

Healthcare Vigilance and Artificial Intelligence Methods in Pharmacovigilance

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ABSTRACT

Pharmacovigilance plays a critical role in ensuring drug safety through the detection, assessment, monitoring, and prevention of adverse drug reactions (ADRs) [1]. However, the rapid growth of healthcare data, increasing medicine use, and limitations of traditional reporting systems have created severe challenges such as significant underreporting, delayed signal detection, and heavy manual workloads [2]. Artificial Intelligence (AI) has emerged as an innovative solution to strengthen modern pharmacovigilance systems by improving the efficiency, accuracy, and speed of drug safety monitoring [3]. This review report thoroughly examines the application of diverse AI technologies in pharmacovigilance and evaluates their impact on broader healthcare vigilance frameworks [4]. Advanced methods such as Machine Learning (ML), Natural Language Processing (NLP), predictive analytics, and data mining are increasingly utilized to analyze large-scale heterogeneous healthcare databases, extract hidden ADR patterns, and support real-time post-marketing safety surveillance [5]. These computational technologies enhance initial signal detection, automate routine individual case processing, minimize human errors, and profoundly improve clinical and regulatory decisionmaking for healthcare professionals and regulatory authorities [6]. The study highlights how AI-powered systems significantly reduce manual operational workloads while facilitating the early identification of potential drug safety risks [7]. Furthermore, AI improves the active management of vast volumes of clinical, electronic health record, and social media data, leading to more proactive and efficient pharmacovigilance workflows [8]. Despite these undeniable technical advantages, critical challenges such as data privacy concerns, a distinct lack of standardized datasets, algorithm transparency ("black-box" models), ethical issues, and high implementation costs remain key barriers to widespread institutional adoption [9].

Keywords: Pharmacovigilance, Artificial Intelligence, Adverse Drug Reactions, Machine Learning, Natural Language Processing, Signal Detection, Healthcare Vigilance.

1. INTRODUCTION TO PHARMACOVIGILANCE

1.1 Historical Context and Definition

Pharmacovigilance represents the science and activities dedicated to detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems [10]. This critical medical field has evolved substantially since its formal inception in the 1960s following the thalidomide tragedy, an event that highlighted the absolute and urgent need for systematic, structured post-marketing drug surveillance [11]. According to the World Health Organization (WHO), pharmacovigilance explicitly encompasses "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems" [12]. The fundamental goal of pharmacovigilance is to ensure maximum patient safety by identifying previously unrecognized adverse drug reactions (ADRs) or detecting shifts in the known patterns and frequencies of established ADRs, thereby supporting comprehensive riskbenefit assessments for pharmaceutical medications throughout their entire lifecycle [13].

The operational scope of modern pharmacovigilance has expanded considerably from its initial, narrow focus on spontaneous reporting systems [14]. Today, the field addresses complex multi-faceted challenges including drug-drug interactions, drug utilization in special patient populations (such as pediatrics and geriatrics), medication errors, lack of expected clinical efficacy, and underlying quality issues or manufacturing defects affecting pharmaceutical products [15]. The growing complexity of contemporary therapeutic regimens, combined with an increasingly diverse global pharmaceutical landscape, has necessitated more sophisticated, scalable approaches to drug safety monitoring that can actively keep pace with rapid medical advancements and the unprecedented explosion of available health data [16].

1.2 Significance and Burden of ADRs

Adverse drug reactions represent a substantial public health concern worldwide, contributing significantly to patient morbidity, mortality, and overall healthcare costs [17]. Recent large-scale clinical studies indicate that ADRs account for approximately 2.7% to 15.7% of all hospital admissions and occur in nearly 17% of already hospitalized patients [18]. This public health burden is particularly pronounced in vulnerable elderly populations (>60 years), with an estimated 15% to 35% of older patients experiencing a significant ADR during their hospital stay [19]. The economic impact associated with these events is equally staggering, with estimated annual clinical management costs reaching \$30.1 billion in the United States alone [20].

These clinical and financial statistics underscore the critical importance of establishing robust, highthroughput pharmacovigilance systems capable of detecting safety signals in a timely and sensitive manner [21]. Traditional pharmacovigilance methodologies, which primarily relied on passive spontaneous reporting and manual expert assessment, have proven increasingly inadequate in the face of rapidly growing data volumes and therapeutic complexity [22]. This physical and operational limitation has directly driven the active exploration, development, and system-wide adoption of artificial intelligence technologies to enhance clinical monitoring capabilities, maximize processing efficiency, and ultimately protect patient safety more effectively in an increasingly complex pharmaceutical landscape [23].

2. LITERATURE REVIEW OF PHARMACOVIGILANCE AND AI INTEGRATION

The literature surrounding AI integration highlights a definitive historical progression [24]. The discipline became critical after the thalidomide tragedy in the 1960s, which established the baseline necessity for ADR monitoring [24]. Over the subsequent decades, the traditional methods relying on manual assessment and spontaneous reporting systems have become increasingly inadequate due to the exponential explosion of health data and the staggering complexity of modern therapeutic regimens [25]. Artificial Intelligence (AI) in this context introduces machine learning (ML), natural language processing (NLP), and deep learning architectures, all utilized to process vast datasets for drug safety [26]. AI has emerged as a transformative solution to these data challenges by automating routine tasks and enabling proactive, real-time safety monitoring [27].

[ARTIFICIAL INTELLIGENCE (AI)]



[DATA SCIENCE]



[DATA ANALYTICS]



[DATA INFRASTRUCTURE]



[DATA COLLECTION]

Fig 1: Applications and Hierarchical Layering of Artificial Intelligence in Pharmacovigilance [47]

2.FUNDAMENTALS OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

2.1 Core Concepts and Definitions

Artificial intelligence (AI) represents a prominent branch of computer science focused on creating systems capable of performing tasks that typically require human intelligence [32]. In the specific context of pharmacovigilance, AI encompasses various advanced computational technologies including machine learning, deep learning, natural language processing, and predictive analytics [33]. Machine learning (ML), a critical subset of AI, involves mathematical algorithms that can automatically learn complex patterns from data without being explicitly programmed for specific tasks, thereby systematically improving their performance through iterative experience [34]. Natural language processing (NLP) enables computers to understand, interpret, and generate human language, which is particularly valuable for extracting highly specific safety details from unstructured clinical narratives, free-text medical literature, and unstructured social media posts [35].

The relevance of AI to pharmacovigilance lies primarily in its unique capability to process and analyze vast, heterogeneous datasets far beyond human capability, identify complex hidden multi-variable patterns, and generate actionable safety insights [36]. These computational capabilities are particularly valuable in addressing the systemic limitations of traditional pharmacovigilance systems, which struggle severely with the immense volume, variety, and velocity of contemporary healthcare data [37]. AI technologies can effectively automate routine data tasks, enhance statistical signal detection sensitivity, and provide robust predictive insights that enable proactive rather than reactive drug safety monitoring [38].

2.2 Key AI Technologies and Their Applications

Machine learning algorithms can be broadly categorized into supervised learning (using labeled training data), unsupervised learning (finding novel patterns in unlabeled data), and reinforcement learning (learning dynamically through interaction with an environment) [41]. In pharmacovigilance, supervised learning approaches such as random forests, support vector machines (SVM), and gradient boosting machines (GBM) have demonstrated particular utility in classifying complex ADR reports and predicting adverse clinical outcomes [42]. Unsupervised learning methods like clustering algorithms help identify novel patterns and unexpected drug associations in pharmacovigilance data that might not be anticipated using conventional statistical approaches [42].

Table 1: Key AI Technologies and Their Primary Applications in Pharmacovigilance [39, 40]

AI Technology	Primary Function	Pharmacovigilance Applications
Machine Learning	Identifies complex patterns in data to make robust predictions	ADR prediction, risk factor identification, signal detection [40]
Natural Language Processing	Processes and analyzes unstructured human language data	Extraction of ADR information from clinical notes, social literature, and social media [40]
Bayesian Networks	Models complex probabilistic relationships between variables	Causality assessment, seamless integration of diverse evidence sources [40]

Natural language processing has emerged as a particularly valuable technology for pharmacovigilance due to the heavy predominance of unstructured text in healthcare data [43]. NLP techniques range from traditional rule-based systems to advanced deep learning approaches like Bidirectional Encoder Representations from Transformers (BERT) [44]. Controlled studies have demonstrated NLP's profound effectiveness in extracting ADR information from diverse sources, with one study achieving an exceptional F-score of 0.97 when processing PubMed sentences [45]. This

capability significantly enhances the utilization of rich clinical information contained in electronic health records, medical literature, and patient-generated content that would otherwise be extremely challenging to analyze systematically [46].

3. DATA SOURCES FOR AI-DRIVEN PHARMACOVIGILANCE

3.1 Traditional and Emerging Data Sources

The overall effectiveness of AI-driven pharmacovigilance systems depends fundamentally on the underlying quality, diversity, and volume of data available for computational analysis [49]. Traditional pharmacovigilance has primarily relied on spontaneous reporting systems (SRS) such as the FDA Adverse Event Reporting System (FAERS), EudraVigilance, and the WHO's VigiBase database, which systematically collect individual case safety reports (ICSRs) from healthcare professionals and consumers [50]. These repositories contain millions of validated reports and have been the cornerstone of drug safety surveillance for decades [51]. However, they suffer from well-documented limitations including high rates of underreporting, duplicate entries, variable data quality, and selective reporting biases [52].

The expanding universe of electronic health records (EHRs) represents a rich source of longitudinal patient data that can actively complement spontaneous reporting systems [53]. EHRs contain comprehensive clinical information including longitudinal diagnoses, prescriptions, laboratory results, medical procedures, and unstructured clinical narratives, providing valuable context for assessing potential adverse drug events [54]. Similarly, claims databases offer another highly structured data source containing information on drug utilization, healthcare encounters, and macro costs [55]. Additionally, real-world evidence (RWE) derived from registries, observational cohorts, and specialized monitoring programs provides insights into drug safety in routine clinical practice beyond the strictly controlled environment of clinical trials [56].

3.2 Novel Data Streams and Their Potential

Social media platforms and patient forums have emerged as unconventional but highly valuable data sources for pharmacovigilance [57]. Patients increasingly share first-hand experiences with medications on platforms like Twitter (X), Facebook, and specialized health communities, often providing immediate, unfiltered accounts of potential adverse effects [58]. While this data is typically noisy and highly unstructured, AI-powered approaches have demonstrated a unique capability in extracting meaningful safety signals [59]. One study using conditional random fields (CRF) achieved F-scores of 0.72 and 0.82 for ADR detection from Twitter and DailyStrength, respectively [60]. Wearable devices and mobile health applications represent another emerging data stream, generating continuous physiological data that may indicate adverse reactions through subtle changes in vital signs, activity patterns, or other biometric parameters [61].

The scientific literature remains a mandated source for pharmacovigilance activities, with thousands of potentially relevant articles published monthly [62]. Automated literature monitoring using natural language processing can dramatically accelerate the identification of case reports and safety studies across multiple languages and medical journals [63]. The integration of these diverse data sources enables a more comprehensive understanding of drug safety profiles, though it introduces significant challenges related to data standardization, interoperability, and privacy protection that must be addressed through appropriate technical and governance frameworks [64].

[Heterogeneous Sources: EHR, Social Media, Wearables]

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▼

[AI Cognitive Core (NLP / ML / Deep Learning)]

└─► [Ensemble Models: Predictive Toxicology]

└─► [Deep Learning: Advanced Signal Detection]

Fig 2: Flow and Core Architectures of AI in Drug Safety, Toxicology, and Pharmacovigilance [65, 66]

4. AI APPLICATIONS IN ADR DETECTION AND SIGNAL MANAGEMENT

4.1 Signal Detection and Validation

Signal detection represents one of the most established applications of AI in pharmacovigilance, focusing on identifying potential relationships between drugs and adverse events that warrant further investigation [70]. Traditional signal detection methods have primarily relied on disproportionality analysis techniques such as proportional reporting ratios (PRR) and Bayesian confidence propagation neural networks (BCPNN) [71]. However, machine learning approaches have demonstrated superior performance in many contexts, with studies reporting area under the receiver operating characteristic curves (AUCs) of 0.92–0.99 for various ADR detection tasks [72]. Ensemble methods like random forests and gradient boosting machines have shown particular promise, effectively handling the high-dimensional, sparse nature of pharmacovigilance data while capturing complex nonlinear relationships [73]. AI technologies also enhance signal validation processes, which determine whether statistically identified signals represent potentially causal relationships [73]. Natural language processing techniques can rapidly scan relevant literature, clinical trial data, and biological databases to gather supporting evidence for signal evaluation [74]. Knowledge graphs that integrate drug, disease, gene, and pathway information can provide biological plausibility assessments for potential signals [75]. These approaches help prioritize signals for expert review, reducing the manual workload and enabling safety teams to focus on the most clinically significant potential issues [76].

4.2 Automation and Efficiency Improvements

AI-driven automation significantly enhances the operational efficiency of various pharmacovigilance processes [77]. For instance, the vigiMatch algorithm developed by the Uppsala Monitoring Centre applies machine learning and natural language processing to identify duplicate case reports, improving data quality and ensuring the integrity of safety analyses [78]. At a regional pharmacovigilance center, implementation of an expert-defined Bayesian network for causality assessment reduced case processing times from days to hours while minimizing subjectivity and improving reliability [79]. Integrated AI platforms like ArisGlobal's LifeSphere have demonstrated a 40–50% reduction in false-positive signals and approximately an 80% acceleration in signal evaluation processes [80].

Table 2: Performance Metrics of Core AI Applications in Pharmacovigilance [81, 82]

Application Area	AI Technology Used	Performance Achieved	Source / Ref
Social Media Mining	Conditional Random Fields (CRF)	F-score: 0.72 (Twitter), 0.82 (DailyStrength)	Ref [4 / 81]
EHR Analysis	Bi-LSTM with Attention Mechanism	F-score: 0.66	Ref [4 / 81]
ADR Prediction (Duodenal Ulcer)	Deep Neural Networks (DNN)	AUC: 0.94–0.99	Ref [4 / 81]
ADR Prediction (Hepatitis Fulminant)	Deep Neural Networks (DNN)	AUC: 0.76–0.96	Ref [4 / 81]
Predictive Modeling (Nivolumab)	Gradient Boosting Machine (GBM)	AUC: 0.95	Ref [4 / 82]
Predictive Modeling (Docetaxel)	Gradient Boosting Machine (GBM)	AUC: 0.92	Ref [4 / 82]
Duplicate Detection	vigiMatch Algorithm (UMC)	Significant improvement in data quality	Ref [5 / 82]
Causality Assessment	Bayesian Network	Processing time reduced from days to hours	Ref [2 / 82]

[DATA INPUT] —► [AI ANALYSIS] —► [SIGNAL DETECTION] —► [REGULATORY DECISION]
(EHR/Literature) (Pattern Recog.) (Validation) (Real-time Safeguards)

Fig 3: Architecture of an AI-Enhanced End-to-End Pharmacovigilance System [82]

5. AI IN PREDICTION, RISK ASSESSMENT, AND CAUSALITY EVALUATION

5.1 Predictive Modeling for ADR Risk

Predictive modeling represents a paradigm shift from reactive signal detection to proactive risk anticipation in pharmacovigilance [84]. Machine learning algorithms can analyze patient-specific factors including demographics, clinical characteristics, genetic markers, concomitant medications, and social determinants to stratify ADR risk at the individual level [85]. For example, Hu et al. developed ML models that achieved 88.06% accuracy in predicting ADRs in older inpatients, identifying key risk factors such as polypharmacy, age, and specific medical conditions [86]. These

models enable targeted monitoring and preventive interventions for high-risk patients, potentially reducing the incidence of serious adverse drug reactions [87].

Different machine learning algorithms offer distinct advantages for various prediction tasks [88]. Random forest models excel at identifying risk factors for specific ADRs like drug-induced liver injury, handling missing data effectively while maintaining high accuracy [89]. Deep neural networks can identify complex drug-drug interactions by analyzing molecular structures and pharmacological properties [90]. Recurrent neural networks capture temporal patterns in longitudinal patient records, recognizing that ADR risk evolves over time based on treatment sequences and disease progression [91]. The selection of appropriate algorithms depends on data characteristics, prediction goals, and interpretability requirements for clinical implementation [92].

5.2 Causality Assessment and Bayesian Approaches

Causality assessment determines the likelihood that a suspected drug caused an adverse event, representing a critical and challenging pharmacovigilance task traditionally reliant on expert judgment [93]. AI systems, particularly those based on Bayesian networks, have demonstrated significant potential to enhance this process by providing structured, transparent, and consistent evaluations [94]. Bayesian networks use directed acyclic graphs to represent conditional dependencies between variables, enabling the integration of diverse evidence sources including patient characteristics, temporal relationships, dechallenge/rechallenge information, and biological plausibility [95]. The implementation of expert-defined Bayesian networks at pharmacovigilance centers has yielded impressive results, reducing processing times from days to hours while maintaining high concordance with expert judgment [96]. These systems improve consistency by minimizing the subjectivity inherent in manual assessments and providing clear audit trails of the reasoning process [97]. Furthermore, Bayesian approaches can naturally incorporate prior knowledge and update probability estimates as new evidence emerges, making them particularly suitable for the evolving nature of drug safety information throughout a product's lifecycle [98]. The transparency of well-designed Bayesian networks also facilitates regulatory review and clinical validation, addressing important concerns about the "black box" nature of some AI approaches [99].

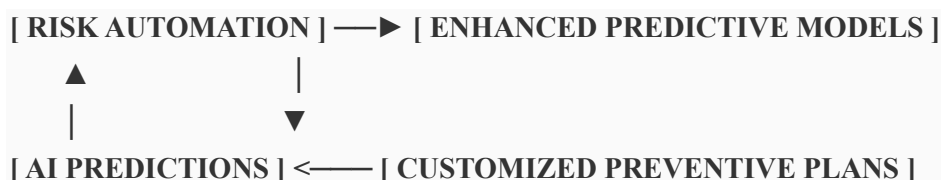


Fig 4: Functional Core Cycle of AI in Lifecycle Risk Management [100]

6. IMPLEMENTATION CHALLENGES AND ETHICAL CONSIDERATIONS

6.1 Data Quality and Algorithmic Limitations

The performance of AI systems in pharmacovigilance is fundamentally constrained by data quality issues in the underlying source data [101]. Common problems include incomplete reporting, coding inconsistencies, information biases, and limited clinical context in spontaneous reports [102]. EHR data often contains documentation variations, missing values, and fragmentation across healthcare systems [103]. Social media data presents additional challenges regarding verification, specificity, and potential for misinformation [104]. These data limitations can introduce biases and inaccuracies that propagate through AI systems, potentially leading to false signals or missed safety concerns [105]. Algorithmic transparency represents another significant challenge, particularly for complex models like deep neural networks that function as "black boxes" with limited interpretability [106]. The lack of clear explanations for AI-generated recommendations raises concerns about trust, verification, and accountability, especially in regulatory

decision-making contexts [107]. This limitation has spurred the development of explainable AI (XAI) frameworks that aim to make model outputs more interpretable to pharmacovigilance experts and regulators [108]. Additionally, many AI models demonstrate limited generalizability across different therapeutic areas, patient populations, or healthcare systems, raising questions about their broad applicability without extensive validation in specific use contexts [109].

6.2 Regulatory and Ethical Considerations

The integration of AI into pharmacovigilance occurs within a complex regulatory landscape that continues to evolve [110]. Regulatory agencies including the FDA and EMA have begun issuing guidance on AI implementation, emphasizing requirements for rigorous documentation, ongoing performance monitoring, bias mitigation, and human oversight [111]. The FDA's January 2025 guidance on AI for regulatory decisionmaking and EMA's September 2024 reflection paper on AI in the medicinal product lifecycle represent important steps toward standardized frameworks [112]. However, significant regulatory challenges remain, including how to validate adaptive AI systems that continue learning post-deployment and how to establish appropriate thresholds for acceptable performance across different pharmacovigilance tasks [113].

TRADITIONAL WORKFLOW:

[Manual Case Processing] —► Requires WEEKS to Assess

AI-POWERED WORKFLOW:

[EHR + Literature Streams] —► [AI Cognitive Core] —► THOUSANDS of Cases in REAL-TIME

Fig 5: Workflow Comparison: Traditional Manual Systems vs. Real-Time AI Systems [114]

7. FUTURE DIRECTIONS AND CONCLUSION

7.1 Emerging Trends and Technologies

The future evolution of AI in pharmacovigilance will likely be shaped by several emerging technologies and methodological advances [115]. Federated learning approaches enable collaborative model training across institutions without sharing sensitive patient data, addressing privacy concerns while improving model generalizability [116]. The integration of multi-omics data (genomic, proteomic, metabolomic) will enhance personalized risk prediction by incorporating biological susceptibility factors into ADR assessments [117].

Generative AI applications are emerging for tasks such as automated case narrative generation, literature summarization, and synthetic data creation for model training [118]. The European Union's Horizon Europe program has identified AI-powered signal detection as a priority research area, funding initiatives to develop "evidence-based and practical guidance, with aligned perspectives of public and private stakeholders, on the use of artificial intelligence for signal detection and other pharmacovigilance applications" [118]. This regulatory-academic-industry collaboration reflects the growing recognition that realizing AI's full potential in pharmacovigilance requires coordinated efforts to address technical, regulatory, and implementation challenges [119]. Future systems will likely evolve toward more integrated, proactive safety monitoring that spans the entire product lifecycle from clinical development through post-marketing surveillance [120].

7.2 Conclusion

The integration of artificial intelligence into pharmacovigilance represents a complete paradigm shift from traditional reactive surveillance toward proactive, predictive safety monitoring [123]. AI technologies including machine learning, natural language processing, and Bayesian networks demonstrate significant potential to enhance the efficiency, accuracy, and comprehensiveness of adverse drug reaction detection and assessment [124]. Evidence from systematic reviews indicates that machine learning algorithms generally outperform traditional disproportionality methods, with pooled sensitivity and specificity of 78.1% and 70.6% for development studies, and even higher performance (81.5% sensitivity, 79.5% specificity) in studies incorporating external validation [125].

Despite this massive promise, the widespread implementation of AI in routine pharmacovigilance practice faces significant challenges related to data quality, algorithmic transparency, regulatory acceptance, and ethical considerations [126]. Addressing these limitations will require intense collaborative efforts among researchers, regulators, industry stakeholders, and the healthcare community to develop robust validation frameworks, ensure algorithm fairness, and establish appropriate governance structures [127]. As these challenges are progressively addressed, AI-powered pharmacovigilance systems will play an increasingly vital role in safeguarding patient safety, enabling more personalized risk-benefit assessments, and enhancing public health outcomes in an era of therapeutic complexity and big data [128]. Continued advancements in AI technologies are expected to create smarter and more reliable pharmacovigilance systems that will improve global healthcare outcomes and ensure safer use of medicines worldwide [129].

REFERENCES

1. Artificial intelligence (AI) in pharmacovigilance: A systematic review on predicting adverse drug reactions (ADR) in hospitalized patients. *Research in Social and Administrative Pharmacy*. 2025;21(6):453–462.
2. Artificial intelligence in pharmacovigilance: A narrative review. *PMC*. 2025;47(4):932–944.
3. Artificial Intelligence: Applications in Pharmacovigilance Signal Management. *PMC*. 2025;39(3):183–198.
4. Artificial intelligence in pharmacovigilance: advancing drug safety monitoring. *PMC*. 2025;16:20420986251361435.
5. AI and Big Data for Safety Signal Detection in Pharmacovigilance. *BauPharma*. 2025.
6. Charting the frontier of healthcare with big data and AI. *ScienceDirect*. 2025.
7. AI-Powered Signal Detection in Pharmacovigilance. *Horizon Europe*. 2025.
8. Hu et al. Machine learning for prediction of ADRs in older inpatients. 2024.
9. Nikfarjam et al. Natural language processing for ADR detection from social media. 2025.
10. Yang et al. Deep learning for free-text ADR reports. 2024.
11. Bate A, Lindquist M, Edwards IR, et al. A Bayesian Confidence Propagation Neural Network method for adverse drug reaction signal generation. 1998.
12. DuMouchel W. Bayesian data mining in large frequency tables, with an application to the FDA spontaneous reporting system. 1999.
13. Li et al. Bi-LSTM with attention mechanism for EHR analysis. 2024.
14. Mohsen et al. Deep neural networks for ADR prediction. 2024.
15. Bae et al. Gradient boosting machine for adverse event prediction. 2024.
16. Zhao et al. Multi-task deep learning for drug–ADR interactions. 2024.

17. Hussain et al. BERT fine-tuned for social media mining. 2024.
18. Kompa et al. Review of signal detection methods. 2023.
19. Painter et al. Scope of methods in signal detection. 2023.
20. Salas et al. AI in Individual Case Safety Report (ICSR) management. 2024.
21. Kassekert et al. AI applications in pharmacovigilance. 2024.
22. Uppsala Monitoring Centre. vigiMatch algorithm for duplicate detection. 2024.
23. ArisGlobal. LifeSphere AI platform performance metrics. 2025.
24. FDA. Sentinel network for drug safety monitoring. 2024.
25. European Medicines Agency. Reflection paper on artificial intelligence in the medicinal product lifecycle. 2024.