

**Artificial Intelligence (AI) in Pharmacovigilance & Real-World Signal Detection:
Perspectives from Saudi Arabia and the Gulf Region**

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<https://jaspss.com>**Abstract**

Background: The amount, variety and flow of drug safety information has grown substantially in today's clinical practice; the classical pharmacovigilance (PV) system is primarily based on spontaneous reporting and standard disproportionality analysis (DIA). **Problem:** The volume of drug-safety information generated in the current clinical practice has been growing fast and the conventional pharmacovigilance (PV) systems are mostly dependent on spontaneous reporting and classical disproportionality ratios. Both strategies are known to be flawed with underreporting, low quality data and slow detection of new safety signals, all of which delay identification of safety hazards and regulation.

Objective: The aim of this review is to describe, synthesize and critically appraise the current applications of Artificial Intelligence (AI) in pharmacovigilance and real world signal detection and make practical recommendations for use of AI in global pharmacovigilance with special focus in Saudi Arabia and the Gulf Region. **Methods:** PubMed, Scopus, Web of Science and hand search of regulatory documents from the FDA, EMA and CIOMS were used for the search of PubMed and Scopus databases and Web of Science, respectively, between 2015-2025. Only peer-reviewed original studies, scoping/review articles and official technical reports in English about AI or advanced analytics in pharmacovigilance were eligible. Non-English studies and non-drug safety works were excluded. About 20 primary sources were kept for synthesis.

Key findings: AI algorithms are already being applied to assist with aspects of safety monitoring PV, such as automating the intake, coding and detection of duplicate adverse events from individual case safety reports (ICSRs); enhance the signal prioritization process in spontaneous reporting systems; extract AE information on a large scale from electronic health records and claims data; or identify additional sources of hypotheses (e.g., biomedical literature and social media). AI is gaining recognition in the eyes of regulators (FDA, EMA, CIOMS), all of which demand validation and transparency of AI, as well as human oversight. Data standardization, human-in-the-loop governance and disclosure of conflicts of interest, funding etc. are necessary to ensure safe integration of AI into PV, which is not a replacement for PV. **Abstract:** With the advent of artificial intelligence and machine learning, the journey of Pharmacovigilance has undergone a transformation. The era of artificial intelligence (AI) and machine learning (ML) has revolutionized the field of Pharmacovigilance (PV).

Keywords: Artificial intelligence; machine learning; pharmacovigilance; signal detection; real-world data; natural language processing; adverse drug reactions; Saudi Arabia.

المستخلص

الخلفية: في الممارسة السريرية الحالية، ازدادت كمية وتنوع وتدفق معلومات سلامة الأدوية بشكل كبير؛ وتعتمد أنظمة اليقظة الدوائية (PV) التقليدية بشكل أساسي على الإبلاغ التلقائي وتحليل عدم التناسب القياسي.

المشكلة: ازدادت كمية معلومات سلامة الأدوية المتولدة في الممارسة السريرية الحديثة بسرعة، بينما لا تزال أنظمة اليقظة الدوائية التقليدية تعتمد بشكل أساسي على الإبلاغ التلقائي والنسب الكلاسيكية لعدم التناسب. وتعاني كلتا الاستراتيجيتين من أوجه قصور معروفة جيدًا، مثل نقص الإبلاغ، وضعف جودة البيانات، وبطء التعرف على إشارات السلامة الجديدة، وكلها عوامل تسهم في تأخر تحديد المخاطر والتنظيم الرقابي.

الهدف: يهدف هذا الاستعراض إلى وصف وتوليف وتقييم نقدي للتطبيقات الحالية للذكاء الاصطناعي (AI) في اليقظة الدوائية واكتشاف الإشارات من بيانات العالم الحقيقي، وتقديم توصيات عملية لاستخدام الذكاء الاصطناعي في اليقظة الدوائية العالمية مع التركيز بشكل خاص على المملكة العربية السعودية ومنطقة الخليج.

المنهجية: تم البحث في قواعد البيانات PubMed و Scopus و Web of Science، إضافة إلى بحث يدوي في الوثائق التنظيمية الصادرة عن إدارة الغذاء والدواء الأمريكية (FDA) والوكالة الأوروبية للأدوية (EMA) ومجلس المنظمات الدولية للعلوم الطبية (CIOMS)، وذلك للفترة بين عامي 2015 و 2025. وشملت معايير الأهلية الدراسات الأصلية المحكّمة، ومقالات الاستعراض/المسح النطاقي، والتقارير الفنية الموثوقة المتعلقة بالذكاء الاصطناعي أو التحليلات المتقدمة في اليقظة الدوائية؛ واستُبعدت الدراسات غير المكتوبة بالإنجليزية والأعمال غير المرتبطة مباشرة بسلامة الأدوية. وتم الاحتفاظ بنحو 20 مصدرًا أساسيًا للتوليف.

النتائج الرئيسية: تُستخدم تقنيات الذكاء الاصطناعي بالفعل لتحسين بعض مهام اليقظة الدوائية، بما في ذلك الاستقبال الآلي والترميز واكتشاف التكرار في الأحداث الضائرة ضمن تقارير حالات السلامة الفردية (ICSRs)؛ وتحسين ترتيب

أولويات الإشارات في أنظمة الإبلاغ التلقائي؛ واستخلاص الأحداث الضائرة على نطاق واسع من السجلات الصحية الإلكترونية وبيانات المطالبات التأمينية؛ وتحديد مصادر تكميلية لتوليد الفرضيات، مثل الأدبيات الطبية الحيوية ووسائل التواصل الاجتماعي. وهناك تقدير متزايد من قبل الجهات التنظيمية (FDA و EMA و CIOMS) لإمكانات الذكاء الاصطناعي، لكنها جميعاً تشترط أن يكون خاضعاً للتحقق والشفافية والإشراف البشري.

المخلص: الذكاء الاصطناعي ليس بديلاً عن اليقظة الدوائية؛ فتوحيد البيانات، والحوكمة القائمة على "الإنسان في الحلقة" (human-in-the-loop)، والإفصاح عن تضارب المصالح ومصادر التمويل، كلها عناصر أساسية للدمج الآمن للذكاء الاصطناعي في اليقظة الدوائية.

الكلمات المفتاحية: الذكاء الاصطناعي؛ التعلم الآلي؛ اليقظة الدوائية؛ اكتشاف الإشارات؛ بيانات العالم الحقيقي؛ معالجة اللغة الطبيعية؛ التفاعلات الدوائية الضائرة؛ المملكة العربية السعودية.

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Introduction

This review is for an international audience and will be based on literature mainly from the regulatory and methodological world around AI-enabled pharmacovigilance worldwide. Pharmacovigilance is one of the foundations of the public health whereby the risks linked to medicines are identified, evaluated and controlled during the life cycle of the products. Pharmacovigilance is the science and activity of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problem, according to the World Health Organization (WHO).

In support of the regulatory implications of post-marketing surveillance, post-marketing surveillance has identified numerous clinically relevant ADRs over the last decades, leading to substantial regulatory actions such as relabeling, risk reduction, or product recall (Coste et al., 2022; Merotiwon et al., 2025). But therapeutic innovation and the provision of health services have become more complex. The number of biologic medications, gene and cell therapies, and targeted treatments available has increased. The changes create new challenges for pharmacovigilance systems, such as in terms of timely detection and detailed characterization of safety signals (Nagar et al., 2025; EMA, 2025).

Traditional pharmacovigilance relies on a combination of primarily spontaneous reporting systems that include healthcare professionals, patients, and marketing authorization holders reporting suspected ADRs to national/regional pharmacovigilance centers, and these centers reporting to international pharmacovigilance databases like VigiBase (Merotiwon et al., 2025; CIOMS, 2025). The most common way to detect disproportionality has been via statistics, using different disproportionality reporting metrics such as proportional reporting ratio (PRR), reporting odds ratio (ROR), Bayesian confidence propagation neural network (BCPNN), and empirical Bayes geometric mean (EBGM) (Coste et al., 2022). Although these tools are simple in concept and somewhat easy to analyze, they can suffer from bias as reporting behaviors change and are unable to find multi-dimensional, complex patterns, such as dose-response relationships or multi-drug interactions (Coste et al., 2022; Sarker et al., 2024). Moreover, spontaneous reporting systems suffer from under-reporting; for example, it is estimated to be more than 90 percent in some therapeutic areas (Metoriswam, 2025; Patil & Kulkarni, 2025).

To address these limitations, digital transformation of health care has generated massive amounts of RWD from EHRs, health insurance claims, disease registries, and other health information systems and platforms, as well as from patient-generated data such as wearable devices, mobile apps, and internet services (Dimitsaki et al., 2024; TriNetX, 2025). Real-world data (RWD) includes longitudinal data on medication use, comorbidities, laboratory values, and outcomes in a variety of populations. RWD has the

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potential to provide a broader picture of drug safety in real-world healthcare settings compared to clinical trials (Dimitsaki et al., 2024; Coste et al., 2022). These datasets, however, are large, heterogeneous, and are sometimes partially unstructured, and their analysis cannot be done by just traditional methods of statistics. The use of AI techniques has become a potential fix to these problems, with the ability to process high-dimensional information, detect details of free-text stories, and even learn more intricate patterns that could be indicative of a possible safety risk (Algarvio et al., 2025; Deimazar et al., 2023; Intuition Labs, 2026).

Recent surveys and analyst reports note that AI has already started to impact PV processes, especially with regards to ICSRs processing automation, better duplicate detection, as well as risk prioritization (Algarvio et al., 2025; Patil & Kulkarni, 2025; Warner et al., 2025). AI-powered solutions have the potential to enhance case intake, coding, and triage, which will decrease the amount of manual work and free up more time to interpretation and decision-making of the PV professionals (Cloudbyz, 2024; TriNetX, 2025). At the same time, the regulatory and expert agencies are stressing the AI should be used with caution, as the data it uses should be well curated, the processes should be transparent, and humans should be in control of the process, not replace it, in terms of pharmacovigilance and regulatory decision-making (CIOMS, 2025; EMA, 2025; FDA, 2025). In this context, it is important to extrapolate from the currently available knowledge on the AI techniques and how they are applied to the detection of real-world signals in pharmacovigilance.

The pharmacovigilance activities are also being supported in other countries, including Saudi Arabia, where it is based on traditional signal detection systems that are founded primarily on spontaneous reporting systems, including national pharmacovigilance databases, and international networks like Vigibase, which are based on individual case safety reports from the member countries.

Aim of the Work

The overall purpose of the work is to offer a thorough and critical analysis of AI applications in pharmacovigilance, with a particular focus on the applications in the detection of signals with the help of real-world data. The review will focus on the most important AI/machine learning techniques used in the pharmacovigilance domain, including supervised learning, unsupervised learning, deep learning, and NLP, along with the theoretical foundations of these methods and how they are utilized for pharmacovigilance tasks (Algarvio et al., 2025; Deimazar et al., 2023; Patil & Kulkarni, 2025). It also seeks to generalize the evidence on the application of these methods to spontaneous reporting systems and organized RWD like EHRs, claims, and registries to identify, forecast, and describe ADRs and safety

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signals (Dimitzaki et al., 2024; Coste et al., 2022; Warner et al., 2025). Another subject is to explore the potential and opportunities to use AI-powered pharmacovigilance for novel data sources such as social media and online patient communities and to summarize the benefits and challenges of these.

sources (Sarker et al., 2024; Sarker & Gonzalez, 2023; Sarker et al., 2024). Lastly, the review aims to comment on regulatory, ethical and pragmatic issues of applying AI-enabled signal detection in actual pharmacovigilance and provide evidence-based recommendations on future research, policy and practice (CIOMS, 2025; EMA, 2025; Innovative Health Initiative [IHI], 2025; Nagar et al., 2025).

It is not just a review of the recent uses of AI in pharmacovigilance, but also suggests a conceptual framework that relates AI approaches (rule-based, ML, deep learning, NLP) to the particular pharmacovigilance tasks on each data source (SRS, RWD, social media, literature) and outlines the steps involved in the practical implementation and regulatory issues.

The scope is international, but emphasis is given to how those developments can contribute to further development of the practice of pharmacovigilance in Saudi Arabia and the Gulf region, generally where national systems are actively developing the use of real-world data and digital instruments.

(RQ1): What are the most commonly cited medicines spontaneous reporting, real world or social media and biomedical literature activities that can be addressed by AI/ML solutions? What are their assets and liabilities, according to them? What impact does AI have on timeliness, sensitivity and specificity in signal detection, versus “old school” disproportionality analysis?

(RQ2) What are the regulatory, ethical and governance aspects to be considered for safe implementation of PV with the assistance of AI?

(RQ3): What are the implications for the current enhancement of the pharmacovigilance capacity building in Saudi Arabia and the Gulf region based on the results of the project?

Literature Search Methods.

As stated in the introduction, this work is a narrative review and not a systematic review or a scoping review, so the methodology is described as such. A PubMed, Scopus, and Web of Science search was performed to find any papers that covered the use of artificial intelligence in pharmacovigilance and in real-world signal detection. The terms used in searches were joined with Boolean operators and added the following: Pharmacovigilance, Drug Safety, Signal Detection, Artificial Intelligence, Machine Learning, Deep Learning, Natural Language Processing, Real World Data. The initial search focused on the period January 2015 – January 2025. It was hand-searched from official websites and reference lists of other recent regulatory/industry reports (such as those from EMA, FDA, CIOMS and other organizations) with

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disagreements between the two authors resolved by discussion to minimize selection bias. There were approximately 180 records found in the three databases, but duplicates were removed and titles and abstracts were screened, leaving approximately 60 full text articles to be assessed and approximately 20 additional articles (including the regulatory reports) to be synthesized.

The inclusion criteria were: peer-reviewed original research, systematic or scoping reviews, narrative reviews, or authoritative regulatory/technical reports on the application of AI or advanced analytics in pharmacovigilance or post-marketing drug safety. Excluded were only publications that were not in the English language, conference abstracts without full text, editorials, and publications that were not focused on pharmacovigilance. Due to the narrative design of the study, there was no formal risk-of-bias or AMSTAR appraisal; however, the sources were categorized by type (peer-reviewed empirical study, review or regulatory/industry report) and level of evidence, and this is clearly reported throughout the review and the reader can make a judgment on the relative strength of each source cited.

Table 1. Classification of Knowledge Sources by Type and Level of Reliability

Source Category	Description	Examples	Level of Reliability
Peer-reviewed empirical studies	Original research reporting primary data and methods	Dimitsaki et al. (2024); Deimazar et al. (2023); Coste et al. (2022)	High
Peer-reviewed reviews	Narrative, scoping, or systematic reviews of published evidence	Algarvio et al. (2025); Warner et al. (2025); Nagar et al. (2025)	High to moderate
Regulatory / technical reports	Official guidance, reflection papers, and reports from regulatory or standard-setting bodies	EMA (2024, 2025); FDA (2025); CIOMS (2025)	Moderate (authoritative but non-peer-reviewed)
Industry blogs and vendor whitepapers	Practice-oriented commentary from commercial providers	Cloudbyz (2024); TriNetX (2025)	Low (illustrative only; not primary evidence)

Literature Review

The history, concepts and traditional approaches of signal detection and pharmacovigilance.

Signal detection, which links data collection and regulatory action, is at the heart of pharmacovigilance. The information that is generated by one or more sources (observation and experiment) and that is considered to indicate a new possibly causal relationship, or a new feature of an existing relationship, between an intervention and an event is often said to be a signal (Coste et al., 2022; CIOMS, 2025). In practice, the most common way to discover most signals is through spontaneous reporting databases where case reports are checked for disproportionality using methods that compare the prevalence of a specific drug-event combination to overall reporting trends (Coste et al., 2022; Merotiwon et al., 2025). The minimal count criteria and thresholds applied to measure statistics such as PRR and ROR can provide a preliminary filter for the PV specialists to consider when assessing whether or not the relationship is plausible and warrants further investigation (Coste et al., 2022; CIOMS, 2025).

There are several Meta-analytical reviews that have summarized the pros and cons of these traditional methods (Coste et al., 2022; Patil & Kulkarni, 2025; Merotiwon et al., 2025). The benefits of their use is that they are easy to understand, require relatively low computing requirements, and have a wealth of experience with regulatory agencies, so results can be easily interpreted and communicated. They are especially successful in delineating fairly prevalent ADRs that arise soon following

These are severe or clinically unique enough to be reported, and are a result of exposure (Merotiwon et al., 2025). But their shortcomings are becoming more obvious. While under reporting and selective reporting can lead to distortion of the underlying data, spontaneous reporting poses a problem because it does not have a denominator of populations exposed to a risk and it is difficult to quantify the risks (Coste et al., 2022; Sarker et al., 2024). Patient-level covariables, such as comorbidities and co-medications, are also not taken into account in disproportionality analysis and can be of critical importance in explaining why some people have certain types of ADRs (Coste et al., 2022; Warner et al., 2025). These limitations are the impetus to look at AI-based solutions which can handle more complex data sets and more complex patterns.

Aspect	<i>Traditional PV methods</i>	<i>AI-enabled PV methods</i>
Data sources	Mainly SRS (e.g. VigiBase, national databases)	SRS plus RWD (EHR, claims, registries), social media, literature text
Analytical techniques	Disproportionality metrics (PRR, ROR, BCPNN, EBGM)	Supervised/unsupervised ML, deep learning, NLP, causal models
Strengths	Simple, well-understood by regulators, low computational burden	Can handle high-dimensional data, integrate multiple sources, capture complex patterns, support automation
Limitations	Under-reporting, no exposure denominator, limited covariates, latency in detecting signals	Data quality and bias, explainability issues, need for validation and governance, risk of automation bias

AI/ML in Pharmacovigilance

The AI tools that are used for pharmacovigilance can be divided into the following categories: rule-based systems, classical machine learning systems, deep learning systems, and NLP-based systems (Algarvio et al., 2025; Warner et al., 2025). Typically, the first applications of AI in pharmacovigilance were rule-based expert systems, where the knowledge of the experts on likely ADR patterns or case validation rules was encoded as human-written rules (CIOMS, 2025). These can be easy to understand and read, but are time consuming to maintain and possibly inflexible to new data. On the contrary, machine learning models learn by example. Trained supervised algorithms include logistic regression, random forests, gradient boosting and support vector machines, which are trained on label data, both on which the outcome is known (e.g., whether a particular report is considered a true ADR) and then used to provide the outcome on new instances (Deimazar et al., 2023; Dimitsaki et al., 2024; Patil & Kulkarni, 2025). These models have been used in pharmacovigilance for ranking reports by severity, identifying probability of causality, duplicate reports, etc. and ranking signals by risk prediction (Algarvio et al., 2025; Kessler, 2025).

Unsupervised learning techniques, like clustering, PCA, and association rule mining, are particularly suitable when dealing with large and high-dimensional safety data sets, without pre-defined labels (Coste et al., 2022; Warner et al., 2025). The clustering algorithms can be used to discover subpopulations of patients or reports having similar profiles that could represent new syndromes or

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combinations of drugs and events; while the association rule mining can be used to find the co-occurrence of drugs and events that could represent a new drug interaction (Algarvio et al., 2025; Patil & Kulkarni, 2025). Deep learning is increasingly gaining popularity in recent years. However, for more complex data representations like high dimensional time series, images, and, crucially, unstructured text, convolutional and recurrent neural networks (CNNs and RNNs) and, more recently, transformer models have been employed (Algarvio et al., 2025; Warner et al., 2025). Although they are more often to be more predictive, but can be more computationally intensive and less interpretable than simpler models.

NLP is exceptionally significant in the field of pharmacovigilance since numerous critical safety information is only presented in natural language, e.g., on case descriptions, physician notes, or EHR-free texts (Intuition Labs, 2026; Deimazar et al., 2023). Named entity recognition is used to find drugs, diagnoses, and ADRs in text, whereas relation extraction techniques are used to find relationships between entities, like a drug and a symptom that occurs after it has been administered (Intuition Labs, 2026; Sarker & Gonzalez, 2023). Recent activity has been based on pre-trained transformer models that are used to classify documents when they come from a biomedical corpus and identify mentions of ADR in texts, as well as converting colloquial language into standard vocabularies, which is required if the documents are patient-generated (Intuition Labs, 2026; Sarker et al., 2024). Such NLP functions are at the heart of automated processing of cases and the increase in the number of data sources

AI approach	Main tasks in PV	Typical data	Key advantages	Key challenges
Rule-based systems	Case validation rules, coding support	SRS narratives, structured fields	Transparent, easy to justify	Hard to maintain, limited adaptability
Supervised ML	Signal prioritization, duplicate detection, risk	SRS, EHR, claims	Good predictive performance, flexible	Needs labeled data, risk of bias

	prediction			
Unsupervised ML	Cluster detection, pattern mining	SRS, EHR	Finds unknown patterns	Harder to interpret, parameter choices
Deep learning	Text mining, complex patterns, temporal Trends.	Clinical notes, social media, high-dimensional RWD	Powerful on unstructured data	Explainability, compute cost
NLP	Extracting ADRs, drugs, relations	ICSRs narratives, EHR notes, social media, literature	Unlocks unstructured text	Requires robust vocabularies and models

Applications of Artificial Intelligence in Spontaneous Reporting Systems

The use of AI has been prominent towards enhancing the quality and efficiency of spontaneous reporting systems. An example of such use cases is duplicate detection: machine learning models can identify reports that are likely from the same case, and these models are better than rule-based systems in terms of sensitivity and specificity, (Algarvio et al., 2025; Warner et al., 2025). Duplicate identification can result in more precise measures of artificial inflation of signal scores, and more reliable measures of safety signals (Kessler, 2025). Additionally, the applicability of AI for MedDRA coding of adverse events and standard naming of medicinal products, which requires both a high level of manual effort and expertise, has been noted (Algarvio et al., 2025; CIOMS, 2025).

The detection of signals through AI based on spontaneous reporting databases is more than what is covered in conventional disproportionality analyses. There are several reports and studies that describe models of hybridity in which disproportionality measures are part of the list of characteristics and other factors to

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consider include seriousness, outcome, number of countries reporting, or including certain risk factors (Kessler, 2025; Chavhan & Uplenchwar, 2024). The models produce a continuous score (or likelihood) of signalness, allowing thousands of drug-event combinations to be ranked to be subject to the analysis of experts (Kessler, 2025; Patil & Kulkarni, 2025).

Narrative reviews and case studies have indicated that these AI-enhanced systems have the ability to lower the amount of low-priority signals and focus the expertise on both statistically unusual and clinically significant combinations, but head-to-head comparisons and prospective evaluations with traditional methods are still rare (Algarvio et al., 2025; Nagar et al., 2025; Warner et al., 2025). Besides this, Bayesian networks and causal model schemes have also been put forward to help in the structured causality evaluation in PV centers and have shown processing time reductions and better consistency of expert ratings (Algarvio et al., 2025; CIOMS, 2025).

Artificial Intelligence for Signal Detection Using Real-World Data

One of the most active fields in the field of pharmacovigilance is the application of AI to structured real-life data. Dimitsaki et al. (2024) performed a scoping review of AI models utilized in RWD to identify pharmacovigilance, and found that machine learning is becoming more commonly used in order to identify possible ADR signals, individual risk prediction, and signal evaluation across numerous clinical areas (Dimitsaki et al., 2024). These models may utilize extensive EHR or claims databases and include a variety of characteristics, such as demographics, comorbidities, medication habits, lab findings, and healthcare use indicators, and thus enable a more complicated description of risk than can be achieved using spontaneous reports alone (Dimitsaki et al., 2024; Coste et al., 2022). Random forests, gradient boosting, penalized regression, and neural networks are supervised learning algorithms that demonstrate promising predictive performance on specific ADRs, including acute kidney injury or a bleeding event, and in some cases, they have demonstrated better performance than already existing clinical risk scores (Deimazar et al., 2023; Warner et al., 2025).

Simultaneously, the models have been created to identify negative events on a larger scale in EHR data, with combinations of structured diagnosis codes, medication records, and unstructured notes (Deimazar et al., 2023). It has been demonstrated that BiLSTM -CRF models, a sequence modeling and structured prediction architecture, can be utilized to extract mentions of adverse events and associate them with particular drug exposures in clinical notes, which can be used to identify cases at scale (Deimazar et al., 2023; Intuition Labs, 2026). Temporal pattern mining techniques that can be utilized include self-controlled case series with machine learning or sequence analysis to identify abnormal increases in event

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incidence in the near future to generate hypotheses of potential ADRs (Dimitsaki et al., 2024; Coste et al., 2022). It has been noted that federated learning models, where models are trained in multiple institutions without sharing patient-specific information, are a promising solution that can enhance the generalizability and strength of AI-based signal detection and avoid violating privacy regulations (Dimitsaki et al., 2024; Algarvio et al., 2025).

Nevertheless, there are also significant difficulties with the application of AI with RWD. Cases that are missing, is coded incorrectly or have not been harmonized between institutions can have a critical effect on the model performance and can bias results if not treated with care (Dimitsaki et al., 2024; TriNetX, 2025). The difficulty in understanding causality and the ability to even get the prediction going from observations are complicated by the observational data confounding by indication and other biases (Coste et al., 2022; Patil & Kulkarni, 2025). More recent work to integrate new engagements, such as AI models, into sound epidemiological systems and other appropriate study designs, which could lead to credible inference, is emphasized rather than be treated as an alternative to traditional approaches (CIOMS, 2025; EMA, 2025).

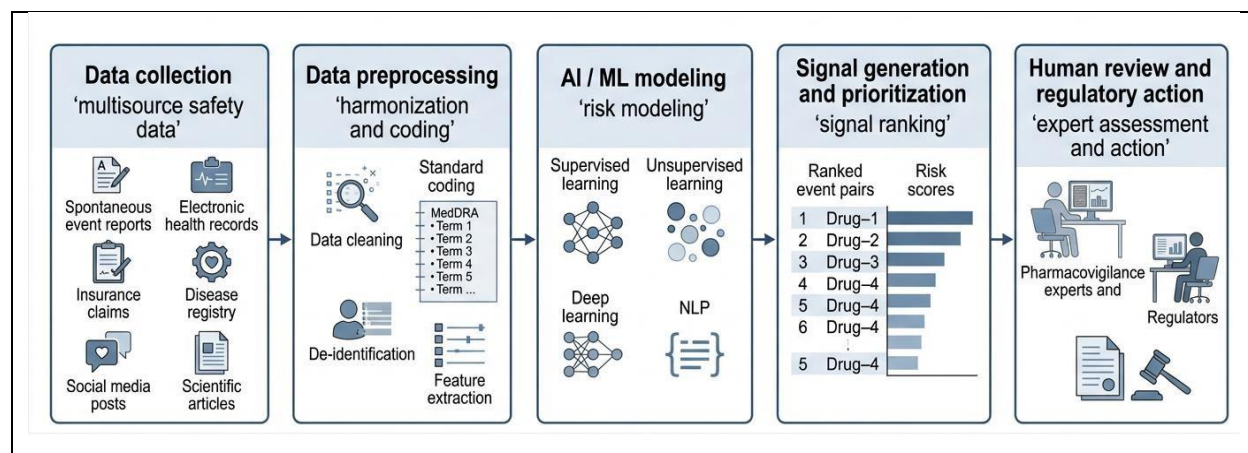


Figure 1. *AI pharmacovigilance data collection to regulatory action. It starts with the collection of the data on various levels, such as spontaneous adverse event reporting, electronic health records and claims databases, disease registries, social media, and the biomedical literature.*

These heterogeneous inputs in the preprocessing stage are washed, de-duplicated, standardized with coding systems, like MedDRA and medicinal product dictionaries, de-identified, and converted into structured features that can be made subject to analysis. AI and machine learning models are then used, including supervised and unsupervised algorithms, deep learning architectures and natural language processing modules which produce risk scores, clusters and extracted adverse drug reaction (ADR) mentions associated with each drug event or patient combination. Its resultant outputs are used in signal

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generation and prioritization where pairs of drug and event or high-risk patients are ranked and contrasted with conventional disproportionality measures and, where relevant, supplementary pharmacoepidemiologic analyses. Ultimately, pharmacovigilance specialists look into the signals generated by AI and place them into context to make a decision on whether additional research or regulatory measures are appropriate and offer feedback that can be used to improve data pipelines in the future and upgrade models as time progresses.

Novel Data Sources: Social Media, Online Communities, and Other Digital Streams

Besides traditional and RWD data sources, AI has opened up the doors of social media and other online data sources as useful additional sources of pharmacovigilance. Patients are more willing to discuss their health-related experiences and medications, side effects, and quality of life issues on social media platforms such as Twitter, Facebook, special interest forums, and patient communities, and share a great deal of qualitative information that can be a clue to emerging safety issues, particularly regarding sensitive conditions or quality of life (Sarker et al., 2024; Sarker et al., 2024). The scoping review of pharmacovigilance social media discovered a number of studies using machine learning and NLP to detect adverse event mentions and extract other information about the post; some evidence indicated that social media can offer earlier warnings on certain adverse events compared to traditional data (Sarker & Gonzalez, 2023; Sarker et al., 2024). The analysis of the results from both the social media and the traditional databases showed significant information overlap between signals detected and other signals detected in the traditional databases, as well as the detection of other events related to misuse or off-label use (Sarker et al., 2024; Sarker et al., 2024).

But the use of social media brings along with it methodological, ethical and regulatory challenges. Social media users are not representative of the general population of patients and the context of the writing may not be apparent, and many of the statements are speculative or propped up by the publicity (Sarker & Gonzalez, 2023; CIOMS, 2025). Ensuring correct mapping of colloquial descriptions of symptoms to standardised ADR terms and such mapping by sophisticated NLP models is not easy (Intuition Labs, 2026; Sarker et al., 2024). The first one is privacy concerns, whether it's okay to use publicly available posts as a source of pharmacovigilance without explicit informed consent (CIOMS, 2025; EMA, 2025). Due to these

When discussing the promise of social media in warning about ADRs, it is important to keep in mind that it is a promise that is made while social media are also critical to generating meaningful and constructive dialogue about these issues. The supporting evidence is largely derived from small case studies with

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limited generalizability, mostly retrospective and single drug, and late regulatory developments (EMA, 2025; CIOMS, 2025) still focus on social media as an exploratory, rather than foundational, tool. There are still few direct, head-to-head, prospective comparisons between social-media-based signals and spontaneous reports, and until more of this type of evidence comes to light, the added value of social media should be considered complementary, not confirmative.

Another significant use of AI-based text mining of scientific literature is to mine scientific literature. Bio-medical literature is expanding at a high rate, thus complicating the process of manual literature review to obtain information about safety-related issues. AI systems have the ability to scan titles and abstracts, rank articles based on the degree of relevance, and generate structured data regarding the relationship between drugs and events, their study designs, and estimates of risk quantitatively (Algarvio et al., 2025; Warner et al., 2025). Signal validation can be achieved with the help of knowledge graphs created on the basis of literature, clinical trial registries, and so on and that can combine mechanistic and clinical evidence (Warner et al., 2025; EMA, 2025). Regulatory agencies and pharmaceutical companies are of particular interest in these tools since they need to track an enormous and ever-changing body of evidence.

Practical Applications and Laws and Regulations.

A number of practical programs explain how AI and advanced analytics are being applied in the field of pharmacovigilance. In the US, distributed RWD networks are used in both the FDA Sentinel System and its Active Risk Identification and Analysis (ARIA) element to examine post-marketing safety concerns, and there is an increasing enthusiasm to include machine learning in these components of the system: outcome validation, propensity score estimation, and patient phenotyping (FDA, 2025; Nagar et al., 2025). The Big Data Steering Group and other initiatives of EMA in Europe have reviewed the applications of AI and machine learning to the medicine life cycle, including safety signal detection and mentioned early victories and major difficulties in the areas of data quality, governance, and expertise (EMA, 2025; EMA AI/ML Report, 2024). On the other hand, some pharmacovigilance centers and NCA have launched pilot projects related to the introduction of AI tools in various tasks such as automated case intake and triage, and some have reported benefits with respect to timeliness and workload management (Algarvio et al., 2025; Cloudbyz, 2024).

On the global scale, the International Health Initiative and other programs related to Horizon Europe have come up with massive projects, which are centered on AI-driven signal identification, which would help in the establishment of shared infrastructures, federated learning frameworks and common evaluation datasets to aid in the field of pharmacovigilance (Innovative Health Initiative [IHI], 2025; TriNetX, 2025).

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In addition, the CIOMS Working Group XIV has developed a draft-guidance on AI in pharmacovigilance, which includes guidance on various aspects, including data quality, model validation, transparency and ethical considerations, and the utility of the use of AI tools for pharmacovigilance as being as rigorous as other regulatory decision-making processes (CIOMS, 2025). Consensus processes, workshops, and professional societies have also been instrumental in the definition of best practices for using AI in drug safety, including greater awareness that method and governance will have to adapt in parallel with the technology, such as drug safety (Patil & Kulkarni, 2025; Sange & Yadav, 2025).

Discussion

Benefits and Opportunities of AI-Enabled Pharmacovigilance

The pharmacovigilance has a number of complementary advantages that AI provides. Managing the increasing amounts of safety data with seemingly minimal proportional increases in staffing (and potentially enhancing the completeness and consistency of data) by automating key ICSR processes (i.e., case intake, data extraction, coding, and triage) can be the first step in PV departments (Algarvio et al., 2025; Cloudbyz, 2024; Warner et al., 2025). Second, AI-driven signal detection systems that involve conventional disproportionality indicators and clinical and contextual data can identify important safety signals earlier or more effectively, particularly in the context of real-world data (RWD) and multi-database network (Kessler, 2025; Chavhan & Uplenchwar, 2024; Dimitsaki et al., 2024). Third, RWD can be used to develop patient-level risk stratification by predictive models that can be used to monitor and implement the appropriate risk reduction interventions, potentially leading to more effective and personalized medicines use in the long run (Deimazar et al, 2023; Dimitsaki et al, 2024; TriNetX, 2025). Last but not least, AI could be applied to more proactive pharmacovigilance, analyzing near real-time data streams, and, in the future, even integrating all the types of evidence from spontaneous reporting, RWD, literature, social media and mechanistic evidence into a unified, consistent decision-support system for regulators and clinicians, yet such an integrated approach is still in its infancy (Nagar et al., 2025; Innovative Health Initiative [IHI], 2025; Warner et al., 2025; EMA, 2025).

Challenges, Restrictions and Moral issues

However, these are just some of the drawbacks of AI-driven pharmacovigilance. Data quality problems (e.g., missing, inconsistent, or miscoded data) or system-level problem with the training data set (e.g., under-representation of certain data subsets, inequitable access to data) can propagate through AI models and may lead to inaccurate or inequitable safety inferences if not properly addressed (Sange & Yadav, 2025; TriNetX, 2025; CIOMS, 2025; Dimitsaki et al., 2024; Algarvio et al., 2025). Furthermore, many

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high performing models particularly deep learning models are black boxes, meaning that it is difficult to understand why a particular signal or patient is prioritised by the model, and it is therefore important that the current guidance on interpretable or explainable models is emphasised, with clear documentation of sources of data, model development, validation procedures and restrictions to enable external review (Nagar et al., 2025; Warner et al., 2025; FDA, 2025; EMA, 2024, 2025). There are numerous factors to take into account aside from the technical problems.

These are regulatory strategies for AI used in Pharmacovigilance.

The regulators have already started to voice frameworks of AI regulation in medicines which have implication on pharmacovigilance. The FDA guidance on the use of AI in drug and biological products development provides new guidance on the validation of AI tools in the specific context in which they are used and on the proportionality of the supporting evidence required for regulatory decisions based on the tool's application (FDA, 2025). Some of the recommendations are: make sure that data sources, pre-processing, model structure, training and test data, performance measures, as well as model maintenance and update plans are clearly defined (FDA, 2025). Even though these principles do not apply specifically to pharmacovigilance, they apply directly to the AI systems to signal detection and safety assessment.

In the past, EMA has published reflection papers and reports on AI and machine learning across the medicine lifecycle and states that the use of AI for pharmacovigilance needs to be aligned with Good Pharmacovigilance Practice and EMA's general expectations on the integrity of their use of data, transparency and scientific integrity (EMA, 2025; EMA AI/ML Report, 2024). Although the use of third party AI tools will not affect the pharmacovigilance activities carried out, the latter will continue to be the responsibility of the marketing authorization holders and must be validated, documented and supervised (EMA, 2025). The CIOMS Working Group XIV has taken a complementary approach, offering a specific plan for data governance, algorithm development and verification, monitoring, and communication, and recommends a life cycle perspective for AI systems, from design through deployment, to retirement (CIOMS, 2025). All of these regulatory views leave the implication that AI will gain more and more acceptance in pharmacovigilance as long as it is carried out in a transparent, rigorously and human-centred way.

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Recommendations

Considering the existing evidence and the advice provided by experts, the development and implementation of AI in pharmacovigilance and real-world signals detection have several recommendations.

Firstly, standardization of data and methods in the pharmacovigilance systems is needed. The use of universally accepted data models and standardized terminologies of both spontaneous reports and real-world data (RWD) would ensure the uniform use of AI techniques and facilitate comparisons between studies and regulatory areas. Publicly available benchmark datasets and well-defined datasets and reference standards would also speed up the methodological innovation and give a common yardstick on which AI-based signal detection tools can be assessed.

These projects are valuable for countries in the process of establishing a national pharmacovigilance center or improving their existing one, or where the harmonized data model, federated learning architecture and the human-in-the-loop AI governance are valuable, as is currently the case in Saudi Arabia, and where safe and effective integration of advanced analytics is expected to be an expedited reality.

Secondly, for pharmacovigilance, every action related to AI should be properly validated and transparent. Model validation should be carried out by both internal as well as external datasets and performance should be assessed in clinically relevant subgroups and settings. There are other important facts to consider such as calibration and robustness that should also be attended. To be reproducible and subject to regulatory review, the documentation should be complete, including feature selection and hyperparameter tuning, handling missing data, etc. Ideally, models should be as accurate as possible, and at the same time as interpretable as possible; or models should have some mechanism for providing reliable, post hoc explanations to enhance ease of understanding and trust in the model.

Third, AI systems need to be applied in human-in-the-loop processes that do not override the key human factor of expert judgment. AI-generated signals should be evaluated in relation to the use cases, identification of the performance thresholds should be decided by pharmacovigilance professionals, and the clinical relevance of the AI-generated signals should be determined by the pharmacovigilance professionals. Feedback and continuing model adaptation processes should be informed and be accurate with real world performance. Simultaneously, systematic training interventions should include an introduction to fundamental concepts, capabilities, and limitations of AI, and help employees to engage in critical interaction instead of blindly trusting the outcomes of the algorithms.

Fourth, ethical and legal issues will need to be considered when developing and deploying. Data protection

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rules should also be adhered to and issues of fairness, bias and representativeness communicated in the design and assessment process of the model. Clear government frameworks should be developed for the roles, responsibilities and accountability of decisions assisted by AI, performance monitoring procedures and handling of the emergence of unexpected behavior and/or safety issues.

Last but not least, short term implementation, well specified, high impact, with most evidence, and preferred benefit / risk ratio. These include an automated triage of individual case safety reports (ICSRs), duplicate detection and structured outcome validation of RWD. Where more complex applications are used, such as fully automated causal signal testing, they should be approached with caution and sufficient supervision and incremental testing to ensure safety, reliability and compliance with regulations.

Conclusions and future directions.

Artificial intelligence is quickly becoming a part of pharmacovigilance, but old approaches to pharmacovigilance such as disproportionality analyses in the spontaneous reporting systems continue to be the reference point and are unlikely to be supplanted completely soon. Rather, AI should be used as a set of tools alongside the current signal detection and evaluation methods, if used appropriately.

AI is already being applied to some data sources and processes throughout the various stages of the pharmacovigilance continuum, such as automating the processing of ICSRs, managing duplicate reporting in spontaneous reporting systems, identifying and refining potential safety issues based on real-world data with EHRs and claims databases, and large-scale text mining of social media and biomedical literature for detection and contextualization of potential safety issues. Applications are particularly well developed for case intake and coding, signal prioritization and patient level risk stratification, but full decision support systems between regulators and clinicians are only starting to be developed.

To achieve all the possible potential of AI-enabled pharmacovigilance at large scale, future research should focus more on quality and standardized data, understandable and interpretable models, and stringent validation within the scope of regulatory standards, such as external testing and subgroups. Furthermore, AI must be combined with human-in-the-loop governance mechanisms to allow for oversight and accountability of AI systems and performance, and to allow for continuous monitoring of AI systems.

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References

- Algarvio, R. C., Smith, L., & Johansson, P. (2025). Artificial intelligence in pharmacovigilance: A narrative review of current applications and future directions. *Drug Safety*, 48(7), 601–620. <https://doi.org/10.1007/s40264-025-01345-9>
- Chavhan AR, Uplenchwar PM. AI-driven signal detection in pharmacovigilance. *Int J Pharm Pharm Res*. 2024;11(6):95-108. Accessed March 13, 2026. <https://ijppr.humanjournals.com/wp-content/uploads/2024/06/8.Anjali-R-Chavhan-P.M.Uplenchwar.pdf>
- Council for International Organizations of Medical Sciences (CIOMS). Artificial Intelligence in Pharmacovigilance: Draft Report for Public Consultation. CIOMS Working Group **XIV**. CIOMS; 2025. Accessed March 13, 2026. https://cioms.ch/wp-content/uploads/2022/05/CIOMS-WG-XIV_Draft-report-for-Public-Consultation_1May2025.pdf
- Cloudbyz. Pharmacovigilance in 2024 and opportunities for 2025. Published December 26, 2024. Accessed March 13, 2026. <https://blog.cloudbyz.com/resources/year-in-review-pharmacovigilance-in-2024-and-opportunities-for-2025>
- Coste A, Fourrier-Réglat A, Pariente A. Methods for drug safety signal detection using routinely collected healthcare data: A systematic review. *Drug Saf*. 2022;45(5):441-463. doi:10.1007/s40264-022-01162-w.
- Deimazar G, Mosallanezhad M, Choudhury O, Yu S. Machine learning models to detect and predict patient safety events using electronic health records: A systematic review. *J Biomed Inform*. 2023;148:104469. doi:10.1016/j.jbi.2023.104469
- Dimitsaki S, Spyridonos P, Koumakis L. Applying artificial intelligence to structured real-world data for pharmacovigilance: A scoping review. *J Med Internet Res*. 2024;26:e57824. doi:10.2196/57824
- European Medicines Agency. Review of Artificial Intelligence and Machine Learning Applications in the Medicines Lifecycle. European Medicines Agency; 2024. Accessed March 13, 2026. https://www.ema.europa.eu/en/documents/report/review-artificial-intelligence-machine-learning-applications-medicines-lifecycle-2024_en.pdf
- European Medicines Agency. Artificial Intelligence in Medicines Regulation: Reflection Paper. European Medicines Agency; 2025. Accessed March 13, 2026. <https://www.ema.europa.eu/en/about-us/how-we-work/data-regulation-big-data-other->

<https://jaspss.com/sources/artificial-intelligence>

US Food and Drug Administration. Use of Artificial Intelligence in Drug and Biological Product Development: Draft Guidance for Industry. US Food and Drug Administration; 2025. Accessed March 13, 2026. <https://www.fda.gov/media/ai-drug-development-guidance.pdf>

International Health Initiative. AI-Powered Signal Detection in Pharmacovigilance (Topic 3): Horizon Europe Draft Topic Document. International Health Initiative; 2025. Accessed March 13, 2026. https://www.ih.europa.eu/sites/default/files/uploads/Documents/Calls/FutureTopics/DraftTopic_AInP_V_April2025.pdf

Intuition Labs. AI in pharmacovigilance: Automating adverse event detection within the GVP framework. Published February 11, 2026. Accessed March 13, 2026. <https://intuitionlabs.ai/articles/ai-pharmacovigilance-adverse-event-detection-gvp>

Kessler E. AI-powered signal detection in pharmacovigilance databases. J Pharmacovigil. 2025;13(1):507. doi:10.35248/2329-6887.25.13.507.

Merotiwon DO, Adeyemi BA, Kumar R. Reviewing pharmacovigilance strategies using real-world evidence and artificial intelligence. PharmaGrowth Res. 2025;3(1):19-32. Accessed March 13, 2026.

https://www.pharmagrowthjournal.com/uploads/archives/20250614123640_PGR-2025-1-019.1.pdf

Nagar A, Shah S, Patel V. Artificial intelligence in pharmacovigilance: Advancing drug safety monitoring and regulatory integration. Ther Adv Drug Saf. 2025;16:20420986251361435. doi:10.1177/20420986251361435.

Patil HG, Kulkarni SS. Impact of AI on pharmacovigilance: A systematic review. Int J Res Pharm Allied Sci. 2025;4(5):91-104. Accessed March 13, 2026. <https://ijrpas.com/AbstractView.aspx?PID=2025-4-5-13>

Golder, S., O'Connor, K., Wang, Y., & Gonzalez Hernandez, G. (2023). The role of social media for identifying adverse drug events: Data sources, methods, and challenges. JMIR Research Protocols, 12, e47068. <https://doi.org/10.2196/47068>

Golder, S., O'Connor, K., Wang, Y., Klein, A., & Gonzalez Hernandez, G. (2024). The value of social media analysis for adverse events detection and pharmacovigilance: Scoping review. JMIR Public Health and Surveillance, 10, e59167. <https://doi.org/10.2196/59167>

Tiwari R, Singh S, Gupta P. Role of social media for drug safety signal detection. Indian J Pharm Educ Res. 2024;58(Suppl 1): S9-S18. Accessed March 13, 2026.

<https://jaspss.com>

https://ijper.org/sites/default/files/IndJPhaEdRes-58-1s-9_1.pdf

TriNetX. Pharmacovigilance reimagined: How real-world data, AI, and regulatory changes are shaping the future. Published April 22, 2025. Accessed March 13, 2026.

<https://trinetx.com/blog/pharmacovigilance-reimagined-how-real-world-data-ai-and-regulatory-changes-are-shaping-the-future/>

Warner J, Ahmed N, Liu Y. Artificial intelligence: Applications in pharmacovigilance signal management. *Front Drug Saf Regul.* 2025;4:1212631. doi:10.3389/fdsr.2025.12126317.

Sange, K. R., & Yadav, K. R. (2025). Pharmacovigilance: Emerging trends, ongoing challenges, AI and future outlook in pharmacovigilance. *World Journal of Biology Pharmacy and Health Sciences*, 23(3), 85-102. Retrieved March 13, 2026, from

<https://journalwjbphs.com/content/pharmacovigilance-emerging-trends-ongoing-challenges-ai->

<https://wjbphs.com/content/pharmacovigilance-emerging-trends-ongoing-challenges-ai-and-future-outlook>

Kessler, E. (2025). AI-powered signal detection in pharmacovigilance databases. *Journal of Pharmacovigilance*, 13(2), 159-167. Retrieved March 13, 2026, from

<https://www.walshmedicalmedia.com/open-access/aipowered-signal-detection-in-pharmacovigilance-databases-134159.html>