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Application of artificial intelligence in adverse drug reaction detection and reporting: A comprehensive review

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Abstract
The adverse drug reaction (ADR) problem globally poses a significant threat to public health, by leading to substantial morbidity and mortality in patients as well as increased healthcare expenses. Current systems for pharmacovigilance rely primarily on spontaneous reporting methods that suffer from challenges related to the underreporting of ADRs, delays in signal detection, and a lack of capacity to adequately process the volume and complexity of expanding healthcare data. AI technologies (especially machine learning, deep learning, and natural language processing) have the potential to overcome these obstacles by providing automated means of analyzing very large and diverse datasets in the area of pharmacovigilance. This narrative review synthesizes the evidence from 20 published peer-reviewed studies from January 2015 through March 2026 that were identified by searching PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar for studies assessing the use of AI methods in common pharmacovigilance functions such as automated ADR coding, signal detection, predicting individual patient risk for experiencing ADRs, and identifying drug-drug interactions. Anticipated major pharmacovigilance systems were reviewed including VigiFlow, VigiBase, the FDA's Adverse Event Reporting System, and EudraVigilance. Overall, based on the data from the studies reviewed herein, AI models were shown to have excellent predictive ability with AUC values reported between 0.77 and 0.96. However, challenges remain — including data quality limitations, issues with model interpretability, and the need to establish guidelines for regulatory approval of so-called "AI models" — yet AI has substantial potential to enhance pharmacovigilance and improve global drug safety monitoring.

Keywords: Adverse drug reactions, Pharmacovigilance, artificial intelligence, machine learning, deep learning, natural language processing, signal detection, drug–drug interactions

Introduction

Adverse drug reactions (ADRs) remain a profound challenge in modern healthcare systems due to their contribution to patient morbidity, mortality, and the high financial burden imposed on global healthcare. Although rigorous drug development processes exist and thousands of volunteers participate in clinical trials before regulatory approval, many adverse effects associated with approved drugs are not identified until after they have been prescribed to patients for extended periods under real-world conditions. Drug development requires an average of 10–15 years and costs in excess of $1 billion to complete. Following market release, new or worsening side effects and drug-induced injuries continue to be documented, underscoring the need for continuous post-marketing safety monitoring and timely recognition of adverse events [1].

Throughout this review, the term Adverse Drug Reaction (ADR) refers specifically to harmful, unintended effects occurring at normal therapeutic doses, while Adverse Drug Event (ADE) encompasses any drug-related harm including medication errors and overdose.

Pharmacovigilance (PV) plays a central role in the evaluation and management of drug safety through the identification, assessment, understanding and prevention of adverse drug reactions (ADRs) and other drug-related problems. Historically pharmacovigilance has relied on spontaneous reporting systems (SRS), clinical case report forms, post-marketing surveillance data from various sources to identify potential safety issues with drugs. Although there are many successes of these methods in identifying drug safety issues, they are often hampered by numerous weaknesses (i.e., under-reporting, delayed signal detection, incomplete data) and cannot adequately respond to the vast amount of data being generated in today's modern healthcare system. As a result, traditional pharmacovigilance systems tend to be reactive rather than proactive because they identify safety issues once a large number of patients have already experienced an impact [2, 3].

Due to an abrupt growth in the digital health realm; including the use of electronic health records (EHRs), the advancement of biomedical literature databases, and the collection of patient-generated data, there is now a significantly higher volume of complex data on drug safety than ever before. As access to large amounts of diverse data becomes available to us, these large and diverse datasets will allow us to apply advanced computational techniques to advance the field of pharmacovigilance. The use of artificial intelligence (AI) technologies, including machine learning (ML), deep learning, and natural language processing (NLP), will provide pharmacovigilance experts with powerful tools to analyse both structured and unstructured data, thus making it possible to identify patterns in adverse drug reaction (ADR) reports, rather than being confined to structured or restricted datasets. Moreover, these technologies will enable pharmacovigilant experts to fast-track their ability to detect potential drug safety signals by processing large volumes of data from a variety of sources, including electronic (EMRs); spontaneous reporting systems (SRSs); social media; and clinical trials [2, 4].

AI Technologies are showing great possibilities in revolutionizing and changing pharmacovigilance processes by providing automated solutions for many key activities,

including signal detection, case management, adverse event coding, and literature review. Machine Learning can discover hidden patterns and connections in large amounts of data, predict likely ADR risks and assist with decision-making for various regulatory agencies and healthcare professionals. Natural Language Processing can also provide ways to extract clinically relevant information from unstructured text (for example, physician notes, study articles, and patient forums) that are typically difficult to analyze with traditional methods. Because of these capabilities, AI has the ability to identify rare and/or previously unrecognized adverse drug reactions more quickly than with traditional pharmacovigilance methods [2].

In addition, pharmacovigilance systems can benefit from using AI and the associated technologies for monitoring drug safety in advanced ways. AI enables pharmacovigilance through a real-time assessment of actual data collected from users of drugs and through the ability to predict models based on the actual data collected. For instance, through longitudinal health history, AI models will be able to identify any delayed adverse effects from medications, assess the potential of interaction between medications, and determine stratification of differing levels of risk in different populations of patients. Thus, using these technologies to automate the monitoring of drug safety will improve the overall functioning, effectiveness, and timeliness of pharmacovigilance, while simultaneously decreasing the manual efforts compared to current manual safety monitoring methods [2].

As AI becomes increasingly integral to drug safety monitoring, a comprehensive understanding of its current applications and future potential is essential. This review systematically examines how AI is being applied in pharmacovigilance through machine learning, natural language processing, and advanced computational methods. It further addresses key pharmacovigilance databases, digital tools, real-world data sources, existing challenges, and emerging directions in AI-driven drug safety monitoring.

Methods

1. Study Design

This study was designed as a narrative review of the published literature pertaining to artificial intelligence (AI), machine learning (ML), deep learning (DL), and natural language processing (NLP) applied to the detection and reporting of adverse drug reactions (ADRs). A narrative review was selected as the most appropriate study design because AI-driven pharmacovigilance spans multiple disciplines, including clinical pharmacology, data science, and regulatory science, necessitating a broad synthesis approach rather than a quantitative meta-analysis. This review focuses on: methods of applying AI in pharmacovigilance; real-world examples of AI applications; digital pharmacovigilance platforms; and barriers to the implementation of AI-based tools in drug safety monitoring [5].

2. Literature Search Strategy

A literature search was conducted across four electronic databases — PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar. The search was restricted to articles published between January 2015 and March 2026 to focus on recent innovations in artificial intelligence in pharmacovigilance and drug safety monitoring.

The following key search terms were used in various combinations: "Artificial intelligence," "machine learning," "deep learning," "natural language processing," "adverse drug reaction," "pharmacovigilance," "drug safety monitoring," "signal detection," "VigiBase," "FAERS," and "electronic health records."

Reference lists of all included articles were also manually reviewed to identify any additional relevant studies not captured during the primary database search.

3. Inclusion Criteria

Articles were included in this review if they satisfied all of the following criteria:

- A professional editorial or peer-reviewed publication;
- In an English language publication;
- Published from January 2015 through March 2026;
- AI, ML, DL or NLP must be applied to detect adverse drug reactions (ADR's), pharmacovigilant, or drug safety monitoring;
- Utilization of accepted pharmacovigilance information sources such as electronic health records (EHR), spontaneous reporting system (SRS), FAERS, VigiBase, EudraVigilance, or clinical trial databases;
- The original research article will consist of a systematic review, or a narrative review or a technical development related to AI-driven ADR detection and reporting.

4. Exclusion Criteria

Articles were excluded from this review if they met any one of the following criteria:

- Conference abstracts, editorial commentary, letter/email correspondence, or opinion documents that provide no substantial data or review contribution
- Non-English language published articles
- Studies solely related to drug efficacy, pharmacokinetics, or pharmaceutical chemistry with no association to ADR detection
- Animal studies/*in vitro* research that do not examine clinical ADR monitoring
- Studies applying artificial intelligence (AI) for reasons other than pharmacovigilance such as drug discovery or imaging diagnosis
- Duplicate publication or secondary report of a previously published dataset
- Articles where there was no ability to obtain sufficient information from the entire text available for review.

5. Study Selection

Following a systematic search of the relevant literature and the application of inclusion and exclusion criteria, A total of 21 peer-reviewed articles was selected for inclusion in this narrative review. These peer-reviewed articles were grouped into three themes: Types of Artificial Intelligence Techniques for Pharmacovigilance; Use of AI Techniques in the Detection and Reporting of Adverse Drug Reactions; Digital Tools and Databases to Support Pharmacovigilance; and Issues and Future Directions.

Artificial Intelligence Techniques Used in Pharmacovigilance

Pharmacovigilance is utilizing more and more AI techniques to process large and complex healthcare data sources for the purpose of improving the identification of adverse drug reactions (ADR). These processes allow researchers to identify new patterns, provide predictors for potential safety signals, and enhance overall drug safety monitoring. Among the most popular AI techniques currently being used are machine learning, deep learning, and natural language processing (NLP) [2].

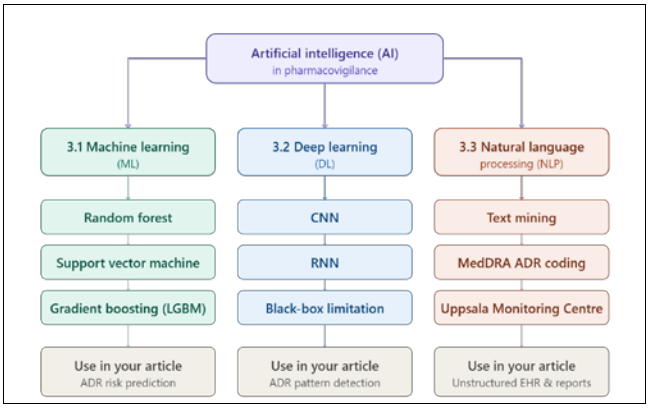

Fig 1: Artificial intelligence techniques used in pharmacovigilance for adverse drug reaction detection and reporting, as reviewed in Sections 3.1–3.3.

CNN = convolutional neural network; RNN = recurrent neural network; LGBM = light gradient boosting machine; MedDRA = medical dictionary for regulatory activities.

1. Machine learning

Machine Learning (ML) is a key element of Artificial Intelligence (AI) and is used extensively for the review of large data sets from healthcare in order to find patterns that can predict Adverse Drug Events (ADEs) and Adverse Drug Reactions (ADRs). ML is utilized to analyze data from clinical trials, historic patient data, and Electronic Health Record (EHR) data; to find associations between medications and their potential adverse effects; this information is then used to create predictive models for Pharmacovigilance.

The predictive algorithms most commonly used for ADR prediction are Random Forests, Gradient Boosting Machines, Support Vector Machines (SVMs). These models can use both structured data (e.g., lab results, medication history, patient demographics) and unstructured data (e.g., clinical notes or medical reports) in order for the ML system to extract meaningful information and improve prediction accuracy.

Gradient Boosting algorithms have performed particularly well in evaluating complex healthcare datasets and identifying potential ADR signals. Utilizing multiple patient-specific factors (e.g., age, medication type and dosage, co-morbidities, and genetics) within an ML model ultimately improves the likelihood that the model will accurately predict ADRs [6].

As a whole, ML is having a very positive impact on improving Pharmacovigilance by providing earlier detection of drug safety signals, better drug safety surveillance, and better assessments of patient risk [7].

2. Deep learning (DL)

Pharmacovigilance (PV) is the process of monitoring the safety and effectiveness of medicines. Adverse drug reaction (ADR) or adverse drug event (ADE) refers to any unintended harm resulting from the use of medicine, including death, hospitalization, or injury. One way PV can be enhanced is by using deep learning (DL) to rapidly identify patterns in large volumes of healthcare data. DL algorithms can also learn from clinical history and other sources of data to develop predictive models that can assist PV relating to the potential of a medicine to cause ADRs [8, 9].

Some examples of DL algorithms in pharmacovigilance include CNNs, which can perform both text and clinical analyses, and RNNs, which can track time series data to detect ADRs faster by analysing drug use over time. Collectively, these approaches allow the PV community to leverage a wealth of data sources for ADR detection and can improve their ability to do so by automatically processing large amounts of data and adaptively improving their predictive accuracy as additional information becomes available. Although models based on DL algorithms can be very accurate and efficient in identifying ADRs and predicting their occurrence, the challenge has been their relative lack of transparency (i.e., the so-called “black-box” effect). Addressing this will require developers to create means of providing explanations that support reliable pharmacovigilance and regulatory decision-making regarding the merits and reliability of medicines [10].

3. Natural Language Processing (NLP)

Natural Language Processing (NLP) utilizes large amounts of unstructured data to identify adverse effects from medications in pharmacovigilance. This free-text data is in various formats, such as ADR reports, EHRs (Electronic Health Records), clinical notes, and social media. By utilizing pattern recognition and linguistic cues, NLP techniques have the potential to identify drug safety issues missed through traditional means when assessing unstructured data sources. For example, the Uppsala Monitoring Centre has used NLP to identify duplicate ADR reports and improve data quality to facilitate faster signal detection and greater efficiency in pharmacovigilance surveillance [11, 12].

AI-powered NLP systems can effectively process patient-reported ADR narratives (see Létinier et al). Combining drug knowledge sources with ML models (e.g., gradient boosting) and using MedDRA terminology allows these systems to automatically extract and code ADR reports. This results in improved accuracy of ADR reporting, reduced manual workload for coders, and the potential for earlier detection of drug safety signals [13].

Applications of Artificial Intelligence in Pharmacovigilance

1. Automated case intake and coding of ADR reports

The use of AI technology allows the identification and coding of adverse drug reaction (ADR) reports through the automation of the intake and coding of adverse reactions from unstructured narratives written by patients. An artificial intelligence pipeline was developed by Pierre Létinier and coworkers utilizing a drug knowledge database coupled with machine learning to identify and code adverse drug reactions (ADRs) using the MedDRA terminology. Utilizing a training set of 2058 patient reports, the authors achieved excellent accuracy (AUC=0.93) by creating a Light Gradient Boosting Machine (LGBM) model. Ultimately, this system has created a reduction in the manual workload on humans, produced an improvement in the consistency of coding for ADR, and improved the efficiency of pharmacovigilance processes [11, 14].

2. Signal detection in large pharmacovigilance databases

AI has made significant improvements to signal detection within large pharmacovigilance databases by utilizing various data mining methodologies (e.g., neural networks, decision trees, and clustering algorithms) to help identify the relationship between drugs and adverse drug reactions (ADRs). Automated signal detection systems have been developed that continuously monitor data from electronic

health records, spontaneous reports, and social media in real time has proven faster and more thorough than manual methods. The creation of "hybrid" models that combine standard disproportionality methods with machine learning methods increases both sensitivity and specificity, therefore providing the opportunity to shift from reactive to anticipatory drug safety surveillance [13].

3. Prediction of individual ADR risk and drug–drug interactions

Artificial intelligence helps improve the detection and prevention of adverse drug reactions (ADRs) by analyzing patient-specific data such as genetics, medical history, and medication profiles. Machine learning models can predict individual ADR risk before drug administration and identify potential drug–drug interactions by analyzing chemical and biological drug properties. These predictive approaches support safer prescribing decisions and enhance personalized pharmacotherapy [1, 15].

Numerous investigations of machine learning models aimed at predicting individual risks of adverse drug reactions (ADR) using data from electronic health records (EHR) have been carried out. For example, a systematic review and meta-analysis carried out by Hu et al. (2024), which included 59 studies, concluded that gradient boosting machines, (XGBoost) and artificial neural networks all had a mean AUC >= 0.80, with a total pooled AUC of 0.77 (with a confidence interval of 0.76–0.78). Random Forest was the most frequently employed algorithm and yielded an AUC of 0.94 when combined with resampling techniques; other common predictor variables were identified as being the investigator's age, duration of hospital stay, the number of medications prescribed, and discharge disposition. In addition, Pramanik et al. (2024) reported an AUC for gradient boosting of 0.89 and an accuracy of 0.85 for CNN-BERT model using clinical text [7, 16].

The ability of deep learning methods to correctly identify DDI predictions is impressive. The study conducted by VO Et Al (2023) was able to successfully construct an ensemble of deep neural networks that predicted 86 different DDI types using the Drug Bank Dataset, while showing an average accuracy rate of 93.8%, exceeding that of any previous single-model techniques. The Predictive power of models built on graph neural networks has also increased. For example, the SSI-DDI framework, which predicts substructure level interactions between drugs, achieved an AUC of 0.9614 on the Drug Bank Benchmark. Similarly, knowledge graph integrated neural networks such as KG2ECapsule have shown great potential, with an increase in PR-AUC of 2.71% over any previous baseline measure for clinically relevant DDI predictions [17, 18].

Digital Tools and Databases for ADR Detection and Reporting

With the growing volume of adverse drug reaction (ADR) reports worldwide, manual processing of pharmacovigilance data has become increasingly challenging. Artificial intelligence and automated systems are now being integrated into pharmacovigilance platforms to improve signal detection, data management, and regulatory reporting. Several digital tools and databases support ADR detection and reporting by facilitating the collection, processing, and analysis of individual case safety reports (ICSRs). Among these systems, platforms such as VigiFlow play a significant role in supporting global pharmacovigilance activities.

1. VigiFlow: Electronic ADR Reporting System

VigiFlow is a web-based data management system for pharmacovigilance developed by the Uppsala Monitoring Centre in cooperation with the World Health Organization. This solution enables national pharmacovigilance centres to efficiently collect, process and analyse reports about adverse drug reactions (ADRs).

VigiFlow supports standardised electronic reporting formats, such as ICH E2B (R3), and has adopted the use of the Medical Dictionary for Regulatory Activities (MedDRA) to code ADRs. ADRs can be reported electronically via integrated reporting tools by healthcare professionals, pharmaceutical organisations and patients. Individuals case safety reports (ICSRs) include all of the same elements found in reports of individual cases with a comprehensive description of the patient, drug exposure, ADR and clinical outcomes.

VigiFlow provides enhanced communication channels for national pharmacovigilance centres to retrofit with international databases; thus, improving global monitoring of drug safety. By allowing pharmacovigilance centres to handle high volumes of data on ADRs and perform preliminary signal detection activities [19].

2. Integration with Global Pharmacovigilance Databases

Researchers are able to use the information on adverse drug reactions collected in VigiFlow to make reports that can be sent to the VigiBase database, which is the largest collection of suspected adverse drug reactions in the world, containing millions of reports from thousands of different countries through pharmacovigilance centres.

Using these reports, researchers and regulatory agencies can examine all available reports on adverse events to determine whether there may be any signals for drug safety by looking for evidence of a correlation between drugs involved in these events and the number of reports filed. Tools such as VigiLyze allow for exploration and analysis of the contents of VigiBase using the statistical method of signal detection so as to facilitate drug safety monitoring [20].

Table 1: Comparison of Major Pharmacovigilance Systems Used for ADR Detection

System	Organization	Main Function	Role in Pharmacovigilance
VigiFlow	Uppsala Monitoring Centre	ADR reporting system	Collection and management of ICSR data
VigiBase	WHO Programme for International Drug Monitoring	Global ADR database	Large-scale signal detection
VigiLyze	Uppsala Monitoring Centre	Data analysis platform	Advanced signal detection and pattern analysis
FAERS	U.S. Food and Drug Administration	ADR reporting database	Post-marketing safety monitoring
EudraVigilance	European Medicines Agency	ADR reporting database	Drug safety monitoring in Europe

Table 1 summarises the primary pharmacovigilance platforms used for ADR detection, their organisational affiliations, and their respective roles in drug safety monitoring

Challenges and Future Directions in AI-Based ADR Detection

The integration of AI and machine learning (ML) into pharmacovigilance and ADR detection — as described in the preceding sections through NLP, deep learning, and signal detection platforms such as VigiFlow and FAERS — holds transformative potential. However, this promise is tempered by a series of persistent challenges that must be addressed before AI-driven tools can be fully adopted in regulatory and clinical pharmacovigilance workflows. At the same time, several compelling future directions are emerging from the convergence of AI, genomics, and real-world evidence generation.

1. Current Challenges

Table 2: Summary of Key Challenges in AI-Based Pharmacovigilance

Challenge	Description	Impact
Data quality & bias	Underreporting in SRS, privacy silos	Misleading ADR signals
Black-box problem	DL models lack interpretability	Regulatory rejection
Generalisability	Models fail on unseen populations	Poor real-world performance
ADR mechanism complexity	Multi-pathway biological reactions	Statistical ≠ causal
Regulatory gaps	No clear AI evidence standards yet	Adoption barriers

1.1 Data Quality, Bias, and Availability

A foundational challenge shared across all AI applications in ADR detection is the quality and representativeness of training data. As discussed in Section 2, ML models for pharmacovigilance rely on large datasets drawn from EHRs, spontaneous reporting systems, and clinical trials. However, these sources are inherently limited by underreporting — a well-documented weakness of spontaneous reporting systems such as FAERS and VigiBase. Biases embedded in training data propagate directly into model predictions, potentially generating misleading ADR signals or missing genuine safety concerns. Data privacy regulations and institutional silos further restrict the availability of patient-level data for model training, making it difficult to develop generalizable AI tools across diverse populations and healthcare settings [1].

1.2 Model Interpretability — The "Black Box" Problem

As highlighted in Section 3.2, deep learning models — while achieving high predictive accuracy — often operate as "black boxes," making their internal decision-making opaque. This lack of transparency is particularly problematic in pharmacovigilance, where regulatory bodies require traceable and auditable reasoning for signal detection and drug safety decisions. Healthcare professionals are frequently reluctant to act on predictions they cannot interpret or validate clinically. Convolutional Neural Networks (CNNs) and Recurrent Neural Networks (RNNs), although powerful in processing clinical text and time-series drug-use data, share this interpretability limitation. Addressing the black-box problem through explainable AI (XAI) frameworks is therefore critical for the adoption of deep learning in regulatory pharmacovigilance [1].

1.3 Generalizability and Model Validation

AI models developed for ADR detection often perform well on benchmark datasets but may fail to generalize to novel drug classes, rare ADRs, or patient populations not adequately represented in training data. The LGBM model developed by Létinier et al. (Section 4.1), while achieving an AUC of 0.93 on its training set, exemplifies this challenge — performance on diverse, real-world patient populations remains to be systematically validated. Building robust, externally validated models requires large, high-quality datasets and adherence to rigorous validation frameworks such as OECD guidelines for QSAR models, which also apply to ML-based pharmacovigilance tools [1].

1.4 Complexity of ADR Mechanisms

Drug-induced adverse reactions arise through multiple overlapping biological mechanisms — including direct cellular damage, immune-mediated hypersensitivity reactions, metabolite-induced toxicity, and off-target pharmacological effects. Accurately capturing this multi-mechanistic complexity within a single computational model remains a significant challenge. AI systems trained predominantly on clinical and spontaneous reporting data (as used in VigiFlow and FAERS) may detect statistical associations but lack the mechanistic depth needed to distinguish causal ADR pathways from confounding clinical factors [1].

1.5 Regulatory and Ethical Considerations

The deployment of AI systems in pharmacovigilance must align with existing regulatory frameworks governing drug safety. Regulatory agencies such as the FDA and EMA require transparency, reproducibility, and accountability in safety monitoring systems. AI tools that generate ADR signals must be validated to a standard acceptable for regulatory submission, yet current guidance on AI-generated evidence in pharmacovigilance remains nascent. Ethical concerns around automated decision-making in patient safety contexts — including algorithmic accountability and the potential for automation bias in clinical settings — also require careful governance frameworks [21].

2. Future Directions

2.1 Real-Time Pharmacovigilance and Continuous Monitoring

One of the most important near-term opportunities is the development of real-time AI-powered pharmacovigilance systems. As remote patient monitoring technologies become increasingly widespread, AI and ML algorithms could be embedded within clinical workflows to enable continuous, prospective ADR surveillance — a significant departure from the reactive, retrospective model that characterizes current spontaneous reporting systems such as FAERS and VigiBase. Building on the signal detection capabilities described in Section 4.2, next-generation platforms could integrate streaming EHR data, wearable device outputs, and patient-reported outcomes to generate near-instantaneous ADR alerts, enabling earlier clinical intervention and reducing patient harm.

2.2 Explainable AI (XAI) for Regulatory Acceptance

Overcoming the "black box" limitation identified in Section 6.1.2 will require a concerted shift toward Explainable AI (XAI) frameworks in pharmacovigilance. XAI techniques — such as SHAP (Shapley Additive explanations), LIME (Local Interpretable Model-agnostic Explanations), and attention-based neural network architectures — allow clinicians and regulators to understand which features (e.g., specific drug-drug combinations, patient comorbidities, genetic markers) drove a model's ADR prediction. This transparency will be essential for building regulatory trust, supporting clinical decision-making, and satisfying the accountability requirements of agencies such as the FDA and EMA. The NLP pipeline described in Section 3.3, for example, would benefit significantly from explainability layers that reveal which textual features triggered an ADR classification.

2.3 Deeper Integration with Electronic Health Records

EHRs represent perhaps the richest untapped resource for AI-driven ADR detection. As noted in Section 1, EHRs contain longitudinal, multi-modal patient data including diagnoses, medications, laboratory results, and treatment histories. Future AI systems should exploit this depth more fully — moving beyond structured data analysis toward comprehensive mining of unstructured clinical notes (as begun with NLP in Section 3.3) to capture the full clinical phenotype of ADR presentations. Seamless, standardized integration between AI platforms and EHR infrastructure will require advances in data interoperability standards (e.g., HL7 FHIR) and federated learning approaches that allow models to be trained across distributed hospital datasets without centralizing sensitive patient information.

2.4 Personalized ADR Prediction through Genomic Integration

The predictive capabilities discussed in Section 4.3 — including AI's ability to model individual ADR risk based on patient-specific genetic and clinical profiles — point toward a future of personalized pharmacovigilance. Integrating genomic data (including pharmacogenomic markers, SNP profiles, and HLA typing) into ML models will allow individualized ADR predictions that account for genetic predispositions to drug hypersensitivity, metabolic variation, and organ-specific toxicity. This approach represents a critical bridge between population-level signal detection and patient-level safety — ultimately enabling prescribers to make genomically informed drug and dosing decisions before ADRs occur.

2.5 Advanced Deep Learning Architectures for Toxicity and ADR Modelling

Emerging deep learning architectures — including graph neural networks, topology-based multitask neural networks, and transformer-based models — are advancing the frontier of molecular-level ADR and toxicity prediction. These models can process complex chemical structures, biological interaction networks, and multi-omics data simultaneously, offering a more mechanistically grounded approach to ADR prediction than conventional statistical signal detection. Coupling these architectures with the large-scale pharmacovigilance databases reviewed in Section 4 (VigiBase, FAERS, Eudra Vigilance) would create powerful end-to-end pipelines capable of predicting both known and novel ADRs from molecular, clinical, and population-level data.

In summary, while the AI methods, tools, and databases reviewed in this article demonstrate substantial progress in ADR detection and reporting, the path to full clinical and regulatory deployment requires resolving key challenges around data quality, model transparency, and ethical governance. The most promising future lies in the convergence of explainable AI, real-time monitoring, EHR integration, and personalized genomic pharmacovigilance — a multi-dimensional approach that could genuinely transform drug safety surveillance and reduce preventable patient harm worldwide.[1]

Conclusion

Artificial intelligence represents a transformative paradigm shift in pharmacovigilance. The studies reviewed herein collectively demonstrate that AI-based approaches — using machine learning, deep learning, and natural language processing — have consistently outperformed traditional manual and statistical methods when analysing large volumes of heterogeneous pharmacovigilance data. when analysing large amounts of heterogeneous pharmacovigilance data.

Machine learning methods such as Gradient Boosting and Random Forest classifiers have also demonstrated substantial predictive capability for assessing the risk of an individual experiencing an ADR, achieving pooled AUC of 0.77 with optimised AUC of > 0.94 for both algorithms. Moreover, deep learning strategies including convolutional neural networks, recurrent neural networks, and graph neural networks achieved > 93% accuracy on predicting drug-drug interactions while natural language processing (NLP) pipelines provided high-throughput automated coding of patient-reported ADRs thus reducing human overhead significantly.

The incorporation of artificial intelligence into established pharmacovigilance databases (VigiFlow, VigiBase, FAERS and EudraVigilance) represents an important infrastructure development that enables real time signal detection and global harmonisation of adverse drug reaction (ADR) data on an unprecedented scale. Hybrid approaches to signals detection by combining classical disproportionality analysis with machine learning methods are enhancing the sensitivity and specificity of safety surveillance, thus facilitating the transition from reactive to proactive pharmacovigilance.

Although there has been significant technical advancement in pharmacovigilance using these technologies, there remain substantial barriers to full clinical and regulatory acceptance. The quality of the data used for training AI uses from spontaneous report systems have poor quality due to under-reporting, are subject to data silos in institutions, and are restricted by patient privacy concerns limit the generalisability and representativeness of AI training dataset. The lack of interpretability in deep-learning methodologies (the "black box" problem) is also a major barrier for regulatory authorities such as the FDA and EMA seeking traceable and auditable evidence used in making decisions about safety. In addition, the complexity of biologic mechanisms associated with ADRs will continue to pose a challenge for any AI system that aims to go beyond statistical association and achieve causal inference.

In order to successfully proceed with this goal, we will need to see the merging of four different, complementary paradigms: (i) Explainable AI (XAI) frameworks that meet regulatory transparency requirements; (ii) Continuous, real-time monitoring systems that are integrated into clinical workflows;(iii) Federated learning approaches that allow for the training of models across institutions without jeopardizing patient confidentiality; and (iv) Pharmacogenomic integration that enables individualised and pre-emptive predictions of ADRs. In addition, advanced deep learning architectures including transformer-based and graph neural networks have a lot of promise in terms of modelling mechanistic toxicity at the molecular level. Achieving this potential will require ongoing collaboration among pharmacologists, data scientists, healthcare providers, and regulatory agencies, as well as establishing standardized global frameworks for validating and accepting pharmacovigilance evidence generated by machine learning. Once these systems are in place, AI-supported pharmacovigilance should allow for a rapid reduction in the world's burden of preventable ADRs and promote a more proactive, precise and patient-centered approach to drug safety monitoring on a global scale.

Conflict of Interest

The authors declare no conflict of interest.

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Ethics Statement

This review did not involve human subjects or animal studies and therefore did not require ethical approval.

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