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ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE: APPLICATIONS, CHALLENGES, REGULATORY PERSPECTIVES AND FUTURE DIRECTION

Sakshi Somnath Zalte [1], Amol U. Gayke[2] , Vikas S. Shinde[3] , Mrunal P. Ghuge .[4]

Department of Pharmacy, JES's S.N.D. College of Pharmacy Babhulgoan (Yeola), India
Corresponding author – sakshi somnath zalte
Email-zaltesakshi15@gmail.com

ABSTRACT-

Pharmacovigilance plays a vital role in protecting public health by detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) and other medicine-related problems. The conventional pharmacovigilance methods often rely on manual processing, spontaneous reporting systems and expert evaluation, which may be limited by underreporting, increasing data volumes, inconsistent data quality and delays in identifying safety signals. Artificial intelligence (AI) has emerged as a promising approach to strengthen drug safety monitoring through automated data processing and advanced analytical techniques. This review explores the applications of AI in pharmacovigilance, focusing on machine learning, deep learning, natural language processing, generative AI, large language models and knowledge graphs. These technologies can support individual case safety report processing, adverse event extraction, duplicate detection, automated medical coding, literature surveillance, predictive risk assessment and early safety-signal detection. The integration of electronic health records, spontaneous reports, scientific literature and other real-world data sources may improve the speed and scope of drug safety evaluation. AI-based tools also offer opportunities to reduce repetitive workloads, improve data consistency and support timely regulatory decision-making. Despite these benefits, important challenges remain, including data privacy, algorithmic bias, limited model interpretability, inadequate training datasets, implementation costs and regulatory acceptance. Addressing these issues requires robust validation, transparent algorithms, harmonized regulatory approaches and appropriate human oversight. Overall AI has considerable potential to transform pharmacovigilance into a more proactive, efficient and data-driven discipline. Responsible integration of AI alongside pharmacovigilance professionals is essential to improve medication safety and support better patient outcomes.

Keywords: Artificial intelligence; Pharmacovigilance; Adverse drug reactions; Machine learning; Natural language processing; Signal detection; Drug safety.

Introduction –

Pharmacovigilance encompasses the scientific discipline and associated activities involved in detecting, evaluating, understanding, and preventing adverse effects or other problems related to medicines. It plays a crucial role in ensuring drug safety.[1] In recent years, artificial intelligence (AI) technologies have become increasingly prominent in healthcare offering considerable advantages for pharmacovigilance. The growing availability of real-world data (RWD) together with progress in computational techniques has enabled automated analyses at a scale previously unattainable. As regulatory authorities and industry stakeholders implement digital transformation strategies, AI is emerging as an indispensable component of contemporary pharmacovigilance systems.[2,3] Recent developments between 2023 and 2025 suggest that both the World Health Organization (WHO) and the International Council for Harmonisation (ICH) recognize the need to advance pharmacovigilance beyond traditional reporting approaches. This includes incorporating artificial intelligence for proactive signal detection leveraging real-world evidence (RWE) derived from electronic health records and patient-reported information, and monitoring complex therapeutic products such as biologics and advanced therapies. Taken together these perspectives position pharmacovigilance as a continuously evolving discipline that responds to the growing complexity of modern treatments and global healthcare systems.[4] Pharmacovigilance activities related to COVID-19 vaccines have played a critical role in addressing public health concerns during the pandemic. Considerable attention has been directed toward pharmacovigilance preparedness to support herd immunity through large-scale vaccination efforts.[5]A large post-implementation pharmacovigilance study used the World Health Organization's global database to examine adverse event reports submitted from more than 130 countries allowing for a thorough evaluation of vaccine safety.[6] Artificial intelligence (AI) and machine learning (ML) are transforming the pharmaceutical industry across the entire drug lifecycle from drug development and design to marketing and post-marketing surveillance. This has brought about a major shift in the pharmaceutical and biotechnology sectors.One of the key advantages of AI and ML in these industries is their ability to process very large datasets quickly far beyond what humans can achieve. Drug design a crucial stage in drug development, has traditionally depended on a trial-and-error approach. AI and ML technologies can help reduce both the time and cost involved by accurately predicting molecular behavior and compound toxicity.Pharmacovigilance has also traditionally relied on conventional data collection and lengthy manual analysis

which can introduce various potential errors. AI and ML have emerged as powerful tools in this area capable of evaluating large volumes of adverse event data and identifying drug–drug interactions in patients. These technologies can also predict possible adverse events based on a patient's medical history, comorbidities, drug interactions, and current medications.

Overall AI and ML have the potential to significantly improve drug delivery and pharmacovigilance by making these processes more accurate, faster, and better tailored to individual patients. However realizing this potential will require further development of these technologiesbgreater attention to ethical concerns and close collaboration among regulators , healthcare providers, and technology experts.[7]

- **Objectives in pharmacovigilance -**

1.Monitor adverse drug reactions and medication-related harm to help safeguard patients and minimize injuries associated with medicines.[8]

2.Support public health by identifying and reducing the risks linked to the use of medicines.[8]

3.Evaluate the benefit–risk profile of medicines to optimise their use and inform sound clinical and regulatory decisions.[8]

4.Improve therapeutic outcomes and minimise risks by promoting the rational and cost-effective use of pharmaceuticals.[8]

5.Facilitate timely and accurate communication of medication safety information to patients, clinicians, and the public to enable informed decisions and risk management.[8]

6.Enhance medication safety monitoring by expanding education and training in pharmacovigilance methods for healthcare professionals and the public.[9]

7.Address the impact of free trade and globalization on the availability and distribution of medicines by coordinating pharmacovigilance efforts across different countries.[9]

8.Adopt a proactive, adaptive approach to pharmacovigilance focused on continual improvement of systems and processes to better detect and manage medication safety issues.[9]

- **Types of AI in pharmacovigilance –**

Table 1

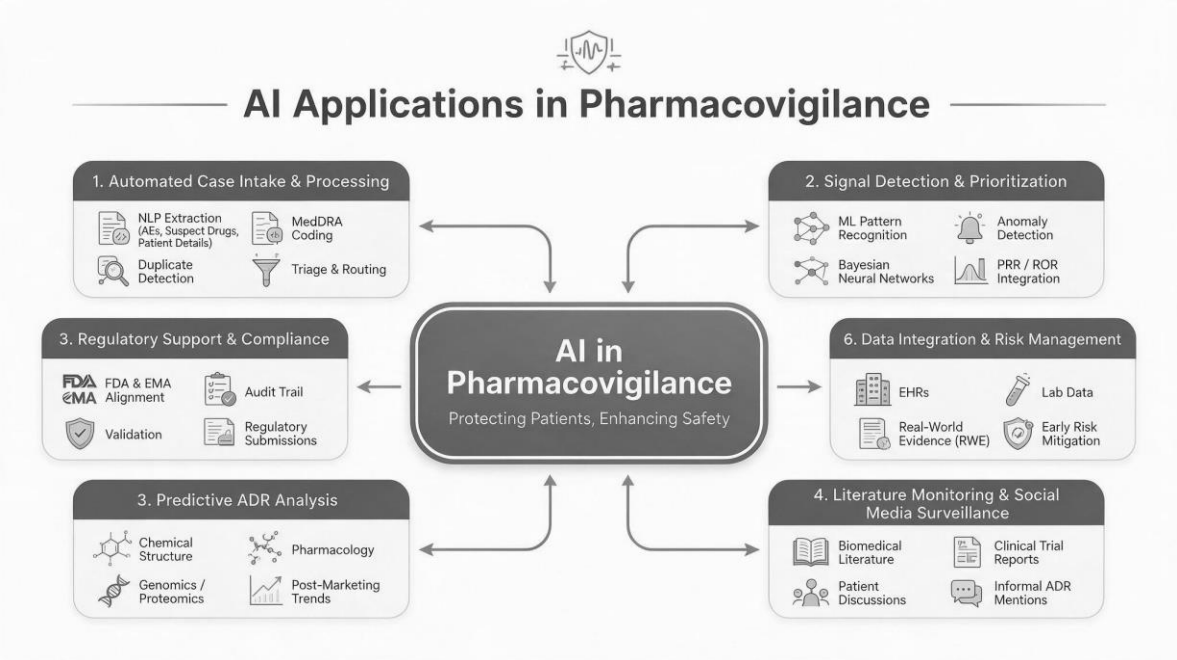
AI category	Main function in pharmacovigilance	Typical application	Reference
Machine learning (ML)	ML techniques learn patterns from existing data and use them to make predictions or classify information.	Used for safety-signal detection, triaging adverse event reports, identifying duplicate cases, and predicting potential medication-related risks	10
Deep learning (DL)	Deep learning can analyze large and complex datasets, including high-dimensional clinical and healthcare information.	Applied to detect adverse drug reactions, identify potential safety signals, predict risks, and recognize complex patterns within pharmacovigilance data.	11
Natural language processing(NLP)	NLP helps computers extract and interpret useful information from unstructured or free-text data.	Used for screening scientific literature, analyzing electronic health records and social media, identifying ADR information, and supporting automated MedDRA coding.	12
Generative AI and Large language model (LLMs)	These models can generate, summarize, and interpret text, making them useful for handling large volumes of pharmacovigilance information	Potential applications include drafting case narratives, summarizing scientific publications, assisting with regulatory	13

		documentation, and responding to medical information queries.	
Knowledge graph and graph AI	These approaches represent and analyze relationships among drugs, diseases, genes, and adverse events.	Useful for improving safety-signal detection, supporting causality assessment, evaluating drug–drug interactions, and integrating information from different data sources.	14

❖ **Application of AI in pharmacovigilance –**

- AI-powered automated case intake and processing uses natural language processing (NLP) models to identify and extract key information from individual case safety reports (ICSRs) then automatically assigns the appropriate MedDRA codes. This significantly shortens processing time while minimizing the likelihood of manual errors.[15]
- Key features include the automatic detection of adverse events, suspect medications, and patient-related information the identification of duplicate cases through similarity-based algorithms and the triage and prioritization of cases according to their severity. Companies such as Pfizer and Roche have implemented AI-enabled safety systems to optimize and streamline their case management processes.[3,16]
- Signal detection has traditionally relied on statistical disproportionality methods such as PRR or ROR. With AI , this process becomes more advanced through machine learning models that can uncover complex patterns anomaly detection algorithms that flag unusual trends and Bayesian neural networks that help estimate the likelihood of adverse drug reactions. By bringing together multiple data sources including electronic health records, laboratory results, and social media AI driven signal detection improves sensitivity while lowering the number of false positives.[17]
- Machine learning models can help anticipate potential adverse drug reactions (ADRs) before they happen in real-world settings. These models draw on information such as a drugs chemical structure, pharmacological properties, genomic and proteomic data, and trends observed through post-marketing surveillance. This predictive capability enables earlier risk management and can guide better informed decisions during drug development.[18]
- Regulatory authorities such as the FDA and EMA are increasingly showing support for the use of AI in pharmacovigilance.[19]

figure1. Application of AI in pharmacovigilance



❖ **Advantages of Ai in pharmacovigilance –**

- By improving operational efficiency AI can help reduce the costs associated with case processing and thereby strengthen pharmacovigilance operations.
- In artificial intelligence (AI) a computer is trained to perform tasks that normally require human intelligence.
- AI is designed differently and possesses an inherent capacity for problem-solving.
- AI offers substantial value and benefits in medical information, pharmacovigilance, and life sciences.[16]

- AI is also used in search engines and in healthcare for medical diagnosis, guiding treatment in clinical settings, detecting conditions, and predicting patient outcomes provided it is appropriately monitored
- Early Detection of Adverse Drug Reactions and Safety Signals[30]
- Increased Efficiency and Productivity[31]
- Improved Accuracy and Data Quality[32]
- Efficient Processing of Large Volumes of Data[33]

❖ **Disadvantage –**

- High Costs: Implementing and maintaining AI systems requires considerable financial investment as well as skilled personnel including data scientists and AI specialists.[17,18]
- Skills Gap: The shortage of trained professionals especially in developing countries. limits the adoption of AI.[17]
- Job Displacement Concerns: The automation of tasks may raise concerns among pharmacovigilance professionals about potential job losses.[3]

❖ **Uses-**

✓ The authors defined machine learning differently across the articles however most definitions referred to the use of algorithms or pattern recognition to accomplish a specific task .[20]

✓ Many of the articles also noted that machine learning can support the development of intelligent automated systems capable of improving and streamlining processes.[21]

Regulatory framework –

The global pharmacovigilance framework is coordinated through collaborative systems designed to standardize drug safety monitoring and improve public health worldwide. A key component of this framework is the World Health Organization Uppsala Monitoring Centre (WHO UMC) which oversees the WHO Programme for International Drug Monitoring. Since its establishment in 1968 the programme has expanded to include more than 170 member countries and relies on VigiBase the worlds largest database of Individual Case Safety Reports (ICSRs) to support global signal detection and the prompt identification of emerging safety concerns.

In addition the International Council for Harmonisation (ICH) develops harmonized guidelines to promote consistent pharmacovigilance practices across different regulatory regions. Important examples include ICH E2E which addresses risk management during product development and ICH E2C(R2) which standardizes post-marketing safety reporting. The Council for International Organizations of Medical Sciences (CIOMS) further supports these initiatives by providing recommendations that address scientific regulatory and public health requirements thereby helping pharmacovigilance function as an integrated global discipline.[22,23]

In India pharmacovigilance oversight is primarily coordinated by the Drug Controller General of India (DCGI) the Central Drugs Standard Control Organization (CDSCO) and the Pharmacovigilance Programme of India (PvPI). These organizations collaborate to safeguard drug safety throughout the product lifecycle from approval to post-marketing surveillance. Operating under the Ministry of Health and Family Welfare the DCGI is responsible for approving new medicines, overseeing clinical trials and implementing regulations in line with the New Drugs and Clinical Trials Rules (NDCTR) 2019. The CDSCO serves as the central regulatory authority requiring pharmaceutical companies to submit Periodic Safety Update Reports (PSURs) and comply with Risk Management Plans (RMPs) based on international standards. Established in 2010 and coordinated by the Indian Pharmacopoeia Commission (IPC) the PvPI operates as Indias national pharmacovigilance network, collecting and evaluating safety reports and contributing data to global signal detection. Recent developments emphasize digital pharmacovigilance to strengthen drug safety and support regulatory decision-making.[23,24] The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) form the foundation of the pharmacovigilance regulatory framework in the United States and the European Union respectively. Both agencies operate comprehensive systems for the ongoing evaluation of drug safety across a products entire lifecycle. In the United States the FDA conducts pharmacovigilance through the Centre for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). It uses tools such as the FDA Adverse Event Reporting System (FAERS) and Med Watch to collect spontaneous reports while the Sentinel Initiative supports active safety surveillance. The FDA also implements Risk Evaluation and Mitigation Strategies (REMS) Periodic Safety Update Reports (PSURs) and Risk Management Plans (RMPs) to identify and reduce potential risks. In Europe the EMA oversees pharmacovigilance through the Pharmacovigilance Risk Assessment Committee (PRAC) and the EudraVigilance database. Recently, both agencies have strengthened their approaches by incorporating real-world evidence, data-driven signal detection, and patient-centered reporting systems to enable earlier identification of safety concerns.

Figure 2

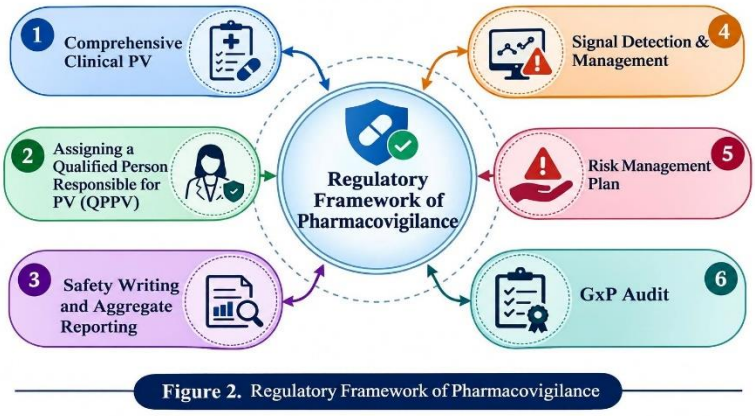


Figure 2. Regulatory Framework of Pharmacovigilance

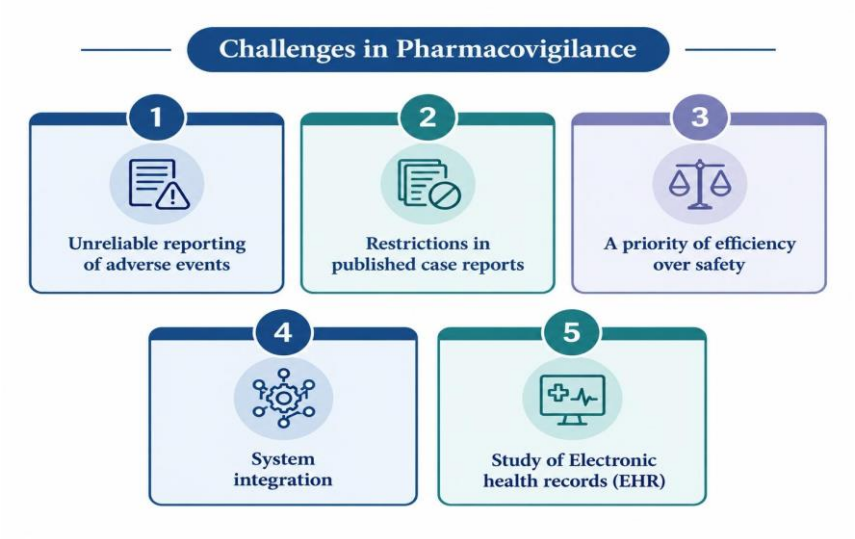
Challenges in pharmacovigilance -

Pharmacovigilance encounters multiple obstacles, notably concerning data integrity, underreporting, insufficient resources, regulatory deficiencies, and technological complexity issues that are particularly pronounced in low and middle income countries (LMICs) as they implement artificial intelligence. A major concern is the underreporting of adverse drug reactions (ADRs) Studies indicate that only 5–10% of such events are recorded in spontaneous reporting systems especially non-serious cases. This is driven by limited awareness among healthcare professionals time constraints and inadequate access to reporting channels resulting in poor-quality data that undermines effective signal detection. In LMICs these difficulties are further compounded by constrained financial and human resources weak national coordination reliance on external funding, high staff attrition and limited integration of public and private healthcare systems into formal pharmacovigilance structures.[25] Technological and infrastructural limitations also substantially hinder progress. Establishing and maintaining effective pharmacovigilance databases is difficult in settings with insufficient IT support, inconsistent data standards, and non-uniform terminology. AI-based pharmacovigilance faces additional barriers including the absence of well annotated datasets variability in clinical language and the challenge of integrating complex information from multiple sources. Moreover the application of AI and machine learning raises concerns regarding data quality, possible algorithmic bias, the lack of transparency in “black box” models, and adherence to data privacy and regulatory requirements. These technologies require thorough validation transparent explainability frameworks and human oversight to ensure their safe and ethical use within regulatory environments.[26,27]

Cultural and organizational factors further complicate pharmacovigilance systems. The existence of multiple overlapping safety organizations may result in ambiguous roles and responsibilities as well as inefficient allocation of resources. Frequent turnover among trained pharmacovigilance professionals and limited opportunities for career progression make staff retention difficult. In addition professionals accustomed to conventional systems may be reluctant to adopt digital innovations .[28]Moreover incorporating pharmacovigilance education into healthcare training curricula and improving awareness among patient healthcare providers and regulators remains a major gap. In LMICs limited patient participation and insufficient understanding of pharmacovigilance importance to public health encourage practices such as self-medication and contribute to the underreporting of ADRs especially within traditional medicine systems. Promoting a reporting culture and integrating pharmacovigilance into routine healthcare practice are essential for ensuring the long-term sustainability of these systems.[29]

Figure 3

Challenges in pharmacovigilance



AI for ADR detection -

ADRs are a major public health concern, affecting patients of all ages. Older adults—particularly those aged over 60 years are at heightened risk with an estimated 15% to 35% experiencing an ADR during hospitalization. This high incidence poses serious challenges to patient safety and places a substantial strain on healthcare systems. The financial impact is also considerable, with annual ADR-related costs estimated at approximately 30.1 billion. These figures highlight the critical need for improved strategies to monitor, detect, and prevent ADRs throughout both the pre-approval and post-approval stages of drug surveillance. Since the late 1990 the use of artificial intelligence in ADR detection has reshaped pharmacovigilance. Its evolution has occurred across three broad stages, driven by developments in statistical methods, natural language processing and machine learning techniques.[33,34]Table 2 presents AI methods used across different pharmacovigilance data source including social media, electronic health records, and regulatory safety databases and summarizes performance metrics such as F-score and area under the ROC curve (AUC). For instance, one study employing a knowledge-graph approach achieved an AUC of 0.92 in identifying known ADR causes.[35]

These findings surpass those of traditional statistical methods which typically achieve AUCs of approximately 0.7–0.8 for similar tasks. However, implementing advanced AI in clinical practice remains challenging because of concerns related to data quality model interpretability, and the requirement for large and diverse training datasets. These limitations are particularly significant for rare adverse reactions and underrepresented patient populations. More recently increasingly sophisticated AI models have been introduced into pharmacovigilance for example, Yang et al. demonstrated that machine learning approaches can successfully extract medication-related information and adverse reaction signals from electronic health records.[36]Their system MADEx (Medication and Adverse Drug Event Extraction) showed strong potential for near-real-time ADR surveillance and early warning by automatically extracting medication and adverse-event information from clinical notes. Compared with earlier methods, MADEx employed improved natural language processing techniques and a novel deep-learning architecture, achieving higher accuracy and faster processing than conventional rule-based systems. More recently multimodal deep learning approaches have been developed to broaden and refine ADR detection. For instance Sahoo et al. introduced a MultiModal Adverse Drug Event dataset that combines ADR-related textual information with visual data enabling the development of models trained on richer, more diverse inputs .[37]

Their findings demonstrated that incorporating visual information from images can enhance ADR detection particularly for adverse reactions that present with visible clinical features. In a related study Harpaz et al. explored multisource safety-signal detection by integrating data from FAERS, insurance claims, MEDLINE citations, and major web-search logs .[38]Their multi-modal approach improved the AUC by roughly 0.04–0.09 compared with methods relying on a single data source and enabled earlier signal identification offering an estimated lead time of 7–22 months prior to official labelling updates. Zhao et al. developed a deep-learning model to predict the severity of drug-related adverse events.[39]By combining multiple forms of data including drug SMILES sequences and semantic vectors representing adverse drug reactions the model enhanced its capacity to identify drug–ADR associations associated with severe clinical consequences, while accounting for both molecular-level and semantic-level relationships. Taken together these investigations indicate that incorporating diverse data modalities can improve the accuracy and robustness of ADR detection frameworks thereby promoting patient safety and expanding healthcare accessibility. Nevertheless despite their high performance many advanced models remain "black boxes," raising concerns regarding transparency and their acceptability in clinical settings. Rudin has therefore argued for the development of inherently interpretable models rather than dependence on post hoc explanation methods particularly in high-risk medical contexts such as ADR detection.[40]

This highlights the ongoing challenge of balancing the use of highly capable AI models with the need for transparency and interpretability in healthcare. To address privacy concerns in ADR detection federated learning enables several institutions to collaboratively develop models without sharing raw patient level data. Choudhury et al. proposed a federated framework for cross-institutional ADR detection, demonstrating that adverse reactions can be predicted effectively while individual patient data remain within each participating institution.[41]Enthoven and Al-Ars noted that federated learning systems may still be vulnerable to privacy attacks highlighting the need for robust security measures.[42]Future studies should prioritize creating AI tools for pharmacovigilance that are more reliable, explainable, and validated in clinical settings. Research must tackle detecting rare adverse drug reactions and ensuring models perform well for populations that are currently underrepresented. Work should also enhance the combination of varied data types while safeguarding patient privacy and build systems that can adjust as drug development and use change over time. As Rieke et al. highlight, researchers must carefully weigh the ethical and regulatory consequences of using AI in healthcare especially for sensitive tasks like ADR identification.[43]

Table2 A comparative overview of AI methods applied to ADR detection across multiple PV data sources, including social media platforms, EHRs, and spontaneous reporting systems

Data source	AI method	Sample size	Performance metric (F-score/ AUC)	References
Social media—Twitter	Conditional random fields	1784 tweets	0.72 (F-score)	Nikfarjam et al.[16]
Social media—DailyStrength	Conditional random fields	6279 reviews	0.82 (F-score)	Nikfarjam et al.[16]
EHR—Clinical notes	Bi-LSTM with attention mechanism	1089 notes	0.66 (F-score)	Li et al.[19]
Open TG-GATEs and FAERS databases (ADR: duodenal ulcer)	Deep neural networks	300 drug–ADR associations	0.94–0.99 (AUC)	Mohsen et al.[20]
Open TG-GATEs and FAERS databases (ADR: hepatitis fulminant)	Deep neural networks	319 drug–ADR associations	0.76–0.96 (AUC)	Mohsen et al.[20]
Korea National Spontaneous Reporting Database (drug: nivolumab)	GBM	136 suspected AEs	0.95 (AUC)	Bae et al.[21]
Korea National Spontaneous Reporting Database (drug: docetaxel)	GBM	485 suspected AEs	0.92 (AUC)	Bae et al.[21]
FAERS	Multi-task deep-learning framework	141,752 drug–ADR interactions	0.96 (AUC)	Zhao et al.[22]
Social media (Twitter)	BERT fine-tuned with FARM	844 tweets	0.89 (F-score)	Hussain et al.[23]
Social media (PubMed)	BERT fine-tuned with FARM	6821 sentences	0.97 (F-score)	Hussain et al.[23]
Eight parenting websites	Disproportionality methods	1290 posts	0.69 (F-score)	Hadzi-Puric and Grmusa[24]

Note: The table highlights performance metrics such as *F*-scores and AUC values, which are key indicators of a model's accuracy and effectiveness. It is important to note that direct comparison between methods is not possible due to differences in dataset nature, size, specific tasks, and evaluation criteria. The table aims to provide an overview of the range of AI applications and their reported performance in the field of PV. Performance metrics like the F-score and AUC are context-specific, and a method's success often hinges on the balance between sensitivity and specificity—key factors in ADR monitoring.

Abbreviations: ADR, adverse drug reaction; AE, adverse event; AI, artificial intelligence; BERT, bidirectional encoder representations from transformers; Bi-LSTM, bidirectional long short-term memory; EHR, electronic health record; FAERS, FDA Adverse Event Reporting System; FARM, Framework for Adapting Representation Models; FDA, Food and Drug Administration; GBM, Gradient Boosting Machine; KAERS, Korea Adverse Event Reporting System; PV, pharmacovigilance; TG-GATEs, Toxicogenomics Project–Genomics Assisted Toxicity Evaluation Systems.

Advantages of Automated ADR Detection-

- ✓ Enables early identification of adverse drug reactions.[33]
- ✓ Improves accuracy and consistency of ADR identification.[30]
- ✓ Integrates multiple real-world data sources for comprehensive safety monitoring.[31]

- ✓ Supports faster regulatory decision-making and post-marketing surveillance [44]

❖ **Signal detection -**

Signal detection is a core pharmacovigilance function focused on discovering new or previously unidentified links between medicinal products and adverse drug reactions (ADRs). As defined by the World Health Organization (WHO) a safety signal refers to information indicating a potential causal association between a medicine and an adverse event that warrants further evaluation. Conventional signal detection has primarily depended on statistical disproportionality techniques including the Reporting Odds Ratio (ROR) Proportional Reporting Ratio (PRR) and Bayesian methods applied to spontaneous reporting databases. While these approaches continue to be useful they are frequently constrained by underreporting, reporting bias and challenges in handling large, heterogeneous datasets. Artificial Intelligence (AI) has therefore emerged as an advanced complementary approach supporting conventional methods through faster and more extensive analysis of complex pharmacovigilance data.[45,30]

❖ **Advantages of AI-Based Signal Detection –**

1) Detects emerging safety signals earlier than conventional statistical methods[12].
2) Analyzes large scale pharmacovigilance datasets efficiently[24].
3) Integrates multiple real world data sources (ICSRs, EHRs, literature, and social media).[33]
4) Reduces false positive signals through intelligent prioritization.[31]
5) Supports timely regulatory decision making and continuous post-marketing safety surveillance.[33]
6) Improves the efficiency and consistency of signal evaluation while complementing expert review.[30]

AI Integration in Pharmacovigilance-

AI has rapidly reshaped many sectors, including pharmacovigilance by improving how adverse drug reactions are tracked and assessed. Predictive modeling illustrates AIs forward looking role in spotting possible drug safety issues, helping safeguard patients by identifying adverse events at an earlier stage .Realworld case studies show that AI algorithms can spot early safety signals and contribute to better patient safety outcomes. Incorporating AI into pharmacovigilance marks a shift toward proactive, data-led approaches for monitoring drug safety, offering significant potential to improve patient outcomes and streamline healthcare management.[46] AI helps analyze vast datasets from varied sources such as social media and electronic health records to uncover potential signals of adverse drug reactions and support timely interventions when needed.[10,47] Although AI promises major advances incorporating it into pharmacovigilance encounters challenges like safeguarding patient data and updating regulatory frameworks. Still the possible gains in medication safety and patient outcomes make ongoing research and development essential[48]AI is already being used in pharmacovigilance to automatically detect and classify adverse drug events from multiple data streams and to monitor social media for emerging safety concerns reducing time and resource demands while boosting accuracy and consistency. While AI-driven pharmacovigilance offers clear advantages it also raises issues such as data privacy and the need to adapt regulatory systems. Ongoing advances promise more proactive, patient focused medication safety monitoring as these technologies continue to evolve.[49]

❖ **Advantages of integration of AI in pharmacovigilance:**

- AI integration streamlines gathering reports of drug adverse effects from multiple sources providing a more complete view of a medications risks and benefits.[50]
- It allows rapid processing of large volumes of data, so we can review many reports and detect patterns or trends more quickly.[50]
- AI helps structure and clarify collected data allowing us to uncover patterns or associations that improve drug safety decision making.[50]
- Integrated AI systems help protect information and prevent data breaches ensuring that sensitive patient records are accessible only to authorized individuals.[50]
- 5.AI adoption has reduced the labor needed for data entry and processing by creating templates for common data and recognizing speech and handwriting. This lets staff spend less time on repetitive tasks and focus on higher-value work.[50]
- By analyzing past data and spotting patterns, AI can help forecast potential safety problems, allowing us to intervene before they escalate.[50]
- It reduces human errors in data entry and processing. Since computers excel at repetitive tasks, the collected information is more likely to be reliable.[50]

❖ **Software and AI-Based Tools Used in Pharmacovigilance-**

Table 3 Software and AI-Based tools used in pharmacovigilance

Software/ Tool	AI/Technology	Pharmacovigilance Application	Major Function	Data Source	Reference
MADEx	NLP / Deep Learning	ADR detection	Extraction of medications adverse drug events and their relationship from clinical notes	EHR/clinical notes	51
Oracle Safety One Argus	AI/ML/NLP	Case processing and triage	Automated intake extraction and processing of adverse event information supports duplicate checking and regulatory reporting	Safety reports, structured and unstructured documents	52
Oracle Empiric Signal	Statistical methods / A supported analytics	Signal detection	Detection, evaluation and prioritization on of potential safety signals	Spontaneous us reporting databases	53
NLP/ML-based literature screening systems	NLP /ML	Literature surveillance	Automated screening classification and extraction of adverse drug event information from scientific literature	Scientific literature	10

Conclusion-

Artificial intelligence is reshaping pharmacovigilance by making the detection and management of adverse drug reactions faster, smarter, and more efficient. It is increasingly being used for case processing, literature screening, signal detection, and overall safety assessment. Technologies such as machine learning, deep learning, natural language processing, generative AI, and knowledge-based systems can process large volumes of varied data, helping identify potential drug-safety signals earlier than traditional methods. That said, AI is not without limitations. Issues such as inconsistent or poor-quality data, algorithmic bias, limited explainability, privacy risks, cybersecurity threats, difficulties in validation, and uncertain regulatory acceptance still need careful attention. These challenges highlight why AI should support pharmacovigilance professionals rather than replace them. With reliable data, thorough validation, ethical governance, appropriate regulatory oversight, and meaningful human supervision, AI can make pharmacovigilance more proactive, dependable, efficient, and ultimately more focused on patient safety. Human expertise remains essential for interpreting AI outputs, particularly in complex safety decisions, and helps ensure accountability and clinical relevance.

Future perspective –

The future of artificial intelligence (AI) in pharmacovigilance lies in developing more proactive, accurate, and patient-centred approaches to drug safety monitoring. Advances in machine learning, deep learning, and natural language processing are expected to improve the identification of adverse drug reactions (ADRs), automate individual case safety report (ICSR) processing, and support the early detection of potential safety signals. Integrating real-world data from electronic health records, spontaneous reporting systems, scientific literature, and other relevant sources may provide a more comprehensive understanding of medicine-related risks. Multimodal AI and knowledge graph approaches also offer opportunities to identify complex relationships between drugs, diseases, and adverse events, potentially improving signal detection and risk assessment [35, 38]. Another important direction is the development of explainable and interpretable AI models. Although advanced deep-learning systems can identify complex patterns, their limited transparency may restrict their acceptance in clinical and regulatory settings. Future research should therefore prioritize models that provide understandable explanations for their predictions and support reliable clinical decision-making. AI systems should also undergo rigorous validation using

independent datasets and real-world clinical settings to assess their accuracy, reliability, and generalizability. Particular attention is required for detecting rare ADRs and improving model performance among underrepresented patient populations [39–43]. Protecting patient privacy while enabling collaboration between healthcare institutions will remain a major priority. Privacy-preserving approaches, including federated learning, may facilitate the development of AI models without requiring the direct sharing of raw patient-level data. However, appropriate cybersecurity measures, data governance, and ethical safeguards will be necessary to address potential privacy risks [41–43]. In addition, collaboration among pharmacovigilance professionals, healthcare providers, researchers, technology developers, and regulatory authorities will be essential to establish appropriate standards for AI validation, transparency, accountability, and implementation.

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