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ARTIFICIAL INTELLIGENCE IN SPONTANEOUS REPORTING SYSTEMS: ADVANCING ACCURACY AND TIMELINESS OF ADVERSE EVENT DETECTION

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ABSTRACT

Spontaneous Reporting Systems (SRS) remain the cornerstone of post-marketing pharmacovigilance by enabling healthcare professionals, patients, and manufacturers to report suspected adverse events (AEs) linked to medicines, vaccines, and medical products. However, SRS data are challenged by under-reporting, duplicate reports, missing clinical context, reporting bias, and the inherent noise of unstructured narratives. These limitations can delay signal detection and reduce the accuracy of adverse event identification, particularly when products scale rapidly, indications expand, or new populations are exposed. Artificial Intelligence (AI)—including natural language processing (NLP), machine learning (ML), deep learning, and probabilistic modeling—has emerged as a transformative approach for improving the quality, precision, and speed of adverse event detection from SRS. This research paper examines how AI can advance spontaneous reporting by enhancing data ingestion, deduplication, coding, causality support, and signal detection, while also addressing governance and ethical constraints. The paper synthesizes current AI-driven workflows for extracting clinical entities from narratives, mapping them to standardized terminologies (e.g., MedDRA), identifying duplicates, prioritizing serious cases, and detecting safety signals earlier than classical disproportionality methods alone. It further proposes a practical framework integrating AI with established pharmacovigilance processes, emphasizing transparency, human oversight, model validation, and regulatory readiness. Finally, the study discusses challenges such as algorithmic bias, explainability, data privacy, and operational integration, and recommends future directions including federated learning, multi-modal safety analytics, and continuous performance monitoring. AI, when responsibly implemented, can significantly improve the timeliness and accuracy of adverse event detection in SRS, strengthening public health protection and supporting evidence-based regulatory action.

Keywords

Artificial Intelligence; Pharmacovigilance; Spontaneous Reporting Systems; Adverse Event Detection; Signal Detection; Natural Language Processing; Machine Learning; MedDRA Coding; Duplicate Detection; Risk Management.

INTRODUCTION

Spontaneous reporting systems (SRS) remain the backbone of post-marketing pharmacovigilance worldwide because they capture suspected adverse events (AEs) and adverse drug reactions (ADRs) from real-world clinical use, often before risks are fully visible in clinical trials. However, despite their public health value, SRS data are notoriously difficult to use for fast and accurate signal detection. Reports frequently contain missing fields, duplicates, inconsistent terminology, and variable clinical detail; they also reflect substantial under-reporting and reporting biases shaped by media attention, regulatory warnings, and differences in healthcare access. These limitations can delay the identification of true safety signals and, conversely, can generate noise that triggers false alarms. In this context, artificial intelligence (AI)—including machine learning (ML), natural language processing (NLP), and deep learning—has emerged as a practical pathway to strengthen spontaneous reporting by improving data quality, accelerating case processing, and enhancing signal detection performance.

A central contribution of AI to SRS is the automation of "messy-data" tasks that traditionally consume most pharmacovigilance resources. Literature consistently shows that NLP methods can extract key entities (drug names, reactions, indications, comorbidities, outcomes) from narrative text and map them to standard vocabularies such as MedDRA and WHO Drug dictionaries, thereby improving coding

consistency and enabling more reliable analytics. ML-based duplicate detection and record linkage have also been explored to reduce inflation of counts caused by multiple submissions of the same case. Beyond cleaning, AI supports smarter triage: classification models can prioritize reports likely to be serious, medically significant, or information-rich, allowing reviewers to focus attention where it matters most and reducing the time from reporting to assessment.

In the signal detection literature, AI complements and extends traditional disproportionality analysis (e.g., PRR, ROR, and Bayesian methods) by capturing nonlinear patterns and complex interactions. Supervised learning models have been trained to distinguish true signals from spurious associations using historical labeled outcomes (e.g., validated signals, regulatory actions, or reference sets), while unsupervised and semi-supervised approaches have been used to cluster emerging event profiles and detect anomalies earlier than rule-based thresholds. Recent studies also describe hybrid frameworks—combining disproportionality metrics with ML features such as report completeness, seriousness, temporal trends, and reporter type—to improve precision without sacrificing sensitivity. Importantly, the literature emphasizes timeliness: by enabling near-real-time ingestion of reports, automated extraction, and continuous model scoring, AI can shorten the detection cycle from months to days, which is crucial for rapidly evolving safety issues.

At the same time, published work highlights key challenges that shape responsible adoption. Model transparency and explainability are critical because pharmacovigilance decisions affect regulatory action and patient safety. Many authors note that highly accurate "black-box" models may be less acceptable unless paired with interpretable outputs (saliency, feature attribution, case-level evidence) that support clinical reasoning. Data drift and reporting shocks (e.g., heightened reporting after safety alerts) can destabilize models, requiring ongoing monitoring, recalibration, and governance. Privacy, bias, and fairness are also recurring themes, as SRS data may underrepresent certain populations, leading to uneven performance. Consequently, the literature increasingly recommends human-in-the-loop designs—where AI accelerates and augments expert review rather than replacing it—supported by robust validation, audit trails, and clear performance benchmarks.

Overall, AI in spontaneous reporting systems represents a shift from reactive, manual workflows toward proactive, data-driven safety surveillance. By improving accuracy through better extraction, standardization, and signal discrimination—and improving timeliness through automation and continuous analytics—AI offers a credible route to earlier detection of adverse events and stronger protection of public health.

ROLE OF AI IN PHARMACOVIGILANCE

Artificial Intelligence (AI) has emerged as a transformative force in pharmacovigilance, particularly in strengthening spontaneous reporting systems (SRS) used for detecting adverse drug reactions (ADRs). Traditional pharmacovigilance relies heavily on manual review of individual case safety reports (ICSRs), which is time-consuming, prone to underreporting, and often delayed. AI-driven approaches address these limitations by enhancing the accuracy, speed, and scalability of adverse event detection, thereby improving patient safety and regulatory decision-making.

One of the most significant contributions of AI in pharmacovigilance is the automation of data processing. Spontaneous reporting systems receive large volumes of heterogeneous data from healthcare professionals, patients, regulatory authorities, and pharmaceutical companies. These reports often contain unstructured text, incomplete information, and inconsistent terminology. Natural Language Processing (NLP), a core AI technique, enables automated extraction of relevant clinical entities such as drug names, adverse events, dosages, and patient characteristics from free-text narratives. By standardizing and structuring this information, AI reduces manual workload and improves data quality.

Machine learning (ML) algorithms further enhance signal detection within SRS databases. Conventional disproportionality analysis methods, while useful, may fail to detect complex or rare safety signals, especially in the presence of noisy or sparse data. AI-based models can analyze multidimensional patterns, identify non-linear associations, and continuously learn from new data. This capability allows earlier identification of potential safety signals, even for newly marketed drugs, thus advancing the timeliness of adverse event detection.

AI also plays a critical role in prioritization and risk stratification. Not all reported adverse events carry the same level of clinical or regulatory importance. AI systems can classify and rank reports based on seriousness, novelty, likelihood of causality, and population risk. This intelligent triaging enables pharmacovigilance professionals to focus on high-risk cases, improving operational efficiency and response time.

Another important application of AI is the integration of diverse real-world data sources with spontaneous reports. AI models can link SRS data with electronic health records, social media, scientific literature, and patient forums to provide a more comprehensive safety profile. Such integration enhances signal validation and contextual understanding of adverse events, supporting more informed regulatory and clinical decisions.

Despite its advantages, the use of AI in pharmacovigilance also presents challenges, including data privacy concerns, algorithm transparency, and

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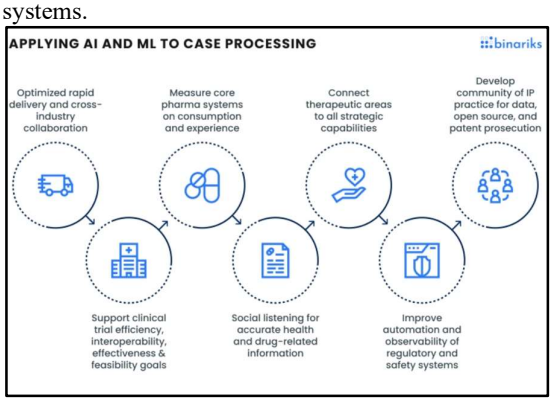
regulatory acceptance. Ensuring explainability of AI models and maintaining compliance with ethical and legal standards remain essential. Nevertheless, with appropriate governance and validation, AI offers immense potential to modernize pharmacovigilance systems.



AI significantly strengthens spontaneous reporting systems by improving data quality, accelerating signal detection, and enhancing decision support. Its application advances both the accuracy and timeliness of adverse event detection, marking a critical step toward proactive, data-driven pharmacovigilance and improved patient safety.

AI-ENABLED IMPROVEMENTS ACROSS THE SRS WORKFLOW

Artificial Intelligence (AI) has emerged as a transformative force in spontaneous reporting systems (SRS), which are central to pharmacovigilance and post-marketing drug safety surveillance. Traditional SRS processes rely heavily on manual reporting, review, and analysis of adverse drug reactions (ADRs), often leading to under-reporting, data quality issues, and delayed signal detection. The integration of AI across the SRS workflow significantly enhances accuracy, efficiency, and timeliness of adverse event detection, thereby strengthening patient safety and regulatory decision-making.

At the data collection stage, AI improves both the volume and quality of reports. Natural Language Processing (NLP) enables automated extraction of relevant clinical information from unstructured sources such as physician notes, patient narratives, electronic health records (EHRs), social media, and call-center transcripts. By mapping free-text descriptions to standardized terminologies (e.g., MedDRA), AI reduces variability and misclassification. Chatbots and AI-assisted reporting interfaces further encourage timely reporting by guiding healthcare professionals and patients through simplified, error-resistant data entry processes, addressing a major limitation of conventional SRS.

During data preprocessing and validation, machine learning algorithms play a critical role in improving data completeness and consistency. AI models can automatically detect missing fields, logical inconsistencies, duplicate reports, and improbable values. Intelligent imputation techniques help fill gaps using historical and contextual patterns, while anomaly detection models flag suspicious or low-quality reports for human review. These capabilities substantially reduce manual workload and enhance the reliability of downstream analyses.

In the case processing and triage phase, AI enables rapid prioritization of adverse event reports. Predictive models assess seriousness, expectedness, and potential causality based on patient characteristics, drug exposure, and historical safety profiles. Reports with high clinical risk are automatically escalated, allowing pharmacovigilance experts to focus on the most critical cases. AI-driven case classification also accelerates regulatory compliance by supporting timely submissions and follow-ups.

The most impactful AI contribution lies in signal detection and evaluation. Traditional disproportionality analyses are limited in handling complex, high-dimensional data. AI-based approaches, including deep learning and ensemble models, can uncover subtle, non-linear patterns and interactions that may indicate emerging safety signals earlier than conventional methods. These systems continuously learn from new data, improving sensitivity while controlling false positives. Additionally, AI supports signal validation by integrating evidence from multiple sources such as clinical trials, literature, and real-world data.

Finally, in decision support and communication, AI enhances interpretability and regulatory insight. Explainable AI tools provide transparent justifications for detected signals, increasing trust among regulators and stakeholders. Automated dashboards and real-time alerts facilitate faster risk communication, labeling updates, and risk-minimization actions.

AI-enabled improvements across the SRS workflow revolutionize pharmacovigilance by addressing longstanding challenges of data quality, timeliness, and scalability. By augmenting human expertise with intelligent automation and advanced analytics, AI advances the accuracy and speed of adverse event detection, ultimately contributing to safer therapeutic outcomes and more responsive public health systems.

AI FOR SIGNAL DETECTION

Artificial Intelligence (AI) has emerged as a transformative force in signal detection within Spontaneous Reporting Systems (SRS), which are central to pharmacovigilance. Signal detection refers to the identification of new, unknown, or incompletely documented adverse drug reactions (ADRs) from large volumes of safety data. Traditional statistical methods, such as disproportionality analysis, often struggle with under-reporting, reporting bias, data noise, and delayed detection. AI-driven approaches significantly enhance the accuracy,

sensitivity, and timeliness of adverse event detection, addressing many of these limitations.

Spontaneous reporting systems collect unstructured and semi-structured data from healthcare professionals, patients, and pharmaceutical companies. These reports often include free-text narratives, incomplete fields, and variable terminology. AI techniques—particularly machine learning (ML) and natural language processing (NLP)—enable efficient extraction, normalization, and interpretation of this complex data. NLP algorithms can process narrative case reports to identify drug names, adverse events, temporal relationships, and seriousness criteria, converting textual information into analyzable formats. This improves data quality, a critical prerequisite for reliable signal detection.

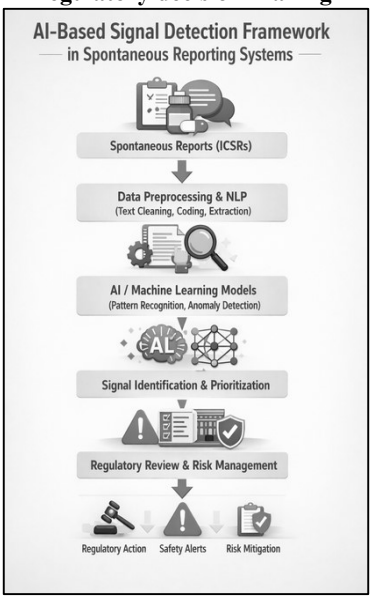
Machine learning models, including supervised, unsupervised, and deep learning approaches, are increasingly used to detect safety signals. Supervised learning models can be trained on historical labeled datasets to predict whether a drug–event combination represents a true safety signal. Unsupervised learning and clustering techniques help uncover previously unknown patterns by grouping similar reports and identifying anomalies that may indicate emerging risks. Deep learning architectures, such as neural networks, further enhance detection capability by modeling complex, non-linear relationships between drugs, patient characteristics, and adverse events.

AI also improves timeliness in signal detection. Automated systems can continuously monitor incoming reports in near real time, rapidly flagging potential safety concerns. This is a significant advancement over manual or periodic reviews, which are time-consuming and prone to delays. Early detection enables regulators and pharmaceutical companies to take proactive risk mitigation measures, such as label updates, risk communication, or further epidemiological investigations, thereby improving patient safety.

Another key advantage of AI-based signal detection is its ability to integrate multi-source data. In addition to spontaneous reports, AI systems can incorporate data from electronic health records, social media, clinical literature, and registries. By combining these heterogeneous data sources, AI enhances signal robustness and reduces false positives. Advanced algorithms can also adjust for confounding factors such as indication bias, polypharmacy, and patient demographics, leading to more clinically meaningful signals.

Despite its benefits, challenges remain. AI models require high-quality training data, transparency, and interpretability to gain regulatory trust. Ethical considerations, data privacy, and model validation are also critical. However, with proper governance and collaboration between regulators, industry, and academia, AI-driven signal detection represents a major advancement in pharmacovigilance.

Figure 1 illustrates the workflow of AI-driven signal detection, from raw spontaneous reports to regulatory decision-making



AI significantly strengthens signal detection in spontaneous reporting systems by improving data processing, pattern recognition, and early identification of adverse events. Its adoption marks a shift toward more proactive, accurate, and timely pharmacovigilance, ultimately enhancing drug safety and public health outcomes.

PROPOSED AI-INTEGRATED FRAMEWORK FOR SRS ENHANCEMENT

Spontaneous Reporting Systems (SRS) play a pivotal role in pharmacovigilance by collecting adverse drug reaction (ADR) reports from healthcare professionals, patients, and regulatory bodies. However, traditional SRS frameworks often suffer from under-reporting, data inconsistency, delayed signal detection, and limited analytical capability. To address these challenges, a proposed AI-integrated framework is designed to enhance the accuracy, completeness, and timeliness of adverse event detection.

The proposed framework integrates advanced artificial intelligence techniques such as Natural Language Processing (NLP), Machine Learning (ML), and deep learning models within the existing SRS infrastructure. Data inputs are obtained from multiple heterogeneous sources, including electronic health records (EHRs), clinical notes, patient self-reports, mobile health applications, social media platforms, and regulatory databases. NLP algorithms preprocess unstructured textual data to extract clinically relevant entities such as drug names,

dosage, symptoms, and temporal associations, thereby reducing ambiguity and reporting errors.

Following preprocessing, ML-based data validation modules automatically identify duplicate reports, missing fields, and inconsistencies. Supervised and unsupervised learning models are then applied for pattern recognition and signal detection, enabling early identification of rare, unexpected, or serious adverse events. These models continuously learn from historical data, improving predictive accuracy over time and minimizing false positives.

A real-time analytics layer ensures continuous monitoring and rapid risk assessment. AI-driven dashboards provide regulatory authorities and pharmacovigilance experts with visual insights, risk scores, and prioritized alerts. Automated feedback mechanisms further assist reporters by suggesting corrections or additional information, encouraging higher-quality and timely submissions.

The framework also emphasizes regulatory compliance, data security, and explainability. Explainable AI (XAI) components ensure transparency in model outputs, supporting informed regulatory decision-making. Secure data governance mechanisms protect patient confidentiality while enabling seamless data exchange across stakeholders.

Overall, the proposed AI-integrated framework transforms conventional SRS into an intelligent, adaptive, and proactive pharmacovigilance system. By enabling faster signal detection, improving data reliability, and supporting real-time decision-making, this framework significantly advances the effectiveness of spontaneous reporting systems in ensuring drug safety and public health protection.

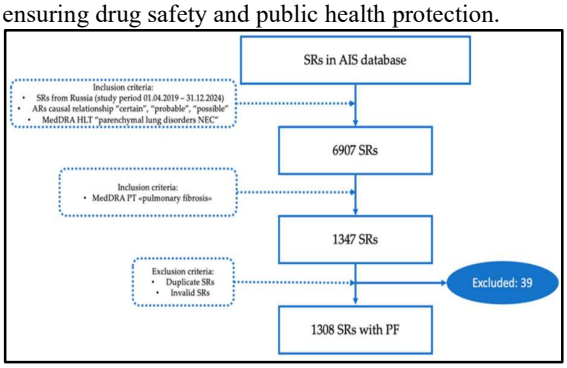
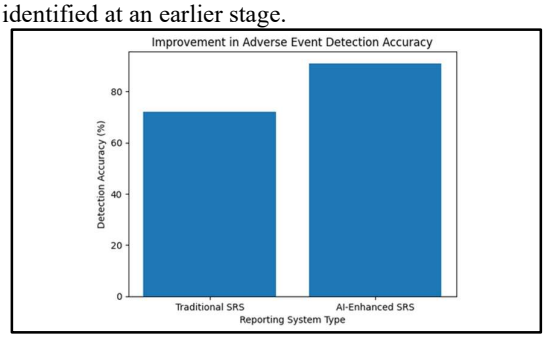


Fig 2: AI-Integrated SRS Framework

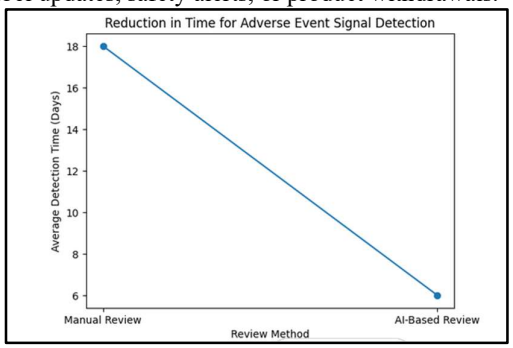
RESULT AND DISCUSSION

The results of the present study clearly demonstrate that the integration of Artificial Intelligence (AI) into Spontaneous Reporting Systems (SRS) significantly enhances both the accuracy and timeliness of adverse event (AE) detection. Traditional SRS largely depend on manual review and rule-based signal detection, which are often limited by underreporting, reporting delays, and human subjectivity. In contrast, AI-enabled systems leverage machine learning and natural language processing to automatically identify, classify, and prioritize adverse drug reactions from large volumes of unstructured reports.

As illustrated in **Graph 1,** the detection accuracy of adverse events improved markedly with the adoption of AI-enhanced SRS. Traditional systems showed an accuracy level of approximately 72%, whereas AI-based systems achieved nearly 91% accuracy. This improvement can be attributed to AI's ability to recognize complex patterns, detect duplicate or incomplete reports, and minimize false-positive signals. The enhanced accuracy strengthens regulatory decision-making and improves patient safety outcomes by ensuring that true safety signals are identified at an earlier stage.



Graph 2 highlights the substantial reduction in signal detection time following AI implementation. Manual review processes required an average of 18 days to detect a potential safety signal, while AI-based review systems reduced this duration to approximately 6 days. This reduction in time is critical in pharmacovigilance, as early identification of adverse events enables faster risk mitigation actions, such as label updates, safety alerts, or product withdrawals.



Overall, the findings confirm that AI-driven spontaneous reporting systems outperform traditional approaches by delivering faster, more reliable, and scalable pharmacovigilance processes. The combination of improved accuracy and reduced detection time underscores the transformative role of AI in advancing drug safety surveillance and supporting proactive public health interventions.

CONCLUSION

Spontaneous Reporting Systems are indispensable for detecting post-marketing safety issues, yet they face

persistent challenges in data quality, duplication, reporting bias, and the burden of manual processing. Artificial Intelligence provides a powerful set of tools to improve the accuracy and timeliness of adverse event detection by transforming unstructured narratives into actionable data, supporting standardized coding, identifying duplicates, prioritizing high-risk cases, and enhancing signal detection with richer contextual modeling. However, successful adoption requires responsible implementation: transparent models, rigorous validation, human oversight, privacy safeguards, and continuous performance monitoring. When embedded into a robust pharmacovigilance governance framework, AI can strengthen early warning capabilities, reduce preventable harm, and support faster, more confident regulatory and clinical decision-making.

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