predict polypharmacy side effects, outperforming all five established methods in terms of accuracy, complexity, and running time speed [31].

## Predictive Modeling

Predictive modelling is an important area of PV that uses statistical and ML techniques to analyse large datasets and identify potential ADRs before they become significant public health concerns. Predictive models are trained on data from various sources, including electronic health records, clinical trials, social media, and other sources of real-world evidence. Ward et al. developed an explainable AI (XAI)-based technique for PV monitoring by quantifying the contribution of specific drugs to Acute Coronary Syndrome (ACS) predictions. Multiple machine learning models were trained to predict ACS-related adverse outcomes for individuals aged over 65 using their health information, and XAI algorithms were used to calculate the drugs that led to these predictions. Rofecoxib and celecoxib were found to have a significant contribution to ACS predictions, and the XAI libraries LIME and SHAP were successful in identifying important features.[32]

## Benefits of AI in PV

AI presents an opportunity for significant advancements in PV by improving the accuracy and efficiency of drug safety surveillance. AI-powered techniques can analyse vast amounts of data from various sources, identifying potential ADRs and DDIs that may have been overlooked by traditional methods. This enhanced ability to identify safety issues can improve patient safety and help healthcare professionals make more informed decisions about prescribing medications, ultimately leading to better patient outcomes.[33]

In addition, AI can enhance signal detection by quickly and accurately identifying potential safety signals that might

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have been missed through manual review of individual case safety reports.[34] This can enable quicker responses to potential safety concerns and reduce the risk of harm to patients. Furthermore, AI can automate certain tasks, such as case processing and data analysis, to increase efficiency in PV.[35–37] This can reduce the workload for PV professionals and improve the speed and accuracy of data analysis.

Finally, AI can help identify patient subgroups that may be more susceptible to ADRs, allowing for personalised medicine and reducing the risk of harm to vulnerable populations.[38]

## Major Challenges

In the field of PV, several challenges need to be addressed to ensure the effective and responsible use of AI algorithms. Firstly, the accuracy and reliability of these models heavily rely on the quality of the data used to train them. However, incomplete, inconsistent, or erroneous data can result in biased or incorrect outcomes, compromising the integrity of the analysis.[39]

Additionally, AI algorithms may perpetuate existing biases in the training data, leading to inaccurate or discriminatory results.[40] This can be particularly problematic in PV, where algorithm bias could potentially lead to the underreporting or over-reporting of AEs.

Standardisation and interoperability are also major issues that need to be tackled in this domain.[41] The lack of uniformity in data collection, storage, and analysis can make it challenging to integrate data from various sources and ensure consistency in data processing and interpretation.

Furthermore, integrating AI technologies into existing PV systems can be challenging, given the potential incompatibility with current workflows and processes.[41] Ethical considerations must also be considered,[42] as the use of patient data raises concerns about privacy and confidentiality. Patients need to understand how their data is being used and protected, and there is a risk of data breaches that can compromise the privacy and security of personal health information.

Even regulatory agencies such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have raised concerns about its use.[43] A significant concern is some AI models' lack of transparency and interpretability, which can make it challenging to comprehend how they make their predictions.[44] This is especially problematic in ADR reporting, where accuracy is crucial to ensure patient safety. Additionally, regulatory agencies are wary of potential biases in AI models that may lead to erroneous predictions and undermine the effectiveness of PV efforts.

To address these concerns, regulatory agencies are actively developing guidelines and standards for the use of AI in PV. These measures aim to ensure that AI models are transparent, reliable, and safe to use in drug safety monitoring. By establishing best practices for developing, validating, and deploying AI algorithms, regulatory agencies strive to promote the responsible use of this technology in PV.

## Prospects

The future of AI in PV is promising, with numerous opportunities to improve drug safety monitoring and enhance patient outcomes.

One of the most significant benefits of AI in PV is its ability to integrate with other technologies. For example, AI algorithms can be combined with EHRs and other health information technologies (HIT) to identify potential ADRs quickly. This integration can also help identify patterns and trends in drug safety data, which can inform drug development and regulatory decision-making.

AI is also expected to play a more significant role in drug development. By analysing large data sets, AI algorithms can help identify potential drug targets, predict the safety and efficacy of drugs, and speed up the drug development process. This expansion of AI in drug development has the potential to reduce the cost of drug development and increase the success rate of clinical trials.

AI-based tools are also being developed to help manage drug safety risks. For example, AI algorithms can help identify patients at high risk of developing ADRs and recommend appropriate interventions to reduce their risk. These tools can also help identify drugs that may have a higher risk of causing ADRs and inform regulatory decision-making.

Finally, the successful integration of AI in PV will require collaboration between industry, regulators, and academia. Industry stakeholders can provide access to large data sets, while regulators can provide guidance on the development and validation of AI algorithms. Academia can contribute to the development of new AI-based tools and the evaluation of their effectiveness.

## Conclusion

PV is a crucial aspect of healthcare that ensures patient safety by monitoring and evaluating the safety and efficacy of drugs. AI has the potential to revolutionise PV by improving efficiency, accuracy, and speed of analysis, leading to enhanced patient safety. With the availability of vast amounts of data, AI can be leveraged to detect AE, signal detection, data mining, and predictive modelling. However, there are also challenges in implementing AI in PV, such as data privacy and security, lack of standardisation, quality and quantity of data, and bias in AI algorithms. The future of AI in PV is promising, with the integration of

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other technologies, expansion in drug development, and the development of AI-based tools for risk management. Collaboration between industry, regulators, and academia is essential to ensure AI's ethical and responsible use in PV. In conclusion, the use of AI in PV holds immense potential for improving patient outcomes and should be further explored and implemented responsibly.

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## References

1. Peters T, Soanes N, Abbas M, Ahmad J, Delumeau JC, Herrero-Martinez E, Paramananda M, Piper J, Smail-Aoudia F, van der Spuij W, Veizovic T. Effective pharmacovigilance system development: EFPIA-IPVG consensus recommendations. Drug safety. 2021 Jan;44:17-28. [Google Scholar] [Pubmed]
2. Luo Y, Thompson WK, Herr TM, Zeng Z, Berendsen MA, Jonnalagadda SR, Carson MB, Starren J. Natural language processing for EHR-based pharmacovigilance: a structured review. Drug safety. 2017 Nov;40:1075-89. [Google Scholar]
3. Gupta R, Srivastava D, Sahu M, Tiwari S, Ambasta RK, Kumar P. Artificial intelligence to deep learning: machine intelligence approach for drug discovery. Molecular diversity. 2021 Aug;25:1315-60. [Google Scholar]
4. Inácio P, Cavaco A, Airaksinen M. The value of patient reporting to the pharmacovigilance system: a systematic review. British journal of clinical pharmacology. 2017 Feb;83(2):227-46. [Google Scholar]
5. Williamson T, Lévesque L, Morkem R, Birtwhistle R. CPCSSN's role in improving pharmacovigilance. Canadian Family Physician. 2014 Jul 1;60(7):678-. [Google Scholar]
6. Murali K, Kaur S, Prakash A, Medhi B. Artificial intelligence in pharmacovigilance: practical utility. Indian Journal of Pharmacology. 2019 Nov 1;51(6):373-6. [Google Scholar]
7. Choudhury A, Asan O. Role of artificial intelligence in patient safety outcomes: systematic literature review. JMIR medical informatics. 2020 Jul 24;8(7):e18599. [Google Scholar]
8. Owoyemi A, Owoyemi J, Osiyemi A, Boyd A. Artificial intelligence for healthcare in Africa. Frontiers in Digital Health. 2020 Jul 7;2:6. [Google Scholar] [Pubmed]
9. Jiang F, Jiang Y, Zhi H, Dong Y, Li H, Ma S, Wang Y, Dong Q, Shen H, Wang Y. Artificial intelligence in healthcare: past, present and future. Stroke and vascular neurology. 2017 Dec 1;2(4). [Google Scholar]
10. Çelik Ertuğrul D, Toygar Ö, Foroutan N. A rule-based decision support system for aiding iron deficiency management. Health Informatics Journal. 2021 Dec 11;27(4):14604582211066054. [Google Scholar]
11. Asiri MA, Almutairi AD, Ozam TS, Al Ahmari RY, Alhazmi SM, Almoudhi AA, Alqahtani TM, Almotheby AH, Alshehri AS, Alqahtani NM. AI-Driven Decision Support Systems: Transforming Hospital Management Strategies. Journal of International Crisis & Risk Communication Research (JICRCR). 2024 Oct 1;7(3). [Google Scholar]
12. Baştanlar Y, Özuysal M. Introduction to machine learning. miRNomics: MicroRNA biology and computational analysis. 2013 Nov 11:105-28. [Google Scholar]
13. Wang J, Elfwing S, Uchibe E. Modular deep reinforcement learning from reward and punishment for robot navigation. Neural Networks. 2021 Mar 1;135:115-26. [Google Scholar] [Pubmed]
14. Esteva A, Robicquet A, Ramsundar B, Kuleshov V, DePristo M, Chou K, Cui C, Corrado G, Thrun S, Dean J. A guide to deep learning in healthcare. Nature medicine. 2019 Jan;25(1):24-9. [Google Scholar]
15. Kleppe A, Skrede OJ, De Raedt S, Liestøl K, Kerr DJ, Danielsen HE. Designing deep learning studies in cancer diagnostics. Nature Reviews Cancer. 2021 Mar;21(3):199-211. [Google Scholar]
16. Vemulapalli V, Qu J, Garren JM, Rodrigues LO, Kiebish MA, Sarangarajan R, Narain NR, Akmaev VR. Non-obvious correlations to disease management unraveled by Bayesian artificial intelligence analyses of CMS data. Artificial intelligence in medicine. 2016 Nov 1;74:1-8. [Google Scholar] [Pubmed]
17. Farag HM, Yunusa I, Goswami H, Sultan I, Doucette JA, Eguale T. Comparison of amitriptyline and us food and drug administration–approved treatments for fibromyalgia: a systematic review and network meta-analysis. JAMA network open. 2022 May 2;5(5):e2212939-. [Google Scholar]
18. Yuvaraj N, Chang V, Gobinathan B, Pinagapani A, Kannan S, Dhiman G, Rajan AR. Automatic detection of cyberbullying using multi-feature based artificial intelligence with deep decision tree classification. Computers & Electrical Engineering. 2021 Jun 1;92:107186. [Google Scholar]
19. Luo Y, Thompson WK, Herr TM, Zeng Z, Berendsen MA, Jonnalagadda SR, Carson MB, Starren J. Natural language processing for EHR-based pharmacovigilance: a structured review. Drug safety. 2017 Nov;40:1075-89. [Google Scholar] [Pubmed]
20. Lu H, Li Y, Chen M, Kim H, Serikawa S. Brain intelligence: go beyond artificial intelligence. Mobile networks and

applications. 2018 Apr;23:368-75. [Google Scholar]
21. Ribeiro-Vaz I, Silva AM, Costa Santos C, Cruz-Correia R. How to promote adverse drug reaction reports using information systems–a systematic review and meta-analysis. BMC Medical Informatics and Decision Making. 2016 Dec;16:1-0. [Google Scholar]
22. Bae JH, Baek YH, Lee JE, Song I, Lee JH, Shin JY. Machine learning for detection of safety signals from spontaneous reporting system data: example of nivolumab and docetaxel. Frontiers in Pharmacology. 2021 Jan 14;11:602365. [Google Scholar] [Pubmed]
23. Suling M, Pigeot I. Signal detection and monitoring based on longitudinal healthcare data. Pharmaceutics. 2012 Dec 13;4(4):607-40. [Google Scholar] [Pubmed]
24. Bate A, Lindquist M, Edwards IR, Olsson S, Orre R, Lansner A, De Freitas RM. A Bayesian neural network method for adverse drug reaction signal generation. European journal of clinical pharmacology. 1998 Jul;54:315-21. [Google Scholar] [Pubmed]
25. Knisely BM, Hatim Q, Vaughn-Cooke M. Utilizing Deep Learning for Detecting Adverse Drug Events in Structured and Unstructured Regulatory Drug Data Sets. Pharmaceutical Medicine. 2022 Oct;36(5):307-17. [Google Scholar] [Pubmed]
26. Martin GL, Jouganous J, Savidan R, Bellec A, Goehrs C, Benkebil M, Miremont G, Micallef J, Salvo F, Pariente A, Létinier L. Validation of artificial intelligence to support the automatic coding of patient adverse drug reaction reports, using nationwide pharmacovigilance data. Drug Safety. 2022 May;45(5):535-48. [Google Scholar] [Pubmed]
27. Wang X, Hripcsak G, Markatou M, Friedman C. Active computerized pharmacovigilance using natural language processing, statistics, and electronic health records: a feasibility study. Journal of the American Medical Informatics Association. 2009 May 1;16(3):328-37. [Google Scholar] [Pubmed]
28. Botsis T, Nguyen MD, Woo EJ, Markatou M, Ball R. Text mining for the Vaccine Adverse Event Reporting System: medical text classification using informative feature selection. Journal of the American Medical Informatics Association. 2011 Sep 1;18(5):631-8. [Google Scholar] [Pubmed]
29. Schmider J, Kumar K, LaForest C, Swankoski B, Naim K, Caubel PM. Innovation in pharmacovigilance: use of artificial intelligence in adverse event case processing. Clinical pharmacology & therapeutics. 2019 Apr;105(4):954-61. [Google Scholar] [Pubmed]
30. Fatehifar M, Karshenas H. Drug-drug interaction extraction using a position and similarity fusion-based attention mechanism. Journal of Biomedical Informatics. 2021 Mar 1;115:103707. [Google Scholar] [Pubmed]
31. Masumshah R, Aghdam R, Eslahchi C. A neural network-based method for polypharmacy side effects prediction. BMC bioinformatics. 2021 Dec;22:1-7. [Google Scholar] [Pubmed]
32. Ward IR, Wang L, Lu J, Bennamoun M, Dwivedi G, Sanfilippo FM. Explainable artificial intelligence for pharmacovigilance: What features are important when predicting adverse outcomes?. Computer Methods and Programs in Biomedicine. 2021 Nov 1;212:106415. [Google Scholar] [Pubmed]
33. Basile AO, Yahi A, Tatonetti NP. Artificial intelligence for drug toxicity and safety. Trends in pharmacological sciences. 2019 Sep 1;40(9):624-35. [Google Scholar] [Pubmed]
34. Salas M, Petracek J, Yalamanchili P, Aimer O, Kasthuril D, Dhingra S, Junaid T, Bostic T. The use of artificial intelligence in pharmacovigilance: a systematic review of the literature. Pharmaceutical medicine. 2022 Oct;36(5):295-306. [Google Scholar] [Pubmed]
35. Chapman AB, Peterson KS, Alba PR, DuVall SL, Patterson OV. Detecting adverse drug events with rapidly trained classification models. Drug safety. 2019 Jan 21;42:147-56. [Google Scholar] [Pubmed]
36. Wunnava S, Qin X, Kakar T, Sen C, Rundensteiner EA, Kong X. Adverse drug event detection from electronic health records using hierarchical recurrent neural networks with dual-level embedding. Drug safety. 2019 Jan 21;42:113-22. [Google Scholar] [Pubmed]
37. Murali K, Kaur S, Prakash A, Medhi B. Artificial intelligence in pharmacovigilance: practical utility. Indian Journal of Pharmacology. 2019 Nov 1;51(6):373-6. [Google Scholar] [Pubmed]
38. Johnson KB, Wei WQ, Weeraratne D, Frisse ME, Misulis K, Rhee K, Zhao J, Snowdon JL. Precision medicine, AI, and the future of personalized health care. Clinical and translational science. 2021 Jan;14(1):86-93. [Google Scholar] [Pubmed]
39. Barry A, Olsson S, Minzi O, Bienvenu E, Makonnen E, Kamuhabwa A, Oluka M, Guantai A, Bergman U, van Puijenbroek E, Gurumurthy P. Comparative assessment of the national pharmacovigilance systems in East Africa: Ethiopia, Kenya, Rwanda and Tanzania. Drug safety. 2020 Apr;43(4):339-50. [Google Scholar] [Pubmed]
40. Belenguer L. AI bias: exploring discriminatory algorithmic decision-making models and the application of possible machine-centric solutions adapted from the pharmaceutical industry. AI and Ethics. 2022 Nov;2(4):771-87. [Google Scholar] [Pubmed]
41. Bates DW, Levine D, Syrowatka A, Kuznetsova M, Craig KJ, Rui A, Jackson GP, Rhee K. The potential of artificial intelligence to improve patient safety: a scoping review. NPJ digital medicine. 2021 Mar 19;4(1):54. [Google Scholar] [Pubmed]

**ISSN: 2278-2044**
**DOI: https://doi.org/10.24321/2278.2044.202527**

42. Chiruvella V, Guddati AK. Ethical issues in patient data ownership. Interactive journal of medical research. 2021 May 21;10(2):e22269. [Google Scholar] [Pubmed]
43. Khan MA, Hamid S, Babar ZU. Pharmacovigilance in high-income countries: current developments and a review of literature. Pharmacy. 2023 Jan 6;11(1):10. [Google Scholar] [Pubmed]
44. Markus AF, Kors JA, Rijnbeek PR. The role of explainability in creating trustworthy artificial intelligence for health care: a comprehensive survey of the terminology, design choices, and evaluation strategies. Journal of biomedical informatics. 2021 Jan 1;113:103655. [Google Scholar] [Pubmed]

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