

Review Article



Artificial Intelligence in Pharmacovigilance, Drug Repurposing, Materiovigilance, and Biovigilance: Current Advances, Indian Perspective, Challenges, and Future Opportunities

Dr Tarun Kumar*

Associate Professor, Department of Pharmacology, AIIMS, Jodhpur, Rajasthan – 342005, India.

*Corresponding author's E-mail: tarunkmr759@gmail.com

Received: 06-06-2026; Revised: 21-08-2026; Accepted: 29-08-2026; Published online: 20-09-2026.

ABSTRACT

Background: Pharmacovigilance, materiovigilance, and biovigilance are essential components of healthcare safety surveillance. Traditional systems face increasing challenges in managing the growing volume and complexity of safety data globally. Artificial intelligence (AI) and machine learning (ML) offer significant potential to enhance signal detection, automate data processing, and generate actionable real-world evidence.

Objective: This review synthesises current evidence on AI applications in pharmacovigilance, drug repurposing, materiovigilance, and biovigilance, with a focus on implementation within the Indian healthcare system and the unique challenges confronting low- and middle-income countries (LMICs).

Key Findings: AI-driven signal detection outperforms traditional statistical methods. India's pharmacovigilance programmes, though expanded to over 1,120 Adverse Drug Reaction (ADR) monitoring centres, continue to face systemic challenges related to underreporting, data interoperability, and workforce capacity. The Ayushman Bharat Digital Mission (ABDM) presents a strategic platform for transformative improvement.

Indian Perspective: Strengthening India's pharmacovigilance infrastructure is critical to address persistent challenges, including an estimated ADR reporting rate of 2–5% of serious events and limited integration of AI-based analytics. The Central Drugs Standard Control Organisation (CDSCO) requires a modernised regulatory framework to facilitate AI-driven surveillance, capitalising on India's large and diverse patient population to improve safety outcomes.

Conclusion: AI technologies hold significant promise for advancing safety surveillance in India and other LMICs. Successful implementation will require robust AI platforms, clear validation standards, sustained infrastructure investment, and workforce development. Emerging technologies, including blockchain-based data integrity, federated learning for privacy-preserving analytics, and precision pharmacovigilance, represent key areas for future development.

Keywords: Artificial intelligence; Pharmacovigilance; Drug repurposing; Materiovigilance; Biovigilance; Indian healthcare systems.

INTRODUCTION

Healthcare safety surveillance has evolved substantially over the past two decades, yet persistent challenges in responsiveness, efficiency, and comprehensiveness remain. Pharmacovigilance, the science of monitoring adverse drug reactions (ADRs), has historically relied on passive reporting systems established in the 1960s¹. Traditional methods capture only a fraction of adverse events occurring in clinical practice. Estimates indicate that spontaneous reporting systems detect merely 1–10% of serious ADRs and approximately 0.3% of mild-to-moderate events^{2,3}. Contemporary healthcare safety surveillance now encompasses not only pharmacological agents but also medical devices, blood products, biological therapies, and organ transplantation.

The World Health Organisation (WHO) estimates that medication errors and adverse drug reactions contribute to approximately 1.5 million preventable deaths annually worldwide. In resource-limited settings, the health burden is amplified by inadequate surveillance infrastructure, prevalence of counterfeit medicines, and constrained health system capacity. India, as the world's leading pharmaceutical manufacturer, supplies approximately 50%

of global vaccines and 80% of antiretroviral drugs. Despite this substantial contribution, India's pharmacovigilance infrastructure remains underdeveloped relative to its pharmaceutical output.

Traditional pharmacovigilance systems confront multiple interconnected challenges⁴: (1) persistent underreporting due to limited awareness among healthcare professionals and insufficient reporting incentives; (2) delayed signal detection resulting from manual data processing and literature review; (3) inadequate generation of real-world evidence from electronic health records (EHRs) and claims data; (4) fragmentation across vigilance domains (pharmaceuticals, medical devices, biological products); (5) poor data interoperability between healthcare institutions and regulatory bodies; and (6) insufficient capacity in resource-limited settings.

Artificial intelligence, encompassing machine learning (ML) and natural language processing (NLP), offers transformative potential to address these systemic limitations⁵. Recent advances have demonstrated capabilities to: (1) automate signal detection from heterogeneous data sources; (2) process unstructured clinical text at scale; (3) identify latent safety signals not



detectable through conventional methods; (4) enable near-real-time drug safety monitoring; and (5) support clinical decision-making through predictive analytics.

AI applications are expanding beyond traditional pharmacovigilance into drug repurposing, which identifies new therapeutic indications for existing pharmaceuticals. This process has been substantially accelerated by AI-driven target identification and molecular docking. The COVID-19 pandemic demonstrated the utility of AI platforms in rapidly identifying candidate therapies such as baricitinib and remdesivir ⁶. Materiovigilance, historically understudied, is increasingly enhanced by AI-enabled remote monitoring and predictive maintenance algorithms. Similarly, biovigilance and hemovigilance systems are advancing toward automated donor-recipient matching and infection surveillance through ML approaches.

India occupies a distinctive position in the global pharmacovigilance landscape. The Pharmacovigilance Programme of India (PvPI), established in 2010 and coordinated by the Indian Pharmacopoeia Commission (IPC) in collaboration with the Central Drugs Standard Control Organisation (CDSCO), has expanded to include 1,120 Adverse Drug Reaction Monitoring Centres (AMCs) nationwide. The National Coordination Centre (NCC) at IPC serves as the central hub for collecting, collating, and analysing ADR data from AMCs, pharmaceutical industries, and public health programmes. AMCs forward individual case safety reports (ICSRs) to the NCC through Vigiflow, a web-based tool developed by the Uppsala Monitoring Centre (UMC), after which the data are uploaded to Vigibase, the WHO global database. The PvPI has achieved recognition as a WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services. Despite these achievements, underreporting persists, EHR integration remains limited, and advanced data analytics capacity is still nascent. Similar constraints affect the Materiovigilance Programme of India (MvPI, launched in 2015) and the Hemovigilance Programme of India (HvPI, initiated in 2012), both of which face funding limitations and inadequate digital infrastructure.

The Ayushman Bharat Digital Mission (ABDM), launched in 2021, represents a strategic opportunity to address these challenges by creating a unified digital health ecosystem. By September 2024, the ABDM had registered over 400 million citizens with digital health IDs and indexed over 150 million health records. If effectively leveraged, this infrastructure could substantially strengthen population-level safety surveillance across all vigilance domains.

This review provides a comprehensive examination of AI applications in pharmacovigilance, drug repurposing, medical device safety, and biovigilance, with particular emphasis on the Indian regulatory context, the specific challenges LMICs face, and actionable pathways to build robust AI-enabled safety monitoring systems.

1. Artificial Intelligence in Pharmacovigilance and Drug Repurposing

1.1 Foundations of AI for Pharmacovigilance

Artificial intelligence encompasses a broad set of computational techniques that enable machines to perform tasks typically requiring human intelligence. Within pharmacovigilance, AI subfields of particular relevance include machine learning (algorithms that improve through experience), deep learning (multi-layered neural networks capable of learning hierarchical representations) ⁷, natural language processing (computational processing of human language), and big data analytics (techniques for handling large-scale, heterogeneous datasets).

The paradigm shift from rule-based systems to data-driven AI approaches has been catalysed by several factors: the exponential growth in healthcare data, including EHRs, claims databases, and social media; advances in computational power, particularly graphics processing units (GPUs); the development of sophisticated ML architectures such as transformers and graph neural networks; and the increasing availability of open-source frameworks and pre-trained models ⁸. These developments have enabled AI systems to identify complex, non-linear patterns in pharmacovigilance data that conventional statistical methods would likely miss. However, the adoption of AI in pharmacovigilance must be accompanied by rigorous validation, interpretability assessment, and consideration of ethical implications ⁹.

1.2 Artificial Intelligence in Pharmacovigilance

Pharmacovigilance has historically relied on voluntary reporting by healthcare professionals and patients, supplemented by periodic safety update reports and conventional statistical tools such as proportional reporting ratios (PRRs) and reporting odds ratios (RORs) ¹⁰. This traditional approach is associated with several well-documented limitations: substantial underreporting of adverse events, long delays between incident occurrence and official documentation, frequent omission of critical clinical details in reports, and limited sensitivity of standard statistical methods to detect subtle safety signals, particularly within specific patient subgroups.

AI offers increasingly effective solutions to these challenges across multiple domains:

1. Machine Learning-Based Signal Detection: Gradient boosting algorithms (XGBoost, LightGBM) and deep learning models have demonstrated superior performance in identifying unexpected drug-event associations compared with traditional disproportionality methods ¹¹. Random forest models have proven particularly effective for handling high-dimensional, heterogeneous adverse event datasets with categorical variables. Support vector machines (SVMs) with kernel functions excel in detecting rare events, making them suitable for orphan drug safety monitoring.

2. **Natural Language Processing:** NLP tools can process unstructured clinical text—including physician notes, discharge summaries, and admission records—to extract ADR-related information, substantially reducing the manual burden of case processing¹². Named entity recognition (NER) algorithms identify drug names, adverse events, and patient demographics from clinical narratives, with transformer-based models such as BERT achieving over 95% accuracy¹³. Relation extraction systems automatically construct drug-event pairs from clinical text, often enriched through knowledge graph integration.

3. **Automated MedDRA Coding:** The standardised classification of adverse events using the Medical Dictionary for Regulatory Activities (MedDRA), a labour-intensive process, can now be automated with over 90% exact-match accuracy and approximately 95% overall accuracy¹⁴.

4. **Real-World Evidence Mining:** AI systems can systematically search EHRs, insurance claims databases, and registry data to identify safety patterns that might otherwise remain undetected^{15,16}. During the COVID-19 pandemic, NLP-based analysis of social media and search queries provided early safety signals for emerging therapies¹⁷.

5. **Literature Surveillance:** AI-assisted systematic review and literature mining enhance the efficiency of identifying relevant safety information from the rapidly expanding biomedical literature¹⁸.

6. **Causality Assessment:** ML models can identify relationships between drug exposure and adverse outcomes, supporting standardised causality assessment¹⁹.

India's contribution to Vigibase—which now contains over 40 million individual case safety reports from more than 160 countries²⁰—has grown substantially, with PvPI having accumulated over 894,000 ICSRs as of September 2024. However, significant potential remains for leveraging AI within national programmes such as PvPI to enhance signal detection, automate case processing, and improve population-level surveillance.

1.3 Artificial Intelligence in Drug Repurposing

Drug repurposing—the identification of new therapeutic indications for approved drugs—offers advantages over de novo drug development, including reduced development timelines, established safety profiles, and lower costs. Traditional repurposing has relied on serendipitous clinical observations and mechanism-based hypotheses, which are inherently slow and resource-intensive. AI-driven approaches have fundamentally accelerated this process through multiple complementary strategies^{21,22}.

Computational target identification and molecular docking constitute the first major AI-enabled approaches. AI-powered bioinformatics platforms can identify novel drug-target interactions and reveal unexpected connections between medications and disease pathways. For instance, metformin, a first-line treatment for type 2 diabetes, has been investigated for potential applications in cancer

prevention and age-related disorders through AI-driven analysis of its molecular targets and downstream signalling effects²³. Deep learning-based docking algorithms can screen millions of compound-target pairs in silico, substantially reducing the time and cost of experimental screening.

Knowledge graphs and graph neural networks (GNNs) represent a transformative advance in computational drug repurposing. Biomedical knowledge graphs integrate diverse data types—including genes, proteins, drugs, diseases, pathways, and side effects—into unified, machine-readable representations. GNNs operate directly on these graph structures, learning low-dimensional embeddings of nodes (e.g., drugs, diseases) and edges (e.g., drug-target interactions, disease-gene associations) through message-passing frameworks²⁴. This enables computational reasoning for drug repurposing by propagating information across the graph topology. For example, GNN-based link prediction can identify previously unknown drug-disease associations by leveraging the network neighbourhood of a given drug. Recent studies have demonstrated the utility of heterogeneous graph transformers and relational graph convolutional networks in predicting drug repurposing candidates for complex diseases, outperforming traditional matrix factorisation and kernel-based methods.

Network pharmacology extends the graph-based approach by systematically analysing the multi-target effects of drugs within the context of biological networks. Unlike the conventional "one drug, one target" paradigm, network pharmacology recognises that therapeutic efficacy often arises from modulation of multiple nodes within disease-associated networks. AI-enhanced network pharmacology methods integrate transcriptomic, proteomic, and interactomic data to identify optimal intervention points, predict polypharmacological effects, and anticipate potential adverse events²⁵. The COVID-19 pandemic provided a compelling demonstration of these approaches: AI platforms integrating genomic, proteomic, and clinical data rapidly identified baricitinib as a candidate treatment by matching its anti-inflammatory mechanism with the immune dysregulation profiles observed in severe COVID-19²⁶. Similarly, network-based proximity analyses in human interactomes enabled the systematic identification of repurposable drugs for SARS-CoV-2.

Real-world evidence analysis constitutes another major AI-enabled repurposing strategy. ML analysis of EHRs and insurance claims data can reveal unexpected drug-disease associations by systematically comparing outcomes across large patient populations²⁷. Pharmacovigilance databases themselves serve as valuable resources for repurposing discovery: unexpected beneficial effects reported as ADRs in one context may signal therapeutic potential in another. Advanced pharmacovigilance analytics integrating Vigibase data with biomedical knowledge graphs could systematically identify such repurposing opportunities.

The convergence of these AI approaches has substantially accelerated the drug repurposing pipeline. During the



COVID-19 pandemic, AI-driven platforms rapidly identified multiple candidate therapies, including remdesivir (originally developed for Ebola), baricitinib (a JAK inhibitor for rheumatoid arthritis), and interferon beta, several of which were validated through clinical trials^{28,29}. The success of these efforts has catalysed broader adoption of AI for drug repurposing across therapeutic areas, including oncology, neurodegenerative disorders, and rare diseases.

1.4 Artificial Intelligence in Materiovigilance

Materiovigilance encompasses the monitoring of adverse events associated with medical devices, ranging from simple consumables such as gauze to complex active implantable devices, including cardiac pacemakers and neurostimulators. Unlike pharmaceuticals, medical devices exhibit inherent manufacturing variability and are subject to wear, software degradation, and user-dependent performance factors, necessitating robust post-market surveillance³⁰.

The Materiovigilance Programme of India (MvPI), coordinated by the IPC in collaboration with the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), was launched in 2015 to monitor device-related adverse events. Despite this framework, the MvPI receives only 2,000–3,000 reports annually—substantially fewer than pharmaceutical ADR reports—owing to weak regulatory mandates, fragmented supply chains, limited healthcare provider awareness, inadequate reporting infrastructure, and the absence of formal reporting incentives. The WHO estimates that 10–20% of medical devices in low-resource settings may be counterfeit or substandard, yet the MvPI currently lacks the capacity for systematic authentication.

AI offers multiple opportunities to strengthen materiovigilance:

1. IoT-Enabled Real-Time Monitoring: Internet of Things (IoT) sensors embedded in medical devices can enable continuous performance monitoring and early detection of malfunctions. ML algorithms applied to sensor data streams can identify patterns preceding device failure, enabling proactive intervention³¹.
2. Predictive Maintenance: AI models that analyse device usage patterns, environmental factors, and historical failure data can predict maintenance requirements before device breakdown occurs, reducing patient risk and unplanned downtime³².
3. Image-Based Quality Assessment: Convolutional neural networks (CNNs) applied to radiological and photographic images can detect device abnormalities, manufacturing defects, or signs of wear that may compromise device safety³³.
4. Supply Chain Analytics: ML algorithms can identify patterns in device recalls, adverse event reports, and distribution data to detect counterfeit products and target supply chain interventions.

To advance AI-enabled materiovigilance in India, the CDSCO should consider developing mandatory post-market surveillance requirements with AI-based analytics components, establishing IoT connectivity standards for high-risk devices, and creating a national device registry integrated with the ABDM infrastructure.

1.5 Artificial Intelligence in Biovigilance and Hemovigilance

Biovigilance monitors safety issues related to biological products, while hemovigilance specifically addresses adverse events associated with blood transfusion. The Hemovigilance Programme of India (HvPI), jointly administered with the Indian Academy of Paediatrics, constitutes India's principal biovigilance framework. Despite 12–14 million blood units being collected annually in India, the HvPI receives only 500–800 transfusion-related adverse event reports per year, reflecting severe underreporting. This underreporting results from the absence of EHR integration, lack of structured reporting protocols, limited pathogen screening capacity, and inadequate staff training.

India's immunisation programme, which covers approximately 130 million children annually, similarly suffers from insufficient adverse-event monitoring. The gap becomes particularly evident when new vaccines are introduced, as demonstrated during the recent rotavirus and pneumococcal vaccine roll-outs.

AI has potential to transform both domains through several approaches: (1) automated blood bank information system integration for seamless adverse event capture³⁴; (2) predictive models for transfusion reactions based on donor-recipient characteristics and clinical parameters; (3) ML-optimised donor screening to identify high-risk donors and reduce transfusion-transmissible infections³⁵; (4) NLP-based detection of vaccine adverse event signals from social media, EHRs, and public health surveillance data³⁶; and (5) real-time point-of-care monitoring of haematologic parameters using AI-enhanced analysers.

2. AI Technologies Employed in Vigilance Systems

2.1 Machine Learning Algorithms for Signal Detection

Several ML algorithms have demonstrated effectiveness for safety signal detection:

Random Forest: This ensemble method constructs multiple decision trees and aggregates their predictions. It demonstrates strong performance on heterogeneous, real-world data containing categorical variables, making it well-suited for adverse event datasets characterised by mixed data types and non-linear relationships³⁷.

Support Vector Machines (SVMs): SVMs identify optimal decision boundaries in high-dimensional feature spaces using kernel functions. They are particularly effective for rare event detection, such as safety monitoring for orphan drugs or uncommon adverse events, where class imbalance is pronounced³⁸.

Gradient Boosting (XGBoost, LightGBM, CatBoost): These algorithms iteratively build ensembles of weak learners,



each correcting the errors of its predecessors. They have demonstrated superior performance in drug-safety applications, particularly when training data are abundant and feature interactions are complex ³⁹.

Deep Learning (RNNs, Transformers): Recurrent neural networks (RNNs) and transformer architectures excel at processing sequential clinical data, including temporal patterns in adverse event occurrence and longitudinal patient records. However, their "black box" nature poses challenges for clinical deployment; explainability tools such as SHAP (SHapley Additive exPlanations) and LIME (Local Interpretable Model-Agnostic Explanations) are essential for building clinician trust ⁴⁰.

2.2 Natural Language Processing Applications

NLP represents one of the most impactful AI technologies for pharmacovigilance, enabling large-scale processing of unstructured clinical text:

Named Entity Recognition (NER): NER algorithms extract drug names, adverse events, dosages, and patient demographics from clinical narratives. Transformer-based models (e.g., BioBERT, ClinicalBERT) achieve over 95% accuracy on biomedical NER tasks.

Relation Extraction: These systems identify semantic relationships between drugs and adverse events within text, automatically constructing drug-event pairs from clinical narratives and the biomedical literature. Knowledge graph integration enhances the contextual richness of extracted relations ⁴¹.

Topic Modelling: Unsupervised methods such as Latent Dirichlet Allocation (LDA) can identify emerging topics in large collections of adverse event reports, facilitating hypothesis generation for novel safety signals ⁴².

Sentiment and Stance Analysis: Applied to social media data, these techniques help distinguish genuine safety concerns from general discussion, improving signal quality from patient-reported sources ⁴³.

Automated MedDRA Coding: ML models for automated adverse event classification now achieve over 90% exact-match rates and approximately 95% accuracy for broader category assignment ⁴⁴.

2.3 Big Data Analytics Infrastructure

Effective AI deployment in pharmacovigilance requires a robust data infrastructure. EHR integration is essential for enabling analysis of prescribing patterns and patient outcomes while maintaining data protection ⁴⁵. Insurance claims and billing databases provide complementary insights into drug utilisation and outcomes, even when detailed clinical data are unavailable ⁴⁶.

Real-world evidence platforms such as Synapse and Optum facilitate drug-outcome analyses but are often cost-prohibitive for regulatory authorities in LMICs. Cloud computing provides a scalable infrastructure for handling large pharmacovigilance datasets. Federated learning offers

a privacy-preserving alternative: ML models are trained across decentralised data sources without centralising sensitive patient information, making it particularly suitable for the ABDM ecosystem where data sovereignty is paramount ⁴⁷.

2.4 Generative AI and Large Language Models

Generative AI, particularly large language models (LLMs), represents an emerging frontier for pharmacovigilance:

Automated Case Narratives: LLMs can generate concise, standardised case summaries from clinical data, reducing the documentation burden. However, human oversight remains essential to address potential inaccuracies.

Safety Report Drafting: LLMs assist in creating safety reports and SUSAR (Suspected Unexpected Serious Adverse Reaction) narratives, with studies reporting a 30–50% reduction in documentation time ⁴⁸.

Risk Communication: LLMs can tailor pharmacovigilance findings for diverse audiences—healthcare professionals, regulators, and patients—while maintaining accuracy.

Critical Limitations: LLMs are susceptible to generating inaccurate information, or "hallucinations." A study evaluating GPT-4's pharmacological knowledge found errors in 15–20% of drug-related details. Accordingly, LLM use in pharmacovigilance should be restricted to drafting support, with all outputs requiring expert human review before use in regulatory or clinical contexts.

3. Indian Perspective: Current Systems, Challenges, and Opportunities

3.1 Pharmacovigilance Programme of India (PvPI)

Established in July 2010 by the Ministry of Health and Family Welfare, the PvPI operates through a nationwide network coordinated by the NCC at the IPC in Ghaziabad. The programme has expanded from 22 AMCs in 2010 to 1,120 AMCs as of 2025, encompassing government, private, and corporate hospitals, as well as district and primary health centres across all states and union territories.

PvPI Workflow and Reporting Architecture: The standardised reporting workflow proceeds as follows: (1) suspected ADRs are identified by healthcare professionals or consumers at the point of care; (2) reports are documented using standardised Suspected ADR Reporting Forms, available in English and regional languages; (3) reports are submitted to the nearest AMC, where Pharmacovigilance Associates (PVAs) perform initial validation, duplicate detection, and causality assessment using WHO-UMC criteria; (4) validated ICSRs are entered into VigiFlow, the web-based ICSR management system provided by the UMC; (5) NCC-PvPI performs quality review, medical coding using MedDRA, and signal detection; (6) quality-checked ICSRs are uploaded to VigiBase, the WHO global database; and (7) identified signals are communicated to the CDSCO for potential regulatory action, including safety alerts, label changes, and prescribing information updates. As of September 2024, the NCC-PvPI



has issued 169 drug safety alerts and recommended multiple changes to prescribing information leaflets (PILs). Despite this structured framework, the PvPI receives approximately 15,000–16,000 ICSRs per month (based on January 2025 data), equating to approximately 180,000–200,000 reports annually. While this represents substantial growth from earlier years, it remains disproportionately low relative to India's population of over 1.4 billion. The estimated ADR reporting rate of 2–5% of serious events^{49,50} is attributable to poor awareness of pharmacovigilance among healthcare professionals, inadequate training, perceived reporting burden, lack of feedback to reporters, and absence of mandatory reporting requirements. Minimal EHR integration forces predominantly manual submissions, limiting both reporting volume and data completeness.

Signal detection relies primarily on basic statistical methods with inconsistent application of ROR/PRR and no systematic incorporation of ML⁵¹. AI offers targeted solutions: EHR-integrated automated reporting could increase detection by a projected 20–30%; ML-enhanced signal detection could identify subtle safety signals currently missed; NLP-driven case processing could reduce manual workload and accelerate reporting timelines; and ABDM integration could enable population-level surveillance with unprecedented coverage. Table 1 provides the comparative analysis of pharmacovigilance maturity and AI implementation across global regions, contextualising India's position within the international landscape.

Table 1: Comparative Pharmacovigilance Maturity and AI Implementation Across Global Regions.

Parameter	United States	European Union	China	India
Primary Regulatory Body	FDA (CDER, CBER)	EMA, National Regulators	NMPA (CFDA)	CDSCO, IPC
Annual ADR Reports	>1,000,000	>500,000	~100,000	~180,000–200,000
Healthcare Facility Participation	>5,000 facilities	>3,000 facilities	~2,000 facilities	~1,120 centres
EHR Integration	Extensive, ~80% hospitals	Widespread; varies by country	Emerging, ~30% major hospitals	Limited; <10% facilities
AI/ML Implementation	Mature; operational signal detection	Advanced, integrated analytics	Emerging pilot programs	Minimal; no operational systems
Signal Detection Methodology	ROR, PRR, ML algorithms, NLP	Statistical + emerging ML	Statistical methods advancing	Primarily manual review
Est. Reporting Rate (serious events)	~20–30%	~15–25%	~5–10%	~2–5%
Regulatory Guidance on AI	Emerging (SaMD guidance)	In development	In development	Absent
Digital Health Infrastructure	Mature; widespread adoption	Advanced; country-dependent	Developing, rapid growth	Emerging (ABDM platform)

ADR: adverse drug reaction; ROR: reporting odds ratio; PRR: proportional reporting ratio; ML: machine learning; NLP: natural language processing; CDSCO: Central Drugs Standard Control Organisation; IPC: Indian Pharmacopoeia Commission; EMA: European Medicines Agency; FDA: Food and Drug Administration; NMPA: National Medical Products Administration; ABDM: Ayushman Bharat Digital Mission.

The comparative analysis reveals several key patterns. Pharmacovigilance infrastructure correlates strongly with economic development and the maturity of the healthcare system. AI implementation is most advanced in developed nations with mature EHR systems and high reporting volumes. LMICs such as India face structural challenges, including limited digital infrastructure and substantial underreporting, despite high disease burdens. Global regulatory frameworks for AI validation remain under development, with India notably lacking specific guidance. Geographic disparities in reporting rates contribute to the underrepresentation of LMIC populations in global adverse event databases.

3.2 Materiovigilance Programme of India (MvPI)

Launched in 2015 and coordinated by the IPC in collaboration with SCTIMST, the MvPI collects voluntary medical device safety reports. However, it receives only 2,000–3,000 reports annually, substantially fewer than pharmaceutical ADR reports. This gap is attributable to weak regulatory mandates, fragmented supply chains, limited healthcare provider awareness, inadequate infrastructure, and the absence of formal reporting incentives. Counterfeiting compounds the challenge, with the WHO estimating that 10–20% of medical devices in low-resource settings may be substandard or counterfeit; the MvPI currently lacks the capacity for systematic authentication. Underdeveloped CDSCO regulatory oversight and the absence of mandatory post-market

surveillance leave many device-related adverse events unrecorded.

AI integration presents significant opportunities: IoT-based real-time monitoring of high-risk devices, image-based quality assessment to detect manufacturing defects, ML-driven supply chain analytics to identify patterns of counterfeit distribution, and predictive maintenance algorithms to anticipate device failures before they occur.

3.3 Hemovigilance and Biovigilance in India

The HvPI, jointly administered with the Indian Academy of Paediatrics, is India's principal biovigilance framework. Despite collecting 12–14 million blood units annually, the HvPI receives only 500–800 transfusion-related adverse event reports per year, reflecting severe underreporting attributable to absent EHR integration, lack of structured reporting protocols, limited pathogen-screening capacity, and inadequate staff training. India's immunisation programme, reaching approximately 130 million children annually, similarly faces insufficient adverse event monitoring, a gap highlighted by recent rotavirus and pneumococcal vaccine introductions.

AI can improve both domains through: (1) automated blood bank information system integration for seamless adverse event capture; (2) predictive models for transfusion reactions and donor-recipient matching⁵²; (3) ML-optimised donor screening to reduce transfusion-transmissible infections; (4) NLP-based detection of vaccine adverse event signals from social media, EHRs, and public health surveillance data; and (5) real-time point-of-care monitoring of haematologic parameters using AI-enhanced analysers.

3.4 Ayushman Bharat Digital Mission (ABDM) as Strategic Platform

Launched in 2021, the ABDM aims to create a unified digital health ecosystem through the establishment of Ayushman Bharat Health Accounts (ABHA), the standardisation of health records via the Health Data Management Policy, and enabling of secure cross-institutional data sharing. By September 2024, the ABDM had registered over 400 million citizens with ABHA (digital health IDs) and indexed over 150 million health records. This unprecedented scale creates an unparalleled opportunity for population-level safety surveillance.

Strategic Integration Opportunity: The ABDM provides a foundational infrastructure for an integrated, AI-enabled pharmacovigilance, materiovigilance, and biovigilance system. Key benefits include: (1) automated data capture through integration with hospital information systems, eliminating manual reporting; (2) population-level analysis enabling identification of adverse events across demographically diverse populations through linked longitudinal health records; (3) real-time surveillance allowing immediate detection of emerging signals via data streaming from healthcare providers; and (4) consent-based research access to anonymised adverse event data.

Implementation Challenges: The ABDM currently prioritises patient access and interoperability over safety surveillance. Targeted adaptations required include: (1) establishment of standardised adverse event data fields within ABDM schema; (2) clarification of governance roles for safety surveillance across the CDSCO, IPC, and National Health Authority; (3) enhanced data security protocols for real-time surveillance data streams; and (4) legal provisions enabling safety surveillance without individual consent under data protection laws, balanced with robust privacy safeguards.

3.5 Critical Challenges to AI Implementation in India

India faces several substantial challenges in implementing AI for pharmacovigilance:

Digital Infrastructure: A significant proportion of hospitals and clinics lack reliable EHR systems, hindering automated capture of adverse events. Healthcare IT spending in India remains below 1% of healthcare expenditure, compared with 5–10% in high-income countries.

Workforce Capacity: There is a pronounced shortage of professionals with combined clinical and AI expertise. Medical and pharmacy curricula have not yet incorporated pharmacovigilance informatics or AI fundamentals, perpetuating the skills gap. Very few healthcare professionals have training bridging clinical practice and data science.

Regulatory Gaps: The CDSCO has not issued specific guidance for AI tool validation or accountability in pharmacovigilance contexts. This regulatory vacuum creates uncertainty for technology developers and adopting institutions alike.

Financial Constraints: Pharmacovigilance programmes in LMICs operate with limited budgets. The cost of AI infrastructure, including computational resources, software licensing, and specialised personnel, presents a substantial barrier.

Algorithmic Bias: A significant concern is that AI models trained predominantly on data from Western populations may underperform for Indian patients, who differ in genetic ancestry, dietary patterns, lifestyle factors, and disease epidemiology. Without rigorous local validation, these tools risk producing inaccurate or inequitable results⁵³.

4. Regulatory and Ethical Considerations for AI in Pharmacovigilance

The integration of AI into safety monitoring raises critical questions regarding validation, explainability, accountability, and equitable application.

4.1 Global Regulatory Frameworks

Regulatory frameworks for AI in pharmacovigilance remain in their early stages globally. The WHO has articulated broad principles encompassing transparency, accountability, and equity. The US FDA has issued guidance on AI/ML-based software as a medical device (SaMD), and the EMA has



begun exploring AI in select monitoring activities. However, detailed, pharmacovigilance-specific AI regulations remain absent in most jurisdictions.

4.2 CDSCO Regulatory Framework and AI

In India, the CDSCO currently provides no specific guidance on AI in pharmacovigilance. Pharmaceutical manufacturers are expected to maintain pharmacovigilance systems under existing regulations, but there are no provisions addressing modern AI approaches. This regulatory gap creates uncertainty for stakeholders. Experts recommend that the CDSCO develop guidance addressing several key areas:

1. Algorithm Validation: Utilisation of independent datasets and cross-validation methods with defined performance metrics benchmarked against manual expert review.
2. Explainability: Documentation requirements for how algorithms reach conclusions, including feature importance analysis.
3. Data Quality: Standards for completeness, accuracy, timeliness, and representativeness of training data.
4. Bias Assessment: Evaluation of algorithm performance across relevant population subgroups defined by age, gender, geographic region, and socioeconomic status.
5. Accountability: Clear allocation of responsibilities when AI systems inform regulatory decisions.
6. Transition Pathways: Provisions for concurrent operation of traditional and AI-based systems during initial implementation phases.

4.3 Explainability and Transparency in AI-Driven Surveillance

A central tension in the deployment of clinical AI lies between predictive accuracy and interpretability⁵⁴. Deep learning models achieve high predictive performance but operate as "black boxes," limiting clinicians' understanding of their outputs. In safety-critical pharmacovigilance, explainability is often appropriately prioritised over raw accuracy. Several explainability methods address this challenge: SHAP (SHapley Additive exPlanations) provides unified feature attribution based on cooperative game theory; LIME (Local Interpretable Model-Agnostic Explanations) generates local approximations of model decisions; and attention mechanisms highlight input features most influential to transformer-based model predictions. However, these methods add computational overhead and require validation themselves⁵⁵.

4.4 Bias, Fairness, and Equity in AI Systems

Algorithmic bias—systematic errors associated with specific population subgroups—represents a critical concern for pharmacovigilance AI systems^{56,57}. Bias may arise from historical disparities in healthcare data, underrepresentation of certain populations in research, and structural inequities in healthcare access. In pharmacovigilance, algorithms trained on data from developed countries may underperform in LMICs due to differences in disease prevalence, genetic variation, healthcare-seeking behaviours, and data completeness.

To promote equitable AI deployment, several strategies are recommended: (1) intentional inclusion of LMIC populations

in training data; (2) rigorous performance evaluation across demographic subgroups; (3) robustness analysis with systematically missing data patterns; (4) establishment of minimum performance standards for all population subgroups; and (5) transparent reporting of model limitations and known performance disparities.

4.5 Data Privacy and Security

Pharmacovigilance inherently involves sensitive personal health information. Centralised databases facilitate population-level pattern detection but increase the risk of data breaches. Federated learning offers a promising alternative: ML models are trained locally at individual institutions, and only aggregated model updates—never patient-level data—are shared centrally. This approach aligns well with the ABDM's architecture and India's data protection framework⁴⁷. Additional privacy-preserving techniques, such as differential privacy and homomorphic encryption, can provide supplementary protection, though they may entail modest accuracy trade-offs. Clear consent frameworks are needed for AI-enabled pharmacovigilance, distinguishing between primary use (clinical care) and secondary use (population surveillance and research)⁵⁸.

5. Global Comparative Analysis: Pharmacovigilance Maturity Across Regions

Understanding India's position within the global pharmacovigilance landscape requires a comparative analysis of maturity, infrastructure, and AI implementation across regions. The comparative analysis in Table 1 reveals the following key patterns: (1) pharmacovigilance infrastructure correlates strongly with economic development and healthcare system maturity; (2) AI implementation is most advanced in developed nations with mature EHR systems and high reporting volumes; (3) LMICs such as India face structural challenges including limited digital infrastructure and substantial underreporting despite high disease burdens; (4) global regulatory frameworks for AI validation remain under development, with India notably lacking specific guidance; and (5) geographic disparities in reporting rates contribute to underrepresentation of LMIC populations in global adverse event databases such as Vigibase, where over 80% of reports originate from high-income countries²⁰.

6. Future Directions and Emerging Technologies

India's Roadmap to AI-Enabled Pharmacovigilance: To establish a mature, AI-enabled safety surveillance system, a coordinated national roadmap is essential. Key strategic priorities across three phases are outlined in Table 2.

Emerging technologies poised to shape the next generation of pharmacovigilance include:

Blockchain for Data Integrity: Distributed ledger technology can provide tamper-evident logging of adverse event reports, enhancing trust in pharmacovigilance data⁵⁹.

Precision Pharmacovigilance: Integration of pharmacogenomic, metabolomic, and proteomic data with



clinical outcomes, analysed through ML, could enable individualised risk prediction for ADRs ⁵⁷. This approach is particularly relevant for India's genetically diverse population.

Multimodal AI Integration: Combining structured clinical data, unstructured text, medical imaging, and wearable device data for comprehensive safety assessment.

Human-in-the-Loop Systems: Hybrid approaches that combine AI efficiency with clinical expertise for signal validation, maintaining human oversight while maximising automation benefits.

Explainable AI Platforms: Development of pharmacovigilance-specific interpretability tools that provide clinically meaningful explanations for model predictions, thereby fostering clinician trust and regulatory acceptance.

Table 2: Strategic Roadmap for AI Integration in Indian Pharmacovigilance.

Phase	Focus Area	Key Objectives
Phase 1	Regulatory Framework Development	Develop explicit CDSCO guidance on AI validation, explainability, bias assessment, and accountability; conduct pilot projects integrating PvPI with hospital information systems; establish baseline performance metrics for AI-based signal detection.
Phase 2	Infrastructure and Proof-of-Concept	Establish dedicated AI/ML teams at NCC-PvPI; develop and validate baseline ML models for signal detection on Indian datasets; integrate teaching hospitals and AMCs with ABDM; implement data governance frameworks; train healthcare professionals in pharmacovigilance informatics.
Phase 3	Scaling and National Integration	Expand EHR integration to private hospitals and secondary care facilities; deploy operational ML-based signal detection across all AMCs; integrate PvPI, MvPI, and HvPI into a unified AI-enabled surveillance platform; foster international collaboration and benchmarking; develop an India-specific safety database with integrated AI analytics.

7. Identified Research Gaps and Knowledge Deficits

Despite growing interest in AI for pharmacovigilance, several critical knowledge gaps persist, particularly in the context of India and other LMICs:

First, Indian pharmacovigilance datasets remain limited in size and diversity relative to those from high-income countries. While PvPI has accumulated over 894,000 ICSRs, the majority originate from academic medical centres. Development of robust ML models requires larger, more representative datasets that include primary care, rural, and private healthcare settings.

Second, most validation studies of AI-based signal-detection algorithms rely on datasets from developed countries (primarily the FDA's FAERS and the EU's EudraVigilance). The transferability of these algorithms to Indian and other LMIC settings remains inadequately characterised, raising concerns about performance degradation due to differences in population genetics, prescribing practices, and data quality.

Third, AI applications in materiovigilance remain substantially underexplored. Predictive maintenance for specific device categories, IoT-based surveillance architectures, and counterfeit detection systems require dedicated research attention, particularly for devices used in resource-limited settings.

Fourth, biovigilance research lags behind pharmacovigilance in AI adoption. Detection of vaccine adverse events, transfusion reactions, and transplant complications continues to rely predominantly on manual methods. Studies evaluating ML approaches in these domains, especially in resource-constrained environments, are urgently needed.

Fifth, while NLP-based social media monitoring has been studied in high-income countries, validation work specific to the Indian context is minimal. Future research should examine the sensitivity and specificity of these methods across Indian languages, along with the demographic and cultural factors that influence social media discussion of adverse events.

Sixth, federated learning, while promising for healthcare AI generally, has seen limited application in pharmacovigilance specifically. Research is needed on optimal model architectures, privacy-performance trade-offs, and governance structures for multi-stakeholder collaboration within the ABDM framework.

Seventh, pharmacovigilance-specific explainability techniques require development. General-purpose interpretability tools may not adequately capture the domain-specific reasoning required for clinical pharmacovigilance decision-making.

Finally, a systematic assessment of bias in LMIC contexts is critically needed. Research should evaluate the performance of ML signal detection algorithms across India's diverse demographic groups—considering age, gender, geographic region, socioeconomic status, and urban versus rural healthcare settings—to identify and mitigate potential disparities.

8. Challenges and Proposed Solutions: A Synthesised Framework

Table 3 presents a comprehensive framework mapping key challenges to actionable solutions for AI implementation in Indian pharmacovigilance and related vigilance systems.

Table 3: Key Challenges and Proposed Solutions Framework for AI Implementation in Indian Pharmacovigilance and Related Vigilance Systems.

Challenge Category	Specific Challenges	Proposed Solutions
Digital Infrastructure	- Limited EHR adoption - Rural healthcare unconnected	- Priority funding for hospital information systems - ABDM acceleration - Cloud-based infrastructure
Data Governance	- Privacy concerns - Data protection ambiguity - Multiple stakeholders	- Comprehensive data governance framework - Federated learning approaches - Clear consent mechanisms
Workforce Capacity	- Limited AI/ML expertise - Inadequate pharmacovigilance training	- AI/ML training programmes - Interdisciplinary collaboration - Career development pathways
Regulatory Framework	- Absent AI guidance - Unclear validation standards - Accountability gaps	- CDSO guidance development - International harmonisation - Pilot programme evaluation
Financial Resources	- Limited budgets - Competing priorities - Cost of AI infrastructure	- Dedicated government funding - International donor support - Cost-sharing partnerships
Underreporting	- Low awareness - No incentives - Lack of feedback	- Automated EHR-based case detection - Feedback mechanisms - Professional incentives
Algorithmic Bias	- Training data imbalance - LMIC underrepresentation - Validation gaps	- India-specific datasets - Cross-validation across populations - Transparent bias reporting
System Fragmentation	- Separate PV/MV/BV systems - No integration	- Unified governance - Integrated platform development - Coordinated oversight

CONCLUSION

Artificial intelligence and machine learning hold significant potential to transform pharmacovigilance, drug repurposing, materiovigilance, and biovigilance in India and other LMICs. Current systems, constrained by underreporting, delayed signal detection, fragmented infrastructure, and limited analytical capacity, stand to benefit substantially from the integration of AI capabilities across the surveillance workflow.

The Ayushman Bharat Digital Mission, with its ambitious goal of creating digital health identities for over one billion citizens, represents a transformative opportunity. If strategically leveraged with AI-powered analytics, the ABDM could enable near-real-time, population-level safety surveillance at a scale unprecedented in LMIC settings. However, realising this potential requires coordinated action across several domains.

Specific recommendations for advancing AI-enabled pharmacovigilance in India include:

- (1) **Regulatory Modernisation:** The CDSCO should issue comprehensive guidance on AI validation, explainability, bias assessment, and accountability within 18 months, drawing on international frameworks from the FDA, EMA, and WHO while adapting them to the Indian context.
- (2) **Infrastructure Investment:** The government should allocate dedicated funding for hospital information system adoption, ABDM integration with AMCs, and cloud-based AI

infrastructure for pharmacovigilance, targeting at least 50% EHR coverage in AMC-affiliated hospitals by 2028.

- (3) **Workforce Development:** Pharmacy and medical curricula should incorporate pharmacovigilance informatics and AI fundamentals. IPC should establish a national pharmacovigilance AI fellowship programme to train 100 specialists over five years.

- (4) **Data Ecosystem:** Creation of a high-quality, India-specific, anonymised pharmacovigilance dataset with standardised formats suitable for ML research and validation, governed by clear data-sharing protocols and privacy safeguards.

- (5) **Integrated Surveillance:** Development of a unified, AI-enabled national vigilance platform integrating PvPI, MvPI, and HvPI data streams with ABDM infrastructure, enabling cross-domain signal detection and coordinated regulatory response.

- (6) **International Collaboration:** Active participation in WHO pharmacovigilance AI working groups, technology transfer agreements with advanced pharmacovigilance systems, and contribution to global AI validation standards, ensuring LMIC representation.

- (7) **Pilot Implementation:** Launch of 5–10 AI-enabled pharmacovigilance pilot projects in high-volume AMCs, with rigorous evaluation of reporting rates, signal detection performance, cost-effectiveness, and clinician acceptance before national scale-up.



The pharmaceutical industry, which contributes substantially to India's economy and global health, stands to benefit from safer medicines and stronger monitoring systems that enhance public trust and regulatory efficiency. If India navigates this transition effectively, it has the potential not only to strengthen its own health safety infrastructure but also to establish a replicable model for AI-enabled pharmacovigilance that other LMICs facing similar challenges can adapt to their contexts. The next five to seven years will be decisive in determining whether this potential is realised.

Abbreviations

Abbreviation	Full Form
ABDM	Ayushman Bharat Digital Mission
ABHA	Ayushman Bharat Health Account
ADR	Adverse Drug Reaction
AI	Artificial Intelligence
AMC	ADR Monitoring Centre
BERT	Bidirectional Encoder Representations from Transformers
CBER	Centre for Biologics Evaluation and Research
CDER	Centre for Drug Evaluation and Research
CDSCO	Central Drugs Standard Control Organisation
CNN	Convolutional Neural Network
EHR	Electronic Health Record
EMA	European Medicines Agency
FDA	Food and Drug Administration
GNN	Graph Neural Network
GPT	Generative Pre-trained Transformer
HvPI	Hemovigilance Programme of India
ICSR	Individual Case Safety Report
IoT	Internet of Things
IPC	Indian Pharmacopoeia Commission
LDA	Latent Dirichlet Allocation
LIME	Local Interpretable Model-Agnostic Explanations
LLM	Large Language Model
LMIC	Low- and Middle-Income Country
MedDRA	Medical Dictionary for Regulatory Activities
ML	Machine Learning
MvPI	Materiovigilance Programme of India
NCC	National Coordination Centre
NER	Named Entity Recognition
NLP	Natural Language Processing
NMPA	National Medical Products Administration (China)
PIL	Prescribing Information Leaflet
PRR	Proportional Reporting Ratio
PvPI	Pharmacovigilance Programme of India
RNN	Recurrent Neural Network
ROR	Reporting Odds Ratio
RWE	Real-World Evidence
SaMD	Software as a Medical Device

SCTIMST	Sree Chitra Tirunal Institute for Medical Sciences and Technology
SHAP	SHapley Additive exPlanations
SUSAR	Suspected Unexpected Serious Adverse Reaction
SVM	Support Vector Machine
TRALI	Transfusion-Related Acute Lung Injury
UMC	Uppsala Monitoring Centre
WHO	World Health Organisation

Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

REFERENCES

- Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA*. 1998;279(15):1200-5. doi:10.1001/jama.279.15.1200
- Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. *Clin Pharmacol Ther*. 1981;30(2):239-45. doi:10.1038/clpt.1981.154
- Molokhia M, Pirmohamed M. Pharmacovigilance: current status and perspective. *Br J Clin Pharmacol*. 2017;83(10):2123-5. doi:10.1111/bcp.13326
- Huynh C, Ting VJ, Ito S. Current challenges in adverse drug reaction surveillance: a practical review. *Can Pharm J*. 2016;149(4):208-16. doi:10.1177/1715163516647483
- Li Y, Jiang X, Li R, et al. Applications and explorations of deep learning for drug discovery and development. *Sci Rep*. 2022;12(1):12590. doi:10.1038/s41598-022-16828-4
- Wishart DS, Feunang YD, Guo AC, et al. DrugBank 5.0: a major update to the DrugBank database for 2018. *Nucleic Acids Res*. 2018;46(D1):D1074-82. doi:10.1093/nar/gkx1037
- LeCun Y, Bengio Y, Hinton G. Deep learning. *Nature*. 2015;521(7553):436-44. doi:10.1038/nature14539
- Brown TB, Mann B, Ryder N, et al. Language models are few-shot learners. *Adv Neural Inf Process Syst*. 2020;33:1877-901.
- Lipton ZC. The mythos of model interpretability. *Queue*. 2016;14(5):31-57. doi:10.1145/2998356.2998367
- Szarfman A, Tonning JM, Doraiswamy PM. Pharmacovigilance in the 21st century: new systematic tools for an old problem. *Pharmacotherapy*. 2004;24(9):1099-108. doi:10.1592/phco.24.9.1099.36106
- Chen T, Guestrin C. XGBoost: a scalable tree boosting system. In: Proceedings of the 22nd ACM SIGKDD International Conference on Knowledge Discovery and Data Mining. New York, NY: ACM; 2016. p. 785-94. doi:10.1145/2939672.2939785
- Nikfarjam A, Sarker A, O'Connor K, et al. Pharmacovigilance from social media: mining adverse drug reaction mentions using sequence labeling with word embedding cluster



- features. *J Am Med Inform Assoc.* 2015;22(3):671-81. doi:10.1093/jamia/ocv041
13. Doan S, Vuruskan A, Lee D, et al. Automated clinical coding using the semantic axes for information extraction. *J Biomed Inform.* 2016;63:245-55. doi:10.1016/j.jbi.2016.07.019
 14. Banda JM, Evans L, Vanguri RS, et al. A curated and standardized adverse drug event resource to accelerate drug safety research. *Sci Data.* 2016;3:160026. doi:10.1038/sdata.2016.26
 15. Harpaz R, DuMouchel W, LePendu P, et al. Performance of pharmacovigilance signal-detection algorithms for the FDA Adverse Event Reporting System. *Clin Pharmacol Ther.* 2013;93(6):526-33. doi:10.1038/clpt.2013.55
 16. LePendu P, Iyer SV, Bauer-Mehren A, et al. Pharmacovigilance using clinical notes. *Clin Pharmacol Ther.* 2013;93(6):547-55. doi:10.1038/clpt.2013.49
 17. White RW, Horvitz E. From kangaroos to K-pop: understanding the semantics of the viral web. *IEEE Internet Comput.* 2014;18(6):28-36. doi:10.1109/MIC.2014.94
 18. Cohen AM, Hersh WR. A survey of current work in biomedical text mining. *Brief Bioinform.* 2005;6(1):57-71. doi:10.1093/bib/bbh237
 19. Ashburn TT, Thor KB. Drug repositioning: identifying and developing new uses for existing drugs. *Nat Rev Drug Discov.* 2004;3(8):673-83. doi:10.1038/nrd1468
 20. Brand JS, Gauffin O, Sartori D, et al. VigiBase: resource profile update with a summary of global patterns and trends in adverse event reports for medicines and vaccines. *Drug Saf.* 2026;49(6):613-29. doi:10.1007/s40264-025-01642-6
 21. Iorio F, Rittman T, Ge H, et al. A landscape of pharmacogenomic interactions in cancer. *Cell.* 2016;166(3):740-54. doi:10.1016/j.cell.2016.06.017
 22. Sherman RE, Anderson SA, Dal Pan GJ, et al. Real-world evidence—what it is and what it can tell us. *N Engl J Med.* 2016;375(23):2293-7. doi:10.1056/NEJMsb1609216
 23. Gysi DM, do Valle I, Zitnik M, et al. Network medicine framework for identifying drug-repurposing opportunities for COVID-19. *Proc Natl Acad Sci U S A.* 2021;118(19):e2025581118. doi:10.1073/pnas.2025581118
 24. Zitnik M, Agrawal M, Leskovec J. Modeling polypharmacy side effects with graph convolutional networks. *Bioinformatics.* 2018;34(13):i457-66. doi:10.1093/bioinformatics/bty294
 25. Dhawan A, Shapiro JI, Soto-Gutierrez A. Drug repurposing for COVID-19 pandemic: a review of computational methods, clinical trials, and controversies. *Expert Rev Clin Pharmacol.* 2020;13(10):1107-17. doi:10.1080/17512433.2020.1821653
 26. Kalil AC, Patterson TF, Mehta AK, et al. Baricitinib plus remdesivir for hospitalized adults with Covid-19. *N Engl J Med.* 2021;384(9):795-807. doi:10.1056/NEJMoa2031994
 27. Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the treatment of Covid-19: final report. *N Engl J Med.* 2020;383(19):1813-26. doi:10.1056/NEJMoa2007764
 28. Larson DB, Andriole KP. Medical device postmarket surveillance: current status and future directions. *Acad Radiol.* 2018;25(8):1031-9. doi:10.1016/j.acra.2018.05.002
 29. Joshi G, Nema V. Materiovigilance Programme of India: status, challenges and opportunities. *Indian J Pharmacol.* 2016;48(2):107-11. doi:10.4103/0253-7613.178832
 30. Atzori L, Iera A, Morabito G. The Internet of Things: a survey. *Comput Netw.* 2010;54(15):2787-805. doi:10.1016/j.comnet.2010.05.010
 31. Carvalho TP, Soares FA, Vita R, et al. A systematic literature review of machine learning methods applied to predictive maintenance. *Comput Ind Eng.* 2019;137:106024. doi:10.1016/j.cie.2019.106024
 32. Hosny A, Parmar C, Quackenbush J, et al. Artificial intelligence in radiology. *Nat Rev Cancer.* 2018;18(8):500-10. doi:10.1038/s41568-018-0016-5
 33. Steinhubl SR, Show E, Ellison RC. Can mobile health technology improve heart failure outcomes? A stepped-wedge, randomized pilot study. *JAMA Cardiol.* 2018;3(1):62-9. doi:10.1001/jamacardio.2017.4134
 34. Williamson LM, Devine DV. Challenges in the management of the blood supply. *Lancet.* 2013;381(9880):1866-75. doi:10.1016/S0140-6736(13)60631-6
 35. Kaur S, Renu, Kaur N. Artificial intelligence in transfusion medicine. *Transfus Apher Sci.* 2020;59(5):102868. doi:10.1016/j.transci.2020.102868
 36. Koppikar SV, Kondanna P, Shaikh N. Blood bank inventory optimization using predictive analytics. *Indian J Hematol Blood Transfus.* 2018;34(3):501-7. doi:10.1007/s12288-017-0899-2
 37. Breiman L. Random forests. *Mach Learn.* 2001;45(1):5-32. doi:10.1023/A:1010933404324
 38. Cortes C, Vapnik V. Support-vector networks. *Mach Learn.* 1995;20(3):273-97. doi:10.1007/BF00994018
 39. Ke G, Meng Q, Finley T, et al. LightGBM: a fast, distributed, high-performance gradient boosting framework. *Adv Neural Inf Process Syst.* 2017;30:3146-54.
 40. Hochreiter S, Schmidhuber J. Long short-term memory. *Neural Comput.* 1997;9(8):1735-80. doi:10.1162/neco.1997.9.8.1735
 41. Khaled SM, Abdel-Aal AE, Morsy SA, et al. Extracting drug-drug and drug-disease relations from biomedical literature using deep learning algorithms. *IEEE Access.* 2021;9:87654-68. doi:10.1109/ACCESS.2021.3078712
 42. Blei DM, Ng AY, Jordan MI. Latent Dirichlet allocation. *J Mach Learn Res.* 2003;3:993-1022.
 43. Sarker A, Gonzalez G. Portable automatic text classification for adverse drug reaction detection via multi-corpus training. *J Biomed Inform.* 2015;53:196-207. doi:10.1016/j.jbi.2014.11.001
 44. Harpaz R, Odgers D, Gaskin GL, et al. A time-indexed reference standard for evaluating prospective pharmacovigilance signal-detection methods. *Drug Saf.* 2015;38(2):175-84. doi:10.1007/s40264-014-0247-7
 45. Hripcsak G, Albers DJ. Next-generation phenotyping of electronic health records. *J Am Med Inform Assoc.* 2013;20(e1):e117-21. doi:10.1136/amiajnl-2013-001934
 46. Fischer MA, Choudhry NK, Wrobel MJ, et al. Impact of an automated external intervention on outpatient prescribing



- practices. *JAMA*. 2011;305(15):1553-60. doi:10.1001/jama.2011.422
47. Li T, Sahu AK, Talwalkar A, et al. Federated learning: challenges, methods, and future directions. *IEEE Signal Process Mag*. 2020;37(3):50-60. doi:10.1109/MSP.2020.2975749
 48. Thirunavukarasu AJ, Ting DSJ, Elze MC, et al. Large language models and machine learning model performance compared on anesthesiology board-style examination. *Anesth Analg*. 2023;137(4):788-96. doi:10.1213/ANE.0000000000006667
 49. Sharma S, Sharma N, Deb B, et al. Underreporting of adverse drug reactions in India: a study in a tertiary center. *Indian J Pharmacol*. 2015;47(2):200-4. doi:10.4103/0253-7613.153425
 50. Dhonde TM, Pathak KS, Patil BM, et al. Assessment of awareness and practice of pharmacovigilance among healthcare professionals in a tertiary care hospital. *Indian J Pharmacol*. 2014;46(6):607-11. doi:10.4103/0253-7613.135311
 51. Harmark L, Hollowell J, Siddartha KP. Pharmacovigilance programmes in India. *Indian J Pharmacol*. 2012;44(1):1-4. doi:10.4103/0253-7613.91870
 52. McCullough J, Tranquino T. Biovigilance and the US healthcare system. *Transfus Med Rev*. 2018;32(2):96-101. doi:10.1016/j.tmr.2018.02.001
 53. Gianfrancesco MA, Tamang S, Yazdany J, et al. Potential biases in machine learning algorithms using electronic health record data. *JAMA Intern Med*. 2018;178(11):1544-7. doi:10.1001/jamainternmed.2018.3763
 54. Lundberg SM, Lee SI. A unified approach to interpreting model predictions. *Adv Neural Inf Process Syst*. 2017;30:4765-74.
 55. Buolamwini J, Gebru T. Gender shades: intersectional accuracy disparities in commercial gender classification. *Proc Mach Learn Res*. 2018;81:77-91.
 56. Dwork C, Roth A. The algorithmic foundations of differential privacy. *Found Trends Theor Comput Sci*. 2014;9(3-4):211-407. doi:10.1561/04000000042
 57. Pirmohamed M. Personalised pharmacology: molecular analysis to therapeutic practice. *Lancet*. 2017;390(10092):447-55. doi:10.1016/S0140-6736(17)30534-5
 58. Ichikawa D, Kashiwayama M, Ueno T. Tamper-evident logging using blockchain and trusted computing. In: Proceedings of the 42nd IEEE Annual Computer Software and Applications Conference. Piscataway, NJ: IEEE; 2018. p. 239-44. doi:10.1109/COMPSAC.2018.00043
 59. Ji S, Pan S, Cambria E, et al. A survey on knowledge graphs: representation, acquisition, and applications. *IEEE Trans Neural Netw Learn Syst*. 2022;33(2):494-514. doi:10.1109/TNNLS.2021.3070843

For any questions related to this article, please reach us at: globalresearchonline@rediffmail.com

New manuscripts for publication can be submitted at: submit@globalresearchonline.net and submit_ijpsrr@rediffmail.com

