IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 1, November 2026
Impact Factor: 8.2

Evolution of Pharmacovigilance Systems: From Spontaneous Reporting to Automated Signal Detection Tools

Puja Vishnu Raut, Sachin Kumbhar, Dr Sanjay K. Bais
Fabtech College of Pharmacy, Sangola, Maharashtra, India

Abstract : *Pharmacovigilance has developed from paper forms and voluntary reports of suspected adverse drug reactions (ADRs) into a data-driven field integrating electronic case processing, statistical data mining, real-world healthcare data and, progressively, artificial intelligence (AI). Voluntary reporting continues to play a central role because it can reveal unexpected harms across products and patient groups after marketing. However, under-reporting, reporting bias, incomplete details and the absence of exposure denominators restrict its ability to calculate incidence or demonstrate causation. Electronic safety databases made it possible to pool reports at scale and apply consistent coding, while disproportionality methods such as the proportional reporting ratio, reporting odds ratio and Bayesian approaches supported more consistent and reproducible screening. Current systems build on these methods by using duplicate detection, natural language processing, machine learning, temporal analysis and integration of electronic health records, claims, registries and literature. Such tools can rank medicine–event pairs for specialist assessment, reduce repetitive tasks and may shorten the interval between the appearance of a possible risk and its investigation. Even so, an alert generated by an algorithm does not establish a causal relationship.*

Bias in source data, confounding, stimulated reporting, poor interoperability, limited explainability and inadequate external validation can generate false positives or conceal genuine risks. This review describes key historical developments, major analytical methods, automated workflows, practical uses, advantages, limitations and implementation needs, including the Indian setting and the Pharmacovigilance Programme of India. The review supports a human-led model of automation: computational methods should make screening faster and more consistent, while clinical, epidemiological and regulatory professionals remain accountable for validating signals, evaluating benefit–risk and deciding on action.

Keywords: Pharmacovigilance, adverse drug reactions, spontaneous reporting, signal detection, data mining, machine learning, artificial intelligence, natural language processing, VigiBase, patient safety.

I. INTRODUCTION

1.1 Drug Safety and Pharmacovigilance

Before approval, medicines undergo evaluation for quality, effectiveness and safety; nevertheless, trials conducted before authorisation cannot reveal every possible risk. Trial participants are often relatively few and carefully selected, and follow-up may be short. Consequently, rare reactions and effects in older people, children, pregnant individuals, people with several conditions or those taking multiple medicines can go unnoticed. Accordingly, safety monitoring must continue throughout the medicine's life cycle after it enters the market. The World Health Organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or other medicine-related problems [1].

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 1, November 2026
Impact Factor: 8.2

An adverse event is any undesirable medical occurrence after a person has been exposed to a medicine, whether or not the medicine caused it. An adverse drug reaction (ADR) refers to a harmful, unintended response for which a contribution from the medicine is reasonably possible. A safety signal is evidence that points to a possible new causal relationship, or a new feature of an already recognised relationship, and therefore needs checking. A signal should be treated as a proposition to investigate, not as a settled finding [1,2].

The thalidomide disaster in the late 1950s and early 1960s exposed the serious consequences of failing to recognise medicine-related harm and helped prompt coordinated international systems for monitoring drug safety. The WHO Programme for International Drug Monitoring, established in 1968, allowed participating nations to exchange suspected ADR reports and recognise patterns that could remain hidden in a single country's database [1,3].

1.1.1 Key Terms in Pharmacovigilance

Term	Definition and relevance
Adverse event (AE)	Any untoward medical occurrence after use of a medicinal product; causality is not required.
Adverse drug reaction (ADR)	A harmful and unintended response for which a causal relationship with the medicine is at least reasonably possible.
Individual case safety report (ICSR)	A structured report containing information about a suspected adverse event in an identifiable patient and reporter, with at least one suspect product and event.
Signal	Information suggesting a new potentially causal association or a new aspect of a known association that merits further investigation.
Signal detection	The process of screening safety data to recognise patterns or associations that may indicate a medicine-related risk.
Signal validation	Assessment of whether the available evidence is sufficient and credible to justify further analysis.
Signal evaluation	Detailed assessment of the evidence, clinical context, alternative explanations and potential public-health impact.

Table 1. Key terms and definitions used in pharmacovigilance.

1.1.2 Objectives of Pharmacovigilance

To protect patients and encourage safe medicine use at every stage of a product's life cycle.

To recognise new ADRs, shifts in the frequency or seriousness of known reactions, drug interactions, medication errors and reduced treatment effectiveness.

To evaluate the benefits and risks of medicines by drawing on clinical, epidemiological and post-marketing information.

To share trustworthy medicine-safety findings with healthcare workers, patients, regulatory bodies and manufacturers.

To enable prompt risk-reduction measures, such as updating labels, issuing warnings, increasing monitoring, limiting use or withdrawing a product when warranted.

To strengthen learning, open reporting practices and the appropriate use of medicines.

1.1.3 Scope of Pharmacovigilance

The field covers spontaneous reports, active monitoring, post-approval safety studies, review of scientific literature, medication-error reports, signal management, risk planning and communication of safety findings. Its remit also progressively covers vaccines, biologics, herbal products, medicine-use practices and digital channels through which patients describe their experiences. Automated signal screening is only one part of this broader framework and cannot substitute for clinical assessment of individual cases [1,4].

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 6, Issue 1, November 2026 Impact Factor: 8.2

1.2 Need for Continuous Safety Surveillance

1.2.1 Limitations of Pre-marketing Trials

Trials conducted before marketing mainly assess efficacy and recognise common short-term harms in controlled settings. Very uncommon events may not emerge because the number of exposed participants is too small. Eligibility rules can leave out groups frequently seen in everyday care, and trials cannot fully reproduce the use of other medicines or patients' real-world adherence. Therefore, knowledge of a medicine's safety profile continues to expand after approval [1,4].

1.2.2 Public-health and Economic Impact of ADRs

ADRs may lead to emergency care, admission to hospital, longer stays, disability and healthcare expenses that could otherwise be avoided. They can also undermine confidence in treatment and cause patients to stop medicines that they need. Timely identification of a well-supported safety concern may prevent further avoidable harm. However, a report count alone does not reveal how frequently an event occurs among all exposed patients; estimates of incidence generally require suitable exposure data and epidemiological designs [5].

1.2.3 Why Reporting and Automation Both Matter

Spontaneous reports serve as an significant early-warning source, although the reports received are incomplete and vary by product, country and period. Digital case processing and automated screening allow safety teams to review large collections of reports in a more consistent way. Automation is most valuable as an aid to professional judgement—not a replacement—and its limitations must be clearly acknowledged [2,6].

1.3 Scope of the Review

This narrative review follows the development from spontaneous reporting through electronic databases and statistical signal screening to multi-source monitoring and AI-supported tools. It describes the main algorithms, workflow, possible benefits, technical and ethical limitations, regulatory context and future developments, including relevance to India.

II. AIM AND OBJECTIVES OF THE REVIEW

Aim: To review the evolution of pharmacovigilance systems from spontaneous adverse-event reporting to automated signal detection tools and to critically discuss the methods, applications, benefits and limitations of these approaches.

2.1 Objectives

To describe the historical development of spontaneous reporting and international pharmacovigilance databases.

To explain how electronic databases and statistical data-mining methods strengthend signal screening.

To outline the role of disproportionality analysis, Bayesian methods, natural language processing and machine learning in automated signal detection.

To compare spontaneous reporting with complementary real-world data sources and integrated surveillance.

To examine the strengths, limitations, governance requirements and human oversight needed for responsible implementation.

To discuss the current relevance of these developments to the Pharmacovigilance Programme of India and propose practical future developments.

III. EVOLUTION OF PHARMACOVIGILANCE SYSTEMS

3.1 Early Development: Spontaneous Reporting

3.1.1 Origins and Principles

In the early period, pharmacovigilance depended on clinicians and other health professionals recogniseing a possible reaction and submitting it to a regional or national centre. These approaches were comparatively low-cost and could reveal unexpected reactions during ordinary use, including events not observed in clinical trials. The WHO international programme organised exchange between countries and reinforced the idea that reports are more informative when considered together [1,3].

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 6, Issue 1, November 2026 Impact Factor: 8.2

3.1.2 Strengths of Spontaneous Reporting

Spontaneous reporting can encompass many medicines, uses, patient populations and care environments. It can bring unusual or serious events to attention even when no specific hypothesis was set in advance, and reports may be submitted by healthcare professionals, patients or marketing authorisation holders depending on the jurisdiction. Reports are especially valuable when an event is rare, clinically distinctive, temporally plausible and reported repeatedly in association with a product [2,6].

3.1.3 Limitations and Sources of Bias

A major weakness is under-reporting, since only some suspected reactions are formally reported. Media coverage, regulatory alerts or legal proceedings can increase reporting, meaning that certain products and events attract more attention than others. Interpretation becomes harder when clinical information is missing, cases are duplicated, diagnoses are uncertain or exposure details are incomplete. Because spontaneous-report databases generally lack a reliable denominator for the number of people exposed, they cannot by themselves establish incidence or prove causation [2,5,7].

3.2 Computerization and Standardized Databases

3.2.1 From Paper Forms to Electronic Case Processing

Replacing paper forms with electronic individual case safety reports (ICSRs) accelerated data entry, structured coding, retrieval and sharing between centres. Common data fields and medical terminology help bring together reports of similar reactions even when different wording is used by reporters. Electronic systems also support case follow-up, duplicate detection, audit trails and more systematic review of incoming information [4,8].

3.2.2 International Databases and Data Standards

VigiBase, maintained by the Uppsala Monitoring Centre on behalf of WHO, aggregates suspected adverse-event reports submitted by national pharmacovigilance programmes. It enables global screening and allows potential signals to be examined across diverse settings. The quality of the database depends on reporting practices, coding consistency, completeness and appropriate interpretation of country- and product-specific reporting patterns [3,9].

Standard formats such as ICH E2B support electronic transmission of ICSRs. Standardised medical dictionaries, including MedDRA, enable consistent coding of clinical concepts. These standards are essential prerequisites for automation because algorithms cannot reliably compare records if similar events are represented inconsistently [8,10].

3.3 Statistical Signal Detection and Data Mining

3.3.1 Disproportionality Analysis

Statistical data-mining methods were developed to search large spontaneous-report databases for medicine–event pairs appearing more often than expected against the database baseline. The proportional reporting ratio (PRR) and reporting odds ratio (ROR) are frequentist approaches. Bayesian methods, including the Bayesian Confidence Propagation Neural Network (BCPNN) and Multi-item Gamma Poisson Shrinker (MGPS), estimate observed-to-expected reporting patterns while applying statistical shrinkage to reduce instability from sparse counts [6,11,12].

These techniques are intended for screening rather than final decision-making. A high disproportionality value means that the medicine–event pair merits further review within that database; it does not prove that the medicine produced the event. Clinical importance, biological plausibility, timing, alternative causes, co-medications, exposure patterns and independent evidence must be considered before conclusions are drawn [6,11].

Method	General principle	Advantages	Important limitations
PRR	Compares the proportion of a particular event among reports for a drug with the corresponding proportion for other drugs.	Relatively easy to calculate and interpret.	Sensitive to sparse counts and reporting patterns; not causal evidence.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 1, November 2026
Impact Factor: 8.2

ROR	Compares the odds of an event rather than other events for one drug against the same odds for other drugs.	Useful screening measure; can be applied to large databases.	Can produce unstable estimates with small cell counts.
BCPNN	Bayesian method estimating dependence between drug and event reporting.	Provides a probabilistic measure and supports shrinkage.	Depends on database composition and assumptions; requires expert interpretation.
MGPS / EBGM	Empirical Bayesian method comparing observed with expected reports.	Shrinks unstable estimates and can prioritise disproportionate pairs.	May still generate false positives or miss signals with low reporting volume.
Temporal and stratified analyses	Examines changes over time or within defined subgroups.	Can highlight emerging patterns and heterogeneity.	Affected by changes in use, publicity, coding and reporting practices.

Table 2. Comparison of common disproportionality and statistical signal-detection methods.

3.3.2 Signal Prioritisation and Human Review

Automated screening identifies candidate medicine–event pairs, which are subsequently ranked according to clinical seriousness, novelty, strength and consistency of association, number and quality of reports, plausibility, preventability and potential public-health impact. Signal review teams examine case narratives, timelines, co-morbidities and alternative explanations. Validation and evaluation are distinct steps: the former asks whether a signal is credible enough to investigate, while the latter assesses the full evidence and possible regulatory implications [4,11].

Figure 1. Evolution of pharmacovigilance signal detection

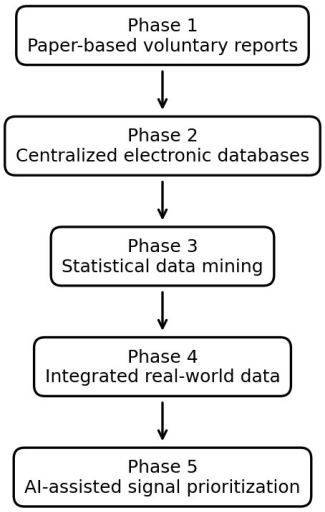


Fig. 1

3.4 Automated Signal Detection Tools

3.4.1 Database Querying and Rule-Based Automation

The first automated approaches used database searches, cut-off values and preset rules to flag report counts or disproportionality results for examination. Rule-based tools are understandable and comparatively straightforward to audit, although their performance relies on well-designed rules and good-quality data. Fixed thresholds may fail to

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 6, Issue 1, November 2026 Impact Factor: 8.2

detect new patterns that do not fit anticipated categories and may generate large numbers of alerts when databases grow or reporting changes [6,11].

3.4.2 Natural Language Processing (NLP)

Natural language processing (NLP) analyses unstructured text found in case narratives, clinical notes, research abstracts and patient submissions. These techniques can help extract medicine names, adverse events, timing, negation, symptoms and pertinent clinical context. Named-entity recognition and text classification may reduce manual extraction work, while language models can help organise narrative information for reviewer assessment. Errors remain possible when language is ambiguous, abbreviations vary, negation is missed or information is outside the model's training data [13,14].

3.4.3 Machine Learning and Artificial Intelligence

Machine learning (ML) methods recognise patterns in data that may be labelled or unlabelled. Supervised methods such as random forests, gradient boosting and support-vector machines can rank drug–event pairs using multiple features; unsupervised methods can cluster reports or recognise unusual patterns; deep-learning approaches can model complex relationships in structured and textual data. Recent reviews describe applications across case processing, signal detection and signal evaluation, while emphasising that performance and generalisability vary across datasets and tasks [14-16].

AI systems can prioritise signals, recognise duplicate cases, extract data from narratives, monitor literature and support consistency checks. Their results should inform decisions rather than independently determine whether a medicine caused an event. A model that performs well on a retrospective dataset may not remain reliable after changes in prescribing, reporting behaviour, coding or patient populations [14-16].

3.4.4 Automated Literature and Multi-source Surveillance

Literature surveillance can use search alerts, text mining and classification to find case reports, observational studies and safety-related publications. Other sources include electronic health records (EHRs), administrative claims, disease registries, poison-centre data and patient-generated information. These sources may provide clinical context, exposure denominators or longitudinal outcomes that are absent from spontaneous reports. Their use requires careful linkage, privacy safeguards, appropriate study design and attention to confounding [17,18].

3.4.5 Signal Detection with Real-world Data

Figure 2. Contemporary signal management workflow

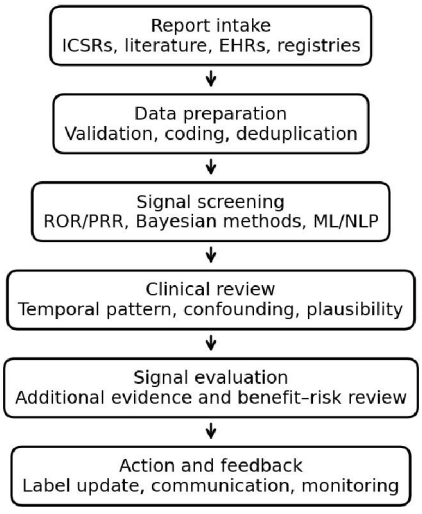


Fig. 2

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 6, Issue 1, November 2026 Impact Factor: 8.2

Real-world data methods can use cohort designs, self-controlled designs, observed-to-expected comparisons and sequential monitoring. In contrast to disproportionality analysis of spontaneous reports, these designs may include data on exposed populations and comparison groups. They can therefore help quantify risk under appropriate assumptions, although incomplete records, misclassification, confounding by indication and unequal healthcare access remain significant threats to validity [17,18].

3.5 Comparison of Traditional and Automated Approaches

Feature	Spontaneous/manual approach	Automated or AI-assisted approach
Data intake	Reports received through forms, telephone, email or electronic portals.	Automated import, format validation and structured extraction from several sources.
Screening	Periodic manual review and simple database queries.	Large-scale routine screening using statistical algorithms, rules and ML ranking.
Narrative review	Human reading and coding of individual case descriptions.	NLP may extract entities and concepts; reviewers verify outputs.
Duplicate handling	Manual comparison and standard database checks.	Similarity models can flag likely duplicates for confirmation.
Speed and scale	Limited by staffing and review capacity.	Can process high volumes quickly, subject to computing and data integrity.
Interpretability	Clinical reasoning is often directly documented.	Some statistical methods are interpretable; complex models may be difficult to explain.
Causal assessment	Requires expert assessment.	Still requires expert assessment; algorithms do not prove causation.
Main risks	Underreporting, delay, inconsistency and reviewer workload.	False positives, hidden bias, drift, poor external validity and automation over-reliance.

Table 3.

3.6 Signal Detection Workflow and Information Requirements

3.6.1 Minimum Information and Case Quality

A valid ICSR usually contains four essential elements: an identifiable patient, an identifiable reporter, at least one suspected medicinal product and at least one suspected adverse reaction or event. Reports should also include, where available, event onset and outcome, dose and route, indication, concomitant medicines, relevant history, laboratory findings and dechallenge or rechallenge information. Better completeness strengthens clinical interpretation and model performance, but identifiable information must be handled confidentially [8,10].

3.6.2 Data Cleaning, Coding and Deduplication

Prior to analysis, systems verify required fields, harmonise medicine and event terminology, address coding differences and recognise possible duplicate cases. Deduplication is particularly significant when the same case is reported by a patient, clinician and manufacturer. Incorrectly merging different cases can lose evidence, while failing to merge duplicates can inflate counts. Automated similarity scores should therefore support, not replace, case-processing rules and human confirmation [8,13].

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 6, Issue 1, November 2026 Impact Factor: 8.2

3.6.3 From Statistical Alert to Regulatory Action

A practical signal-management pathway includes detection, validation, prioritisation, assessment, recommendation, action and communication. Depending on the evidence, actions may include further studies, changes to product information, new warnings, restricted use, targeted monitoring or no action with documented rationale. The decision should reflect the totality of evidence and the seriousness and preventability of the potential harm [4,19].

3.7MApplications and Illustrative Use Cases

3.7.1 Rare or Unexpected Adverse Reactions

A rare event may not appear during clinical trials but may become visible when reports from many countries are pooled. Statistical screening can highlight a disproportionate drug–event pair, after which case narratives, temporal relationships, literature and mechanistic evidence are reviewed.

The example illustrates the role of automation in finding a hypothesis; the signal must still be validated before a causal conclusion is made [3,6].

3.7.2 Vaccine Safety Monitoring

Vaccination campaigns can involve large populations and rapid changes in exposure. Automated systems can help process incoming reports and monitor patterns over time, but the interpretation of events following immunisation must consider background rates, age, coexisting conditions, reporting stimulation and the expected timing of the event. A temporal association alone is not proof that a vaccine caused an event [4,19].

3.7.3 Medication Errors and Drug–drug Interactions

Text extraction and pattern recognition can help recognise reports involving wrong dose, wrong route, accidental exposure or possible interactions. Integration with prescribing and dispensing data may support prevention strategies. However, the underlying record must distinguish an actual reaction from a medication error without harm, a treatment failure or an event caused by the patient's illness [13,16].

3.8 Global and Indian Context

3.8.1 International Cooperation

International exchange through the WHO Programme for International Drug Monitoring allows national systems to contribute reports to a shared evidence base. VigiBase and analytical tools such as VigiLyze support global signal screening and exploration. International pooling increases the opportunity to detect rare patterns, but differences in population, reporting culture, product use and data completeness mean that a global signal still requires local assessment [3,9].

3.8.2 Pharmacovigilance Programme of India (PvPI)

India's Pharmacovigilance Programme of India, coordinated by the Indian Pharmacopoeia Commission, operates through a network of adverse drug reaction monitoring centres and reporting channels. The programme's resources describe standard procedures for receiving and processing reports, causality assessment, quality review and signal detection. Wider use of digital reporting and analytical tools may strengthen the national system, provided reporting completeness, staff capacity, data governance and feedback to reporters are addressed [20,21].

3.8.3 Regulatory and Governance Considerations

Regulatory expectations require medicine-safety information to be evaluated and reported in defined ways, and automated tools used in regulated processes should be fit for their intended purpose. Organisations should document model versions, training data, performance, limitations, validation results, human review procedures, access controls and change management. Privacy, cybersecurity, fairness and explainability should be addressed from the outset rather than after implementation [19,22].

3.9 Challenges and Limitations of Automated Signal Detection

3.9.1 Data Quality and Representativeness

Algorithms learn from available data, which may not represent all patients or all adverse events. Underreporting and selective reporting can create misleading patterns; missing fields and inconsistent coding reduce sensitivity; and

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 6, Issue 1, November 2026 Impact Factor: 8.2

changes in reporting behaviour can look like a change in risk. A sophisticated model cannot fully correct for systematically absent or biased information [7,14].

3.9.2 False Positives, False Negatives and Confounding

A false positive can arise when an apparent association is driven by indication, comorbidity, co-medication, publicity or chance. A false negative may occur when a true signal is rare, delayed, described in varied language or masked by other reports. Thresholds must balance sensitivity and workload, and performance should be examined separately for relevant drugs, events and populations [11,17].

3.9.3 Explainability, Validation and Model Drift

Complex models may provide a score without a clear explanation of the factors that drove it. Without external validation, results may not transfer to another database or country. Model drift can occur as medicines, coding practices and reporting patterns change. Periodic monitoring, documented version control, reproducible evaluation and independent review are therefore essential [14-16].

3.9.4 Privacy, Security and Ethical Use

Combining patient records can strengthen signal assessment but increases privacy and security responsibilities. Data minimisation, lawful access, de-identification where appropriate, secure transmission, audit trails and role-based access are significant safeguards. AI tools should not expose patient details or allow unreviewed model output to trigger disproportionate action against a product or patient group [22,23].

3.10 Future Directions and Recommendations

3.10.1 Human-supervised Automation

A practical future system should automate repetitive tasks while retaining accountable expert review. Models can rank cases, flag missing fields, propose coding and highlight unusual patterns; pharmacovigilance professionals then verify outputs, assess clinical plausibility and document decisions. Clear escalation pathways should be available for serious or unexpected events.

3.10.2 Interoperability and Data Standards

Common terminology, interoperable electronic reporting and consistent data standards can reduce duplication and make it easier to combine reports from hospitals, manufacturers and national systems. Interoperability projects should define data integrity checks and responsibilities for correcting errors. Indian systems can benefit from stronger links between ADR monitoring centres, clinical records and national reporting workflows where lawful and feasible [8,20].

3.10.3 Prospective and External Validation

AI systems should be evaluated on data not used during model development, across different time periods and clinical settings. Prospective pilots should measure more than technical accuracy: valuable outcomes include time to review, proportion of actionable signals, reviewer workload, false-alert burden and evidence of strengthend safety decisions. Transparent reporting of model design and evaluation supports reproducibility [14-18].

3.10.4 Training and Reporting Culture

Technology cannot make up for a lack of incoming reports. Training for doctors, pharmacists, nurses, patients and safety staff should explain how to recognise and report suspected reactions, what information matters and how feedback is used. Multilingual reporting routes and simple mobile interfaces may strengthen access, especially where resources and digital literacy vary.

3.10.5 Responsible Use of Generative AI

Generative AI may assist with summarising case narratives, extracting structured details and drafting review notes, but it can omit, distort or invent information. Outputs should be checked against the source record, and sensitive data should only be processed in authorised secure environments. Generative systems should not independently determine causality or issue regulatory decisions. Governance should specify acceptable uses, auditability and human accountability [15,22,23].

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 1, November 2026
Impact Factor: 8.2

IV. COMPARATIVE ANALYSIS OF PHARMACOVIGILANCE METHODS

Pharmacovigilance has developed through successive layers of data collection and analysis. Spontaneous reporting remains central because it can recognise unexpected events without a predefined hypothesis. Computerised case management strengthens standardisation and retrieval, while quantitative screening helps prioritise drug–event combinations for review. Modern systems progressively combine these methods with clinical records, registries and text-based evidence. No single approach answers every drug-safety question; the choice depends on the event under investigation, data availability, urgency and resources [1,6,11–14].

Method	Main input	Strengths	Important limitations
Spontaneous reporting	Voluntary suspected ADR reports	Broad medicine coverage; valuable for unexpected events	Underreporting, missing data, no reliable exposure denominator
Case-series review	Narratives and clinical details	Clinical context and temporality can be examined	Labour-intensive; small numbers may limit inference
Disproportionality analysis	Drug–event counts in a database	Efficient screening of large report collections	Sensitive to reporting bias, confounding and database composition
Active surveillance	EHRs, claims, registries or cohorts	Can provide exposure denominators and longitudinal data	Cost, access, coding validity and residual confounding
AI/NLP-assisted review	Narratives, literature and structured data	May prioritise cases and extract patterns at scale	Model drift, opacity, bias and need for validation

Table 4. Overview of complementary pharmacovigilance approaches.

The appropriate interpretation is layered: a screening alert should trigger verification, not an automatic conclusion. A clinically significant signal may require case review, epidemiological investigation, mechanistic assessment and consultation with relevant experts. Conversely, failure to cross a statistical threshold does not prove that a medicine is safe, particularly when reporting is sparse or event definitions are inconsistent [6,11,12].

V. STATISTICAL AND ALGORITHMIC SIGNAL DETECTION

Quantitative signal detection examines whether a medicine–event pair is reported more often than expected within a reference database. Common approaches include the proportional reporting ratio (PRR), reporting odds ratio (ROR), and Bayesian methods such as the information component (IC) and empirical Bayes geometric mean (EBGM). These methods differ in their statistical assumptions and handling of sparse counts. Results depend on database size, coding choices, report quality and the comparator population [11–14].

Method	Core idea	Typical interpretation	Caution
PRR	Compares the proportion of an event for one drug with the proportion for other drugs	Elevated PRR can flag disproportionate reporting	Thresholds are screening rules, not proof of causality
ROR	Compares odds of a specific event for a drug versus other reports	Confidence interval and estimate support prioritisation	Can be unstable when cell counts are small
Information Component (IC)	Bayesian shrinkage of observed versus expected co-reporting	Positive lower confidence bound may support a signal	Results depend on model and data characteristics
	Empirical Bayes shrinkage of reporting	Helps stabilise estimates for	Does not remove systematic

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 6, Issue 1, November 2026 Impact Factor: 8.2

EBGM	ratios	sparse data	reporting bias
Machine learning	Learns patterns from labelled or unlabelled examples	May rank cases or combinations for review	Requires representative data and ongoing validation

Table 5. Common signal-detection approaches and interpretation cautions.

A strong safety programme considers findings from multiple perspectives. Statistical outputs should be assessed alongside seriousness, novelty, clinical plausibility, time to onset, dechallenge or rechallenge information, alternative causes and the likely public-health impact. Thresholds can support consistent triage, but they should not replace documented expert judgement [6,11–15].

VI. AUTOMATED SIGNAL MANAGEMENT: WORKFLOW AND HUMAN OVERSIGHT

Automated tools can assist at multiple points in the signal-management process: checking report completeness, standardising medicine and reaction terms, detecting possible duplicates, ranking drug–event combinations, monitoring changes over time and preparing evidence summaries. Human review remains essential because reports may be ambiguous, medical terminology can be inconsistent, and a statistical association may reflect confounding or stimulated reporting rather than a causal effect [4,8,13–16].

Figure 4. Automated Signal Detection Workflow

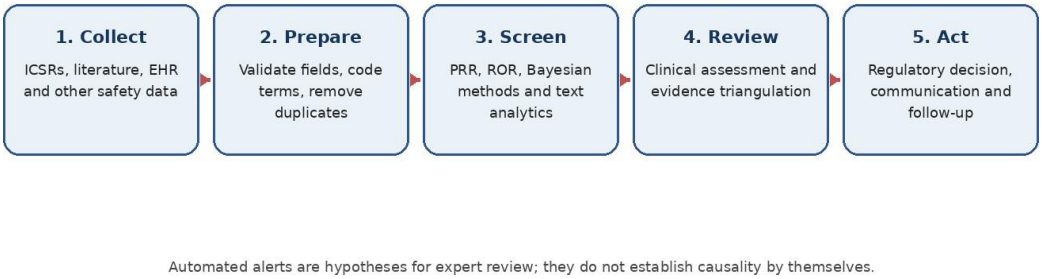


Figure 4.

Human oversight across automated signal-management stages.

Stage	Automated support	Required human check
Intake and validation	Mandatory-field checks and format validation	Confirm case validity and resolve missing critical details
Coding and deduplication	Terminology mapping and similarity scoring	Verify uncertain mappings and potential duplicate cases
Screening	Statistical alerts, ranking and trend monitoring	Assess thresholds, data integrity and clinical relevance
Evaluation	Evidence retrieval and narrative summarisation	Review source records, alternative explanations and plausibility
Action and communication	Draft tracking, deadline reminders and audit logs	Authorise decisions, rationale and safety communications

Table 6.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 1, November 2026
Impact Factor: 8.2

VII. INTEGRATION OF DATA SOURCES AND EVIDENCE TRIANGULATION

Spontaneous reports are an significant early-warning source, but they usually cannot estimate incidence because the total number of exposed patients is unknown. Electronic health records, claims data, disease registries, pregnancy registries, literature and patient-reported information can add complementary evidence. Integration requires careful alignment of drug names, event definitions, timing, patient characteristics and data provenance. Linking datasets must comply with relevant privacy, security and governance standards [4,5,16–18].

Figure 5. Triangulation of Safety Evidence

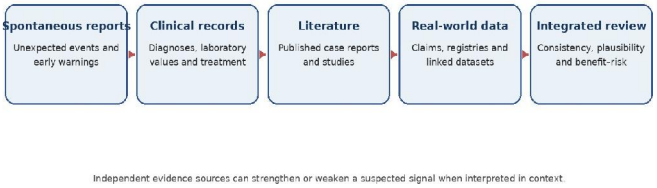


Figure 5. .

Complementary data sources used in safety assessment

Data source	Contribution	Key quality question
Spontaneous reports	Novel, unusual or serious suspected reactions	Is the case valid, sufficiently detailed and possibly duplicated?
Electronic health records	Clinical diagnoses, laboratory results and treatment timelines	Are coding and dates accurate, and is the outcome clinically verified?
Claims and dispensing data	Medication utilisation and healthcare encounters	Does dispensing represent actual exposure, and are outcomes well captured?
Registries and cohort studies	Defined populations, follow-up and possible denominators	Are selection, confounding and missing follow-up adequately addressed?
Scientific literature	Detailed cases, studies and mechanistic context	Is the evidence reliable, independent and relevant to the question?

Table 7..

VIII. IMPLEMENTATION PRIORITIES FOR RESPONSIBLE AUTOMATION

Implementing automation involves much more than installing software. A sustainable system requires a clear safety question, reliable data, validated methods, trained reviewers, transparent procedures and a route for communicating decisions. Before deployment, organisations should define intended use, performance measures, acceptable error rates, escalation criteria, version control and monitoring for changes in data or model behaviour. Any AI-supported output should remain traceable to the underlying evidence [4,15,19–21].

Priority	Recommended activity	Example measure of progress
Data quality	Standardise core fields, coding and follow-up; audit duplicates	Completeness rate; duplicate-review accuracy
Validation	Test algorithms on representative historical and prospective data	Sensitivity, positive predictive value and workload impact
Clinical governance	Set clear responsibilities for signal review and decisions	Documented review time and rationale for each prioritised signal

Copyright to IJARSCT
www.ijarsct.co.in
DOI: 10.48175/IJARSCT-40573

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429 Volume 6, Issue 1, November 2026 Impact Factor: 8.2

Fairness and coverage	Assess performance across products, age groups and care settings	Subgroup performance and gaps in reporting coverage
Privacy and security	Apply access controls, minimisation, secure transfer and audit trails	Access reviews, incident response readiness and compliance checks
Training and feedback	Train reporters and analysts; communicate outcomes where appropriate	Training completion, reporting quality and user feedback
Continuous monitoring	Review drift, alert burden and regulatory updates	Periodic revalidation and documented change management

Table 8. Practical implementation priorities and illustrative measures.

For India, implementation should build on existing PvPI reporting channels and ADR monitoring centres rather than create disconnected systems. Pilot projects can begin with a defined use case, such as duplicate detection or prioritisation of serious reports, and expand only after independent evaluation. Local language support, accessible reporting, workforce capacity and transparent feedback are significant to ensure that digital innovation strengthens—not widens gaps in—safety surveillance [20–22].

These additional tables and figures expand the analytical discussion and complement the existing sections on evolution, limitations, Indian context, future developments and conclusion.

IX. DISCUSSION

The evolution of pharmacovigilance reflects a shift from collecting individual suspicions toward systematic, progressively automated examination of large and diverse safety datasets. Spontaneous reporting remains indispensable because it can capture unexpected harms in routine care and is comparatively inexpensive. Computerization strengthend access, coding and consistency, while statistical data mining made large databases more amenable to routine screening. Newer NLP and ML methods can process free text and rank complex patterns, and real-world data can provide complementary clinical context and, in suitable designs, denominators for risk estimation [2,6,14,17].

It is essential to distinguish generating a signal from establishing evidence of causation. Automated tools may find associations that would be difficult to recognise manually, but reporting biases, confounding and data-quality problems remain. A model score should help determine what to investigate next, not bring the assessment to a close. Robust signal management therefore combines quantitative screening with clinical assessment, epidemiological evaluation, mechanistic reasoning, regulatory judgement and transparent communication [11,19].

In India, improving reporting practices and completeness of case information is just as significant as introducing sophisticated technology. A layered approach is appropriate: standardised electronic reporting and case quality checks first, then reliable statistical screening, followed by carefully validated AI tools where they address a clearly defined need. Implementation should include training, feedback, privacy protection, external validation and monitoring for performance drift. This approach is more likely to deliver sustained patient-safety benefits than introducing complex tools without a strong operational foundation [20,21,24].

Future Prospective

Future pharmacovigilance is likely to combine spontaneous reports with structured healthcare data, literature, patient-generated information and more automated processing. Better NLP may extract clinical information from unstructured narratives; ML may prioritise drug–event pairs; and real-time analytical dashboards may support faster review. These developments could strengthen timeliness and consistency, but their real value must be demonstrated through prospective evaluation, transparent performance measures and evidence that they strengthen decisions. Internationally harmonised standards, responsible data sharing and trained multidisciplinary teams will remain essential.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 1, November 2026
Impact Factor: 8.2

X. CONCLUSION

Pharmacovigilance has progressed from paper-based spontaneous reporting to electronic databases, statistical data mining and emerging AI-assisted signal detection. Each stage has increased the ability to collect, organise and screen medicine-safety information, while introducing new technical and governance challenges. Spontaneous reporting remains a core source of early warnings, and automated methods can strengthen scale, speed and prioritisation. Nevertheless, no algorithm alone can confirm causality or determine the benefit–risk balance of a medicine. Reliable systems require high-quality data, validated methods, expert review, privacy safeguards, regulatory oversight and effective communication. A human-supervised, evidence-based model offers the strongest path toward earlier recognition of medicine-related harm and safer use of medicines.

REFERENCES

1. World Health Organization. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: World Health Organization; 2002.
2. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. Lancet. 2000;356(9237):1255-9.
3. World Health Organization. The WHO Programme for International Drug Monitoring [Internet]. Geneva: WHO; [cited 2026 Oct 27]. Available from: https://www.who-umc.org/global-pharmacovigilance/who-programme/
4. World Health Organization. Tools and innovations in pharmacovigilance [Internet]. Geneva: WHO; [cited 2026 Oct 27]. Available from: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/guidance/operations/tools-innovations
5. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ. 2004;329(7456):15-9.
6. Hauben M, Aronson JK. Defining 'signal' and its subtypes in pharmacovigilance based on a systematic review of previous definitions. Drug Saf. 2009;32(2):99-110.
7. Alatawi YM, Hansen RA. Empirical estimation of under-reporting in spontaneous reporting systems: a review. Drug Saf. 2017;40(7):623-36.
8. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH E2B(R3): electronic transmission of individual case safety reports (ICSRs)—implementation guide. Geneva: ICH; 2013.
9. Lindquist M. VigiBase, the WHO global ICSR database system: basic facts. Drug Inf J. 2008;42(5):409-19.
10. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH E2D: post-approval safety data management: definitions and standards for expedited reporting. Geneva: ICH; 2003.
11. Rothman KJ, Lanes S, Sacks ST. The reporting odds ratio and its advantages over the proportional reporting ratio. Pharmacoepidemiol Drug Saf. 2004;13(8):519-23.
12. Bate A, Evans SJW. Quantitative signal detection using spontaneous ADR reporting. Pharmacoepidemiol Drug Saf. 2009;18(6):427-36.
13. Coloma PM, Avillach P, Salvo F, et al. A reference standard for evaluation of methods for drug safety signal detection using electronic healthcare record databases. Drug Saf. 2013;36(1):13-23.
14. 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.
15. Jiang G, Kiefer RC, Sharma DK, Prud'hommeaux E, Solbrig HR. A review of biomedical and clinical informatics applications of natural language processing and machine learning. Yearb Med Inform. 2017;26(1):116-25.
16. Warner J, Prada Jardim A, Albera C. Artificial intelligence: applications in pharmacovigilance signal

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 1, November 2026
Impact Factor: 8.2

management. Pharm Med. 2025;39(3):183-98.

17. Coste A, Wong A, Bokern M, Bate A, Douglas IJ. Methods for drug safety signal detection using routinely collected observational electronic health care data: a systematic review. Pharmacoepidemiol Drug Saf. 2023;32(1):1-16.
18. Ryan PB, Schuemie MJ, Welebob E, Duke J, Valentine S, Hartzema AG. Defining a reference set to support methodological research in drug safety. Drug Saf. 2013;36 Suppl 1:S33-47.
19. European Medicines Agency. Guideline on good pharmacovigilance practices (GVP): Module IX—signal management (Rev 1) [Internet]. Amsterdam: EMA; 2017 [cited 2026 Oct 27]. Available from: https://www.ema.europa.eu/
20. Indian Pharmacopoeia Commission. Pharmacovigilance Programme of India: toolkit and standard operating procedures [Internet]. Ghaziabad: IPC; [cited 2026 Oct 27]. Available from: https://ipc.gov.in/PvPI/toolkit.html
21. Indian Pharmacopoeia Commission. Pharmacovigilance Programme of India (PvPI) [Internet]. Ghaziabad: IPC; [cited 2026 Oct 27]. Available from: https://ipc.gov.in/
22. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH E2E: pharmacovigilance planning. Geneva: ICH; 2004.
23. U.S. Food and Drug Administration. Sentinel Initiative [Internet]. Silver Spring (MD): FDA; [cited 2026 Oct 27]. Available from: https://www.fda.gov/safety/fdas-sentinel-initiative
24. Barbieri MA, Battini V, Carnovale C, Cocco M, Papoutsi 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.
25. El Sayed I, Bedwany RN, Salama M, Hassan Eltrass AS. Integration of artificial intelligence into pharmacovigilance: a systematic review. Res Social Adm Pharm. 2026. doi:10.1016/j.sapharm.2026.09.001.