



REVIEW ARTICLE

PHARMACOGENOMICS-GUIDED DRUG SAFETY: A REVIEW OF GENETIC SUSCEPTIBILITY TO ADVERSE DRUG REACTIONS AND PERSONALIZED PHARMACOVIGILANCE

K. PRANATHI¹ , G.VENKATA NAGARAJU*² , NAGA SUBRAHMANYAM S² 

¹Department of Pharmacy Practice, Hindu College of Pharmacy, Guntur.

²Professor and Principal, Emmanuel College of Pharmacy, Singannabanda, Maharaju Peta jn, Tagarapuvallasa, Visakhapatnam, Andhra Pradesh.

*CORRESPONDING AUTHOR

Dr. G.V.NAGARAJU

ARTICLE HISTORY: 15.08.2026 RECEIVED: 03.09.2026 REVISED: ACCEPTED: 11.09.2026

ABSTRACT

Digital pharmacovigilance is transforming the collection, processing, evaluation, and monitoring of adverse drug reactions (ADRs) through the integration of emerging digital technologies into drug-safety systems. Conventional pharmacovigilance relies substantially on spontaneous reporting, manual case processing, and periodic safety evaluations, which may be limited by underreporting, delayed submissions, incomplete information, and increasing volumes of safety data. Digital technologies, including artificial intelligence (AI), machine learning (ML), natural language processing (NLP), electronic health records (EHRs), mobile health applications, social media monitoring, cloud computing, and real-world data analytics, offer opportunities to strengthen the efficiency and responsiveness of drug-safety surveillance. This review examines the applications of these technologies in ADR identification, electronic reporting, case processing, safety-signal detection, and post-marketing surveillance. AI-assisted systems can support duplicate detection, adverse-event extraction, report prioritization, and the identification of potential safety signals across heterogeneous data sources. EHRs and real-world databases facilitate active surveillance, while mobile applications and patient-centered digital platforms may improve accessibility and timeliness of ADR reporting. Social media and online health communities provide supplementary information about patient experiences, although the reliability and clinical interpretation of these data require careful evaluation. Despite these advances, important challenges remain, including data quality, interoperability, algorithmic bias, privacy protection, cybersecurity, regulatory compliance, and limited external validation of computational models. Digital systems may also generate false-positive signals and cannot independently establish causality between drug exposure and an adverse event. Effective implementation therefore requires human oversight, standardized reporting procedures, transparent algorithms, and collaboration among healthcare professionals, regulatory authorities, technology developers, and patients. Digital pharmacovigilance should complement established safety-monitoring practices through responsible technology adoption, evidence-based evaluation, and continuous performance assessment. Integrating digital tools into pharmacovigilance workflows may support earlier signal identification, improved reporting efficiency, and more proactive, patient-centered drug-safety monitoring.

Keywords: Digital pharmacovigilance; adverse drug reactions; artificial intelligence; machine learning; natural language processing; electronic health records; mobile health; real-world data; safety-signal detection; drug safety monitoring.

This article is licensed under a Creative Commons Attribution-Non-commercial 4.0 International License. Copyright © 2026 Author(s) retains the copyright of this article.



INTRODUCTION

Pharmacovigilance is the science and set of activities concerned with detecting, assessing, understanding, and preventing adverse effects and other medicine-related problems. It plays a crucial role in protecting public health throughout the life cycle of medicinal products, from clinical development to post-marketing use [1]. Traditional pharmacovigilance systems rely heavily on spontaneous adverse drug reaction reports submitted

by healthcare professionals, patients, pharmaceutical companies, and other stakeholders. Although these systems are essential for identifying unexpected safety concerns, underreporting, incomplete case information, delayed submissions, and difficulties in processing large datasets can limit their effectiveness [2]. The increasing digitization of healthcare has created opportunities to improve pharmacovigilance through electronic reporting platforms, electronic

health records (EHRs), mobile applications, artificial intelligence, and advanced data analytics. These technologies can support the collection and interpretation of safety information from structured and unstructured sources, potentially enabling earlier identification of emerging drug-safety concerns [3].

Digital pharmacovigilance refers to the application of digital infrastructure, computational methods, and connected information systems to the reporting, assessment, analysis, and communication of medicine-related safety information. It encompasses both the digitization of established pharmacovigilance processes and the development of new approaches to active safety surveillance.

The objective of this review is to examine emerging digital technologies used in adverse drug reaction reporting and drug-safety monitoring, discuss their clinical and regulatory applications, and evaluate the challenges that must be addressed for reliable implementation.

2. EMERGING TECHNOLOGIES IN DIGITAL PHARMACOVIGILANCE

2.1. Artificial intelligence and machine learning

Artificial intelligence (AI) and machine learning (ML) are increasingly investigated for automating pharmacovigilance activities. These technologies can analyze large datasets, identify patterns associated with adverse events, classify incoming reports, and prioritize cases requiring human assessment [3,4].

Machine-learning algorithms may support the detection of potential safety signals in spontaneous reporting databases by identifying unusual drug-event associations. Other applications include report classification, duplicate detection, missing-information identification, and prediction of patients who may be at increased risk of adverse outcomes.

A scoping review by Kompa and colleagues examined 393 publications on machine learning in pharmacovigilance and identified opportunities across safety-data intake, processing, and analysis. However, the authors also highlighted limitations in methodological quality and the adoption of best practices, indicating that promising computational methods do not automatically translate into clinically validated systems [3].

Machine learning should therefore be considered a decision-support technology rather than a replacement for pharmacovigilance professionals. Human review remains essential for interpreting signals, evaluating causality, and determining appropriate regulatory action.

2.2. Natural language processing

Natural language processing (NLP) enables computers to extract clinically relevant information from unstructured text. In pharmacovigilance, it can be used to identify suspected adverse reactions described in clinical notes, discharge summaries, scientific publications, patient reports, and online discussions.

NLP systems can identify drug names, symptoms, adverse-event terminology, dosage information, and temporal relationships between medication exposure and an event. More advanced language models may assist with summarization, case classification, and the extraction of structured information from narrative reports.

For example, a patient might describe experiencing dizziness after starting a medicine without using formal medical terminology. An NLP system may recognize the symptom and its potential relationship to drug exposure, allowing the report to be reviewed for possible inclusion in a pharmacovigilance workflow [5]. However, language ambiguity, negation, spelling variations, multilingual content, and the difficulty of distinguishing adverse reactions from disease symptoms can reduce performance. Automated extraction must therefore include appropriate validation and quality-control procedures.

2.3. Electronic health records and electronic reporting

Electronic health records provide information about diagnoses, prescriptions, laboratory findings, clinical outcomes, and medication histories. Integrating EHRs with pharmacovigilance systems can support the identification of potential adverse drug events during routine clinical care.

Electronic reporting platforms can also standardize the submission of individual case safety reports (ICSRs), reduce repeated data entry, and facilitate the transfer of safety information between healthcare organizations and regulatory authorities.

Unlike spontaneous reporting systems alone, EHR-based surveillance may provide denominators and longitudinal clinical information that help investigators evaluate patterns of drug exposure and adverse outcomes. Nevertheless, electronic records can contain missing data, inconsistent coding, and confounding clinical factors, so a suspected event detected automatically must still undergo appropriate assessment [4,6].

2.4. Mobile health applications and patient-centered reporting



Figure 01: Overview of Digital Pharmacovigilance and Drug Safety Monitoring.

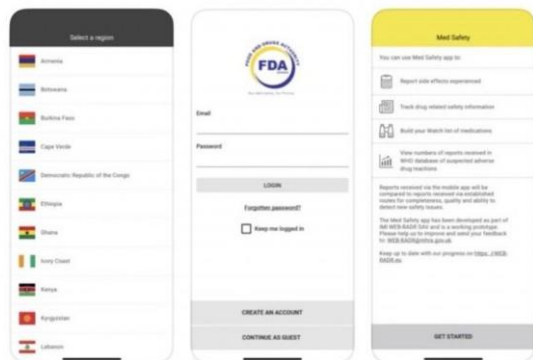


Figure 02: Emerging Digital Technologies in Adverse Drug Reaction Reporting.

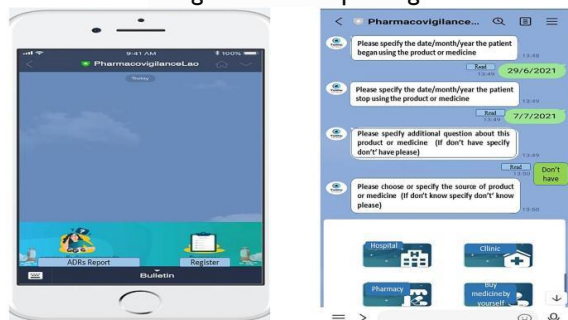


Figure 03: Digital Drug Safety Monitoring and Signal Detection Workflow.

Mobile health applications and web-based reporting portals provide patients with additional ways to report suspected adverse drug reactions. Depending on the system, users may submit the medicine name, dosage, event description, onset date, severity, and relevant medical information.

Potential benefits include improved accessibility, faster submission, and greater participation by patients who may not otherwise report an adverse reaction. Digital reminders and follow-up notifications may also help collect missing information. However, patient-reported information may be incomplete or difficult to verify. Applications should use accessible language, protect sensitive health information, provide clear submission instructions, and direct users to urgent medical care when appropriate. Patient-facing digital reporting should complement established clinical and regulatory reporting channels rather than replace them.

2.5. Social media and online health communities

Social media platforms, online patient forums, and health-related discussion communities provide supplementary information about medication experiences. These sources may help identify emerging concerns, particularly when patients discuss unusual symptoms or reactions that have not yet been widely reported through formal systems.

Digital surveillance techniques can screen online content for suspected drug–event associations and identify topics that warrant further investigation [5].

Nevertheless, social media information presents substantial limitations. Posts may contain misinformation, duplicate accounts, uncertain drug

exposure, incomplete medical histories, or events unrelated to the suspected medicine. Demographic information may also be unavailable, and the number of online mentions cannot reliably establish the incidence of an adverse reaction.

Accordingly, social media monitoring should be treated as a supplementary signal-generation method, with appropriate privacy safeguards and clinical verification.

2.6. Cloud computing and big-data analytics

Cloud computing enables the storage and processing of large volumes of pharmacovigilance data across distributed computing environments. Big-data analytics can combine information from spontaneous reporting databases, EHRs, clinical studies, registries, and other real-world data sources.

These technologies may improve scalability, facilitate collaboration, and support more frequent analysis of incoming safety information. Distributed data architectures can also allow participating institutions to analyze selected information without necessarily centralizing all patient-level records, provided the architecture and governance arrangements support this approach.

However, cloud-based pharmacovigilance requires strong cybersecurity, access controls, data-governance policies, backup procedures, and compliance with applicable data-protection requirements.

3. Digital technologies used in adverse drug reaction reporting

Digital ADR reporting involves more than transferring paper forms into electronic formats. It includes improving the completeness, accuracy, traceability, and accessibility of safety reports.

Table 01: Emerging digital technologies and their applications in adverse drug reaction reporting

Digital technology	Principal application	Potential benefit	Major limitation
Artificial intelligence and machine learning	Case prioritization, classification, and safety-signal detection	Faster processing of large datasets	Algorithmic bias and false-positive signals
Natural language processing	Extraction of adverse events from narrative text	Converts unstructured information into analyzable data	Ambiguity and language variability
Electronic health records	Identification of suspected events during	Longitudinal clinical and medication information	Missing data and confounding factors

	routine care		
Mobile health applications	Direct patient reporting	Improved accessibility and participation	Incomplete or unverified reports
Social media monitoring	Screening online discussions for possible safety concerns	Supplementary and potentially early signal generation	Uncertain exposure and limited representativeness
Cloud computing and big-data analytics	Storage, integration, and analysis of large datasets	Scalability and information sharing	Privacy, cybersecurity, and interoperability risks
Automated case-processing systems	Data entry, duplicate detection, coding, and workflow management	Reduced repetitive manual work	Errors may propagate without human review
Real-world data analytics	Assessment of drug utilization and clinical outcomes	Supports broader safety evaluation	Data-quality and causal-inference challenges

Source: Compiled from published reviews and established pharmacovigilance principles [1–6].

As shown in Table 01, each technology addresses different stages of the pharmacovigilance process. Their greatest potential may be realized through integration rather than isolated implementation. For example, NLP may extract an event from a clinical note, an automated system may structure the information, and a trained reviewer may assess the case before it enters the relevant safety workflow.

4. DIGITAL DRUG-SAFETY MONITORING AND SIGNAL DETECTION

4.1. Spontaneous reporting databases

Spontaneous reporting systems collect suspected adverse reactions from healthcare professionals, patients, and other reporting sources. Examples include the US Food and Drug Administration Adverse Event Reporting System (FAERS) and the World Health Organization's global individual case safety report database, VigiBase [1,7].

Digital analytical methods can help screen these databases for disproportionate reporting of particular drug–event combinations. Statistical methods, including proportional reporting ratios and reporting odds ratios, can identify associations that occur more

frequently than expected within a reporting database [6].

Such associations represent potential safety signals, not proof of causation. Spontaneous reports are affected by underreporting, stimulated reporting, duplicate cases, missing information, and differences in drug utilization. Computational results must therefore be interpreted alongside clinical evidence and other data sources.

4.2. Real-world data and active surveillance

Real-world data include information collected through routine healthcare delivery, such as EHRs, insurance claims, patient registries, and pharmacy records. These data can complement spontaneous reports by supporting the investigation of medication exposure, clinical outcomes, and patterns over time.

Active surveillance systems may use predefined clinical outcomes, validated algorithms, and linked datasets to investigate potential safety concerns. Digital analytical methods can support the identification of populations requiring further assessment and help evaluate whether an observed pattern warrants additional investigation [6,8].

However, real-world data are not automatically reliable simply because they are collected electronically. Differences in coding practices, healthcare access, patient characteristics, and data completeness can affect results.

4.3. Automated case processing

Automated case-processing systems can assist with report intake, data extraction, coding of adverse events, duplicate identification, and prioritization of cases. These functions may reduce repetitive administrative work and allow pharmacovigilance professionals to focus on complex or clinically important reports.

Automation should be accompanied by audit trails, predefined quality checks, performance monitoring, and procedures for correcting errors. Safety-critical decisions should remain subject to appropriate human oversight.

5. ROLE OF DIGITAL PHARMACOVIGILANCE IN REGULATORY SYSTEMS

Regulatory authorities increasingly rely on electronic data exchange, structured safety reporting, and computational tools to support medicine-safety oversight. Digital pharmacovigilance can help standardize reporting formats, improve traceability, and facilitate the review of safety information submitted by marketing authorization holders and healthcare professionals.

The International Council for Harmonisation (ICH) E2B framework supports standardized electronic transmission of individual case safety reports. Standardization improves the exchange and processing of safety information between organizations, although implementation still requires appropriate data

validation and compliance with applicable regulatory requirements [8].

Digital tools can also support signal management by organizing emerging evidence, identifying patterns for further investigation, and assisting with the preparation of safety assessments. In practice, regulatory decisions require the integration of computational findings with clinical evidence, epidemiological analyses, and expert judgment [4,9].

5.1. Integration with pharmacovigilance systems in India
India's Pharmacovigilance Programme of India (PvPI), coordinated by the Indian Pharmacopoeia Commission, provides a national framework for collecting and assessing suspected adverse drug reactions. Digital reporting channels and electronic information systems can help healthcare professionals and patients communicate suspected reactions and support the broader collection of medicine-safety information.

Potential areas for further development include improving interoperability between hospitals and pharmacovigilance centres, expanding electronic reporting, supporting standardized data capture, and evaluating automated methods for prioritizing reports. Such approaches should be aligned with national reporting procedures, privacy requirements, and regulatory guidance.

Digital implementation must also account for India's linguistic diversity, differences in digital literacy, and unequal access to internet-enabled devices. Accessible reporting channels and continued professional training are essential to ensure that digital transformation does not exclude patients or healthcare facilities with limited resources.

6. BENEFITS OF DIGITAL PHARMACOVIGILANCE

The major potential benefits of digital pharmacovigilance include the following:

Improved reporting efficiency: Electronic submission and automated data extraction can reduce repetitive manual work and facilitate faster report processing.

Earlier identification of safety signals: Computational screening can help identify unusual drug–event patterns that require further evaluation.

Improved data integration: Combining complementary sources may provide a more comprehensive understanding of medication exposure and clinical outcomes.

Enhanced patient participation: Mobile applications and online reporting platforms can make ADR reporting more accessible.

Greater consistency: Standardized electronic formats and automated validation may improve the completeness and consistency of safety records.

More efficient resource allocation: Automated triage can help prioritize reports requiring urgent or detailed review [3,4,9].

These benefits are potential advantages rather than guaranteed outcomes. Their realization depends on

implementation quality, data availability, workflow design, and the validation of the technologies used.

7. CHALLENGES AND LIMITATIONS

7.1. Data quality and completeness

Digital systems can process large quantities of information, but the accuracy of their results depends on the quality of the underlying data. Missing medication histories, incorrect drug names, incomplete event descriptions, duplicate records, and inconsistent coding may reduce the reliability of automated analyses.

Data validation, standardized terminology, and appropriate quality-assurance procedures are therefore essential.

7.2. Algorithmic bias and limited validation

Machine-learning models may perform differently across healthcare systems, demographic groups, languages, and clinical settings. Models trained on one database may not generalize to another because of differences in reporting practices, patient characteristics, and data structures.

External validation and ongoing performance monitoring are necessary before computational tools are used for consequential pharmacovigilance decisions [3,9].

7.3. Privacy and cybersecurity

Pharmacovigilance datasets may contain identifiable or sensitive health information. Digital systems must implement appropriate security measures, data minimization, access controls, retention policies, and lawful data-sharing arrangements.

Cloud-based systems and cross-institutional data exchange require particular attention to cybersecurity and governance.

7.4. False-positive signals and causal uncertainty

Automated systems may identify associations that arise from coincidence, confounding, stimulated reporting, or other biases. A drug–event association in a database does not necessarily mean that the medicine caused the event.

Potential signals must be assessed using clinical review, epidemiological methods, and additional evidence where appropriate. Digital tools should support, rather than replace, the established processes of signal validation and causality assessment [4,6].

7.5. Cost, interoperability, and workforce readiness

Implementation may require investment in software, infrastructure, data standards, cybersecurity, and staff training. Systems that cannot exchange information reliably may create fragmented workflows and additional administrative burdens.

Successful adoption therefore requires collaboration between healthcare institutions, regulators, information-technology specialists, pharmacovigilance professionals, and patients.

8. FUTURE PERSPECTIVES

Future developments in digital pharmacovigilance are likely to involve more integrated analytical platforms

capable of processing structured clinical records, narrative reports, published research, and other relevant safety information.

Several areas deserve particular attention:

Advanced language models: Carefully validated language models may assist with information extraction, case summarization, and report triage while retaining human review for safety-critical decisions.

Interoperable health-data systems: Standardized data models and reporting formats may facilitate information exchange across hospitals, pharmaceutical companies, and regulatory authorities.

Real-time and active surveillance: Better integration of longitudinal healthcare data may support more timely investigation of emerging drug-safety concerns.

Patient-centered reporting: Accessible mobile and multilingual platforms may improve participation and reduce barriers to reporting.

Responsible AI governance: Transparent evaluation, auditability, external validation, and continuous monitoring will be important for safe deployment [3,9]. Future research should assess not only the technical accuracy of digital systems but also their impact on clinically meaningful outcomes, reporting completeness, workload, and the timeliness of regulatory action. Prospective implementation studies and independent evaluations are needed to establish whether specific technologies provide measurable benefits over existing processes.

9. CONCLUSION

Digital pharmacovigilance is an evolving approach to improving adverse drug reaction reporting and drug-safety monitoring through electronic reporting systems, artificial intelligence, machine learning, natural language processing, mobile health applications, electronic health records, and real-world data analytics. These technologies can support more efficient case processing, broader data integration, and earlier identification of potential safety signals.

However, digital tools also introduce challenges involving data quality, algorithmic bias, privacy, cybersecurity, interoperability, and the interpretation of potential signals. Automated detection cannot independently establish causality, and computational systems should not replace expert clinical or regulatory judgment.

A sustainable digital pharmacovigilance framework requires validated technology, standardized data exchange, human oversight, robust governance, and continuous performance assessment. With responsible implementation and equitable access, digital technologies may strengthen existing pharmacovigilance systems and support more proactive, responsive, and patient-centered medicine-safety monitoring.

FINANCIAL SUPPORT

None

DECLARATION COMPETING INTEREST

Not Declared

ACKNOWLEDGEMENT

None

INFORM CONSENT AND ETHICAL CONSIDERATION

Not Applicable

REFERENCES

1. World Health Organization. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: World Health Organization; 2002.
2. Hazell L, Shakir SAW. Under-reporting of adverse drug reactions: a systematic review. *Drug Saf.* 2006;29(5):385-96. doi:10.2165/00002018-200629050-00003.
3. Kompa B, Hakim JB, Palepu A, Kompa KG, Smith M, Bain PA, et al. Artificial intelligence based on machine learning in pharmacovigilance: a scoping review. *Drug Saf.* 2022;45(5):477-91. doi:10.1007/s40264-022-01176-1.
4. Warner J, Prada Jardim A, Albera C. Artificial intelligence: applications in pharmacovigilance signal management. *Pharm Med.* 2025;39:183-98. doi:10.1007/s40290-025-00561-2.
5. Harpaz R, Callahan A, Tamang S, Low Y, Odgers D, Finlayson S, et al. Text mining for adverse drug events: the promise, challenges, and state of the art. *Drug Saf.* 2014;37(10):777-90. doi:10.1007/s40264-014-0218-0.
6. Bate A, Evans SJW. Quantitative signal detection using spontaneous adverse drug reaction reporting. *Pharmacoepidemiol Drug Saf.* 2009;18(6):427-36.
7. US Food and Drug Administration. FDA Adverse Event Reporting System (FAERS) public dashboard [Internet]. Silver Spring (MD): FDA. Available from: <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard>
8. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Electronic transmission of individual case safety reports (ICSRs): implementation guide for ICH E2B(R3) [Internet]. Geneva: ICH. Available from: <https://www.ich.org/>
9. Barbieri MA, Battini V, Carnovale C, Cocco M, Papoutsis DG, Heckmann NS, et al. Artificial intelligence in pharmacovigilance signal management: a review of tools, implementations, research, and regulatory landscape. *Expert Opin Drug Saf.* 2026;25(2):207-22. doi:10.1080/14740338.2025.2545926.