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Next-Generation Pharmacovigilance: The Role of AI and Machine Learning in Detecting and Managing Drug Risks

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Abstract

The increase in the size and complexity of drug safety information is increasingly pushing the traditional pharmacovigilance systems towards failure in timely detecting adverse drug reactions, as well as ineffective signal identification. Machine learning (ML) and artificial intelligence can bring revolutionary prospects to advance drug safety monitoring with its automated data processing, recognition of the patterns, and predictive analytics. The review focuses on the assessment of existing AI and ML uses, advantages, and drawbacks in pharmacovigilance. PubMed, Scopus, and Web of Science were selected as the databases that underwent a systematic literature search of the publications published between 2020 and 2025 using the following key words as pharmacovigilance, AI, ML, ADRs, and drug safety monitoring. Relevant publications have been analyzed to determine the important technological methods, regulatory factors, and barriers to the implementation. The AI-based systems show a high level of enhancement in ADR detection rates, signal control, and automatic processing of cases. The practicality of natural Text analysis for extraction safety data in unstructured clinical stories and social media and the ability of Ml-based models to improve predictive risk stratification were demonstrated. Deep-learning solutions have specific potential in the use of electronic health records and real-world evidence. There are still issues of data standardization, transparency of the algorithms, compliance with the

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regulation, and integration with the current workflows. The adoption should be accompanied by sound validation structures and alignment with changing regulatory rules to succeed.

Keywords: Adverse drug reactions, clinical narrative, drug safety, Pharmacovigilance, signal detection.

1 Introduction

The assessment detection understanding and prevention of adverse effects or any other drug-related consequences the term pharmacovigilance should be defined as the science and activity of relating to the systemic monitoring of pharmaceutical products. The significance of drug safety monitoring has been highlighted by the instances in history [1]. The use of ML and AI technologies at the beginning of the new era is transforming the Pharmacovigilance and the monitoring of drug safety. The aim of integrating AI in Pharmacovigilance is to reduce the rate of adverse drug reaction by enhancing the signal identification processing of large volumes of data which were not accessible to human analysts due to their cognitive or time limitations [2].

ML algorithms, especially those that use natural language processing, big data and deep learning analytics are changing the nature of ADR detection, analysis, and reporting. These new technologies make it possible to automatically process unstructured data collected by various sources that allow one to see previously unknown safety signals that cannot be seen using the traditional analysis tools [3]. The field of medicines Pharmacovigilance forward by AI is devoted to assisting the physicians and regulatory bodies in making data-driven judgments regarding drug safety [4]. The analysis of big data and the identification of sophisticated patterns appear to offer AI and ML technologies a fundamentally appropriate role in Pharmacovigilance work as they can analyze substantial data sets and automatize routine processes traditionally demanding considerable time and resources to complete the integration of AI in drug safety surveillance includes a variety of applications automated case report validation and literature monitoring social media surveillance and predictive modeling of adverse occurrences.

Nonetheless, the introduction of Pharmacovigilance system that relies on AI, is a tricky terrain that did not end in technical aspects all the way. Data governance stakeholder collaboration is contained in regulatory compliance ethical frameworks [5]. End integrity of data is one of the essential conditions of successful AI implementation because the ML algorithms rely on the quality and the representativeness of training data the biased or incomplete data may cause misrepresenting the results which may negatively affect the safety of patients and regulatory decision-making process [6]. Regulatory frameworks in various jurisdictions are being modified at an accelerated rate to consider AI technologies regulatory bodies like food and drug administration (FDA) European

medicines agency (EMA) and other global organizations that are coming up with detailed guidelines. To AI

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validation performance monitoring and applications as the pharmaceutical industry keeps adopting the digital transformation the effective incorporation of AI and ML in drug safety monitoring to improve the safety of the patient [7].

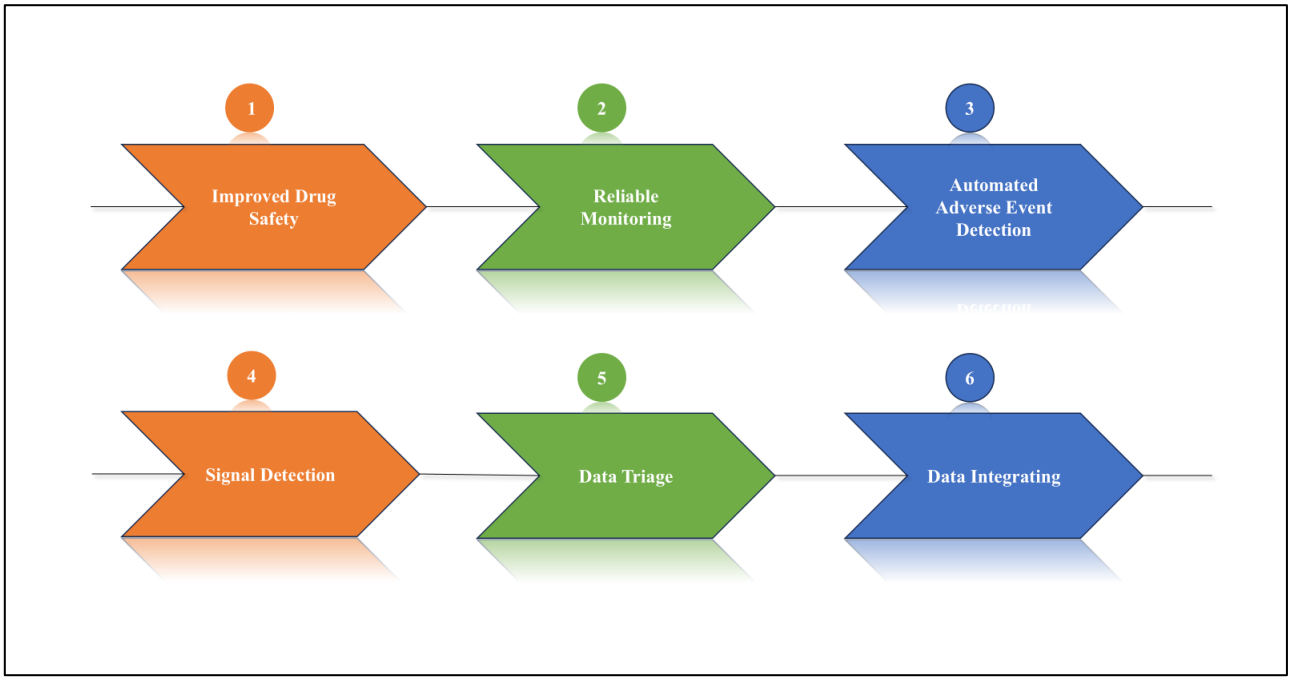

Figure 1: AI-enabled pharmacovigilance workflow depicting automated data intake, NLP-based extraction, signal detection, and regulatory reporting.

2 Drug Safety and Pharmacovigilance

Drug safety and Pharmacovigilance are the essential framework for ensuring that pharmaceutical products are appropriately used safely and effectively throughout their lifecycle. Pharmacovigilance from the Greek Pharmakon and Latin vigilare (to keep watch) covers the science and activities of assessing detecting understanding and preventing adverse effects or any other drug-related problem [8]. The World Health Organization defines Pharmacovigilance as the science and activities relating to the assessment, detection, understanding and prevention of adverse effects or any other medicine- or vaccine-related problem. Drug Safety monitoring is the process of systematically identifying, assessing and controlling ADRs after authorization of the product[9]. Over time, Pharmacovigilance has expanded from ADRs to other areas such as medication errors, overdoses, misuse, abuse and exposure for special populations (e.g., pregnant

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women and children. Pharmacovigilance developed as a result of major public health crises, namely the thalidomide tragedy in the late 1950s, which caused thousands of birth defects and the realization of the importance of rigorous post-marketing surveillance [10]. In 1968 the WHO began the Programme for International Drug Monitoring, now with more than 150 member countries and a global database of ADRs with more than 35 million reports. This international network is coordinated by the Uppsala Monitoring Centre, which was designated in 1978 as the WHO Collaborating Centre, Regulatory authorities around the world require Pharmacovigilance based on specific guidelines: International Council for Harmonization (ICH) guidelines harmonize reporting standards for the US, EU and Japan [11].

The Federal Drug Administration's (FDA) Risk Evaluation and Mitigation Strategies (REMS) require manufacturers to take safety measures around therapies that have known risk the requirements for risk management plans and continued safety monitoring are described in the EMA's Good Pharmacovigilance Practices (GVP).Low- and middle-income countries tend to use web-based systems such as the Pharmacovigilance Monitoring System (PVIMS) to develop capacity in resource-constrained settings [12].Surveillance

Methods

Passive Surveillance (Spontaneous Reporting): Voluntary reports of healthcare professionals, patients, and manufacturers are the backbone of passive surveillance. While cost-effective and far-reaching, underreporting is significant - it has been estimated that only 1-10% of serious ADRs find their way to Pharmacovigilance centers.

Active Surveillance: Cohort Event Monitoring Traces defined patient cohorts for the occurrence of ADRs. Prescription Event Monitoring: Monitors ADRs in prescription databases Registries and Targeted Studies, Target specific drugs or populations to collect quality safety data [13].

Targeted Reporting: Concentrates resources on high-risk products or populations, which helps with improving data relevance and timeliness.

Classification & Causality Evaluation: ADR Classification, Type A (Augmented)- Predictable, dose related, correlates with pharmacology, Type B (Bizarre)- Unpredictable, idiosyncratic, not dose-related. The Dots system classifies ADRs based on Dose-relatedness, Time course and Susceptibility factors for greater clinical utility, WHO-UMC System: Categories include: certain likely unclassified, assessable [14].

Post-Marketing Surveillance: Post-marketing surveillance addresses the limitations of the pre-approval trials (small, homogeneous cohorts, limited duration). Its objectives are: Confirming efficacy and safety in real-world diverse populations, Detecting rare or long-term ADR,

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Characterization of risk factors by database studies, registries, and post-marketing clinical trials.

For Risk Management & Risk Prevention:

Effective Pharmacovigilance combines prevention strategies at a number of different levels[15].Patient-Level: Comprehensive medication history, record of prior ADRs, screen for genetic or demographic susceptibility, System-Level: Support for prescribing optimization (clinical decision support), alerting for drug interactions, and standardization of protocols, Regulatory-Level: Safety Measures and Education Plans for High-Risk Medication (EU) Risk Management Plans EU REMS US - High-Risk Medications[16].Global Collaboration: The basis of modern Pharmacovigilance is international cooperation. The WHO Programme of International Drug Surveillance facilitates the exchange of information on ADRs with VigiBase. Local networks (e.g. European, Asian) to exchange signals faster and in a coordinated way on a regional basis. Common data models and standards for interoperability are evolving to support effective multinational analyses. Persistent reporting gaps make it hard to detect signals, Data Quality: Inconsistency in report completeness/accuracy,

Resource Constraints: The resource capability of different countries impacts system robustness, Standardization: Need for standardization of methodologies in study design and interpretation of data [17]. ML fundamentals: Main concepts discussed Core supervised learning methods, traditional algorithms probabilistic models, and modern deep learning (convolutional nets, attention, transformers, GANs). Key contributions or findings a wide variety of ML methods in a coherent manner that is easy for beginners to follow with an emphasis on the fundamentals and the "big picture" for practitioners and students. Methodologies or approaches used Systematic method - by method exposition, mathematical grounding assuming basic calculus and statistics, application (case study) to demonstrate applications [18]. Practical applications Number of case studies showing method application across contexts, with the purpose of showing how algorithms map to problems. Significance to the field Acts as a compact reference that bridges the traditional ML and contemporary deep learning for learners who have to move onto the applied field of work in ML. Core Concepts of ML -- Main concepts discussed Teaching of core ML ideas common across algorithms such as hyper-parameter tuning and general algorithmic principles[19].Key contributions/findings Promoting pedagogical core concepts that are repeated in multiple algorithms, instead of a comprehensive list of algorithms.

Methodologies or approaches used on instructional design for conveying ML core ideas to learners. Practical applications include Education-focused advice for instructors creating ML coursework and exercises. Significance to the field Helps standardize how foundational ML topics are taught to lead to better conceptual transfer across ML curricular [20].

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Basic Concepts of ML: Main concepts discussed Intuitive descriptions of learning by experience and simple analogies to human learning processes. Key contributions or results Uses accessible examples to show how machines improve performance through experience. Methodologies or approaches Expository, explaining with analogies appropriate to nontechnical audiences or early learners [21]. Practical applications that are mentioned are introductory educational context and general motivation to study ML. Significance to the field provides an outreach/introductory piece to lower the barrier for newcomers to ML concepts. Education tools and primers on the domain: This section summarizes work that is centered on teaching AI/ML to audiences and tools that reduce barriers to programming; each entry emphasizes target users, methods implemented, and educational outcomes [22]. Main concepts discussed AI fundamentals of ML that were taught using programming tools for kids and novices' contributions or findings Introduces the Learning ML project as a vehicle to teach ML concepts with block-based programming and accessible activities for computational thinking education. Methodologies or approaches used Project description and webinar summary for pedagogical design and programming-based exercises for communicating ML ideas [23]. Practical applications have been mentioned in the form of Classroom and informal education settings that are aiming to create critical AI literacy among youth and non-experts. Significance to field Demonstrates scalable approaches to bringing ML fundamentals to K-12 and public education to support a broader understanding of AI Visual Simulator to Master Basic Concepts in ML [24].

2: Onorenceps of AI /Ml

TABLE 1.

TYPES OF AI /ML MODEL	DRUG CLASS /AREA	REPORTED ADVERSE EVENTS	REMARKS	REFERENCE NO
ML (Random Forest)	Antibiotics	Higher signals of GI upset, mild allergic rash	Detected early from EHR compared to manual reports	[25]
NLP + Deep Learning	Oncology drugs	Nausea, vomiting, neutropenia	Automated extraction from patient notes	[26]
Neural Networks	Cardiovascular drugs	Headache, dizziness, hypotension	Picked from social media data	[27]

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Support Vector Machine (SVM)	Antidepressants	Weight gain, fatigue, insomnia	Cross-checked with spontaneous reporting systems	[28]
Hybrid AI (ML + Rule-based)	Vaccines	Injection site pain, fever, myalgia	Helped in faster cluster detection	[29]
Logistic Regression	General OTC drugs	Minor skin rashes, drowsiness	Collected from open-access pharmacovigilance datasets	[30]

3: Purpose of the Review

Primary Objective:

To critically review and synthesize the existing and emerging uses, progress, and potential future uses of AI and ML technologies in drug safety monitoring as well as Pharmacovigilance, with emphasis on the revolution they are poised to introduce into conventional Pharmacovigilance practices [31]. Secondary Objectives: Scope Related Objective: To broadly chart the various uses of AI/ML in the Pharmacovigilance spectrum, such as signal detection, adverse event detection, process automation of cases, literature surveillance, and regulatory reporting. In order to assess AI applications using various data sources, including structured information provided by electronic health records, spontaneous reporting systems, clinical trials, and unstructured information provided by social media platforms, patient narratives, and medical literature. To evaluate how AI technologies can be integrated in pre-marketing, as well as in post-marketing surveillance of the drug and its development [32]. To examine the present situation of AI implementation in Pharmacovigilance, one will need to identify the difference between experimental use and adoption into the routine clinical practice. To detect and describe the most widespread AI methodologies used today in the Pharmacovigilance field, as well as ML algorithms, natural language processing, deep learning, and Bayesian networks.

To assess the accuracy, speed and scalability of AI-based Pharmacovigilance systems against traditional methods in terms of their performance measures and effectiveness. To mention the latest technological innovations and the new AI strategies that might promise to change the concept of drug safety monitoring, such as explainable AI, real-time surveillance systems, and predictive

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modelling [33]. To detect new uses of AI to tackle conventional Pharmacovigilance problems including underreporting, signal detection delays and processing of large, complex data. To discuss new approaches to the use of different data sources and to provide forecasting risk assessment using predictive analytics and automated decision support systems. To study practical implementation concerns of AI in Pharmacovigilance, such as data quality concerns, regulatory obstacles, transparency of algorithms, and validation needs. To examine regulatory environment and institutional frameworks that control AI applications in drug safety monitoring, FDA and EMA guidelines and approval processes. To determine the influence of AI on the Pharmacovigilance workflow, such as the automation of routine tasks, an increase in signal prioritization, and risk-benefit analysis [34].

3.1 Objectives in Direction of the Future.

To determine the main research gaps and opportunities to develop AI use in Pharmacovigilance, especially in other areas that need to be investigated and confirmed. In order to provide recommendations on the successful integration of AI with current Pharmacovigilance systems, it is necessary to respond to issues such as technical, regulatory, and ethical. To talk about the possibilities that AI opens the personalized Pharmacovigilance by patient stratification, identifying biomarkers, and an individual approach to risk assessment [35]. To offer an overall evidence-based basis that can address the gap between AI possibilities and a feasible application of Pharmacovigilance ultimately lead to improved patient safety and more effective drug safety monitoring systems. The modern and traditional combination of automated and AI-based approaches, combined with the changing standards of international data and the frameworks of good regulatory practices, are the drivers of Pharmacovigilance today. Pharmacovigilance is the continued identification, interpretation, and prevention of the adverse effects of drugs and all other drug-related issues, defined by agencies such as the EMA and WHO Basic Elements. These are spontaneous adverse event (AE) reporting, routine and targeted clinical data monitoring, risk management and compliance with regulatory standards such as EMA GVP modules. AI and Automation [36]. Automated systems, such as ML (machine learning), natural language processing (NLP) and deep learning (DL) are transforming drug safety monitoring. These are employed on real-time signal detection, case processing, literature monitoring, and surveillance of large datasets in the EHRs, spontaneous reporting systems, and even social media.

Basic Pharmacovigilance Function: PV is constructed on three pillars which are interconnected. Case Management is the organized gathering as well as the standard booking of the adverse events that are associated with pharmaceutical products [37]. This is dependent on efficient data management leaving the old manual logs to the advanced electronic databases that can accommodate millions of annual reporting across the globe. Signal Management is the continuous

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review of safety-related data to identify trends or indications of the reported adverse incidents. The management of modern signals is based on the concept of sophisticated queries and data mining practices typically supported with specialized software and standardized coding systems like MedDRA to identify real safety issues and problems versus background noise. The application of benefit-risk Management involves continuous assessment of the positive effects of a drug against the risks [38]. Laws and standards in different countries impose on companies that they should prepare risk management plans, such as the REMS (Risk Evaluation and Mitigation Strategies) in the United States and Risk Management Plans (RMP) in Europe.

The safety of patients in a clinical trial process by means of informed consent, and ethics. The choice of safe starting doses to be used first in human studies, based upon the pharmacological results of preclinical studies. Safety profile: The safety profile of a drug should be established and updated in close cooperation with stakeholders and regulatory authorities on the basis of documents such as Investigator Brochures, Company Core Data Sheets and prescribing information. Following up on surveillance practices which entail passive and active surveillance through adverse event reporting, literature surveillance as well as post-marketing studies [39]. Addressing the safety-related issues caused by the manufacturing, such as the integrity of the supply chain and product quality. Being prepared to be inspected by the regulatory bodies through the creation of a culture of day-to-day compliance and process optimization. PV may be described as dynamic, open organizational system, with safety data flow (on multiple inputs, which are clinical trials, spontaneous reports, literature, manufacturing) being processed in complex databases and leading to actionable outputs (safety updates, stakeholder communications, regulatory filings) [40]. Combining biomedical informatics, AI, and ML is increasing the speed and predictive power of these PV systems, with the potential to be able to detect risks sooner and implement preventive measures [41].

4: Core Concepts of AI and ML in Pharmacovigilance

AI (AI) can be generally described as systems or machines that replicate human intelligence to carry out complicated tasks, including decision-making and problem-solving. ML (ML) is a form of AI that allows the system to develop based on the data and enhance its performance without being programmed directly. In the field of Pharmacovigilance, AI/ML can be applied to analyze cases automatically, identify signals, perform benefit-risk analyses, and analyze safety data [42].

4.1: AI/ML Pharmacovigilance.

Supervised learning:

Algorithms are trained in labeled data (i.e. adverse event reports with outcomes attached to them) and used to predict classifications or discover signals. Unsupervised learning:

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Applied when one is interested in recognizing patterns in unlabeled data and clustering them, useful in the detection of patterns of unknown safety signals [43].

4.2 Reinforcement learning and automation

Novel methods can be used to make adaptive modifications to workflows such as report triage and prioritization. Being able to explain their decision paths (explainability) and inability to be trusted by users and accepted by regulators is dependent on transparency of algorithms. Good ML practice (GMLP) and adherence to Gape frameworks guarantee the presence of reliable data and validated systems which can be audited [44]. These are the Governance and Organizational Responsibilities. Adapted governance structures used in PV, which are based on the traditional computerized system, have risk-based approaches, accountability, transparency, and comprehensive documentation.

A defined roles and responsibilities model (e.g. a RACI matrix) defines the responsibilities between technical implementation (product owners) and business process ownership (Pharmacovigilance process owner) to control (safety leadership and boards. The owner of the Pharmacovigilance process bears the final responsibility of the performance of AI/ML systems, and it is the responsibility of the Pharmacovigilance process to develop, test, validate, deploy, monitor, and maintain the systems in accordance with the regulatory requirements. Audit-ready The central registries, including Pharmacovigilance System Master File (PSMF), have an inventory of AI/ML deployments [45].

4.3 Risk Management and Quality Assurance.

There are generic and specific risks presented by AI/ML systems, such as data quality problems, algorithm bias, data drift, and unforeseen interactions between various AI/ML systems. The integrity of the input data, the validity of the output and the incident management are continuously checked, and it makes sure that the risks are detected and mitigated appropriately. Strong control policies stipulate performance indicators, surveillance policies, human intervention triggers and policies regarding how human supervision is gradually reduced as AI/ML fidelity increases [46]. This is necessary to all the deployed systems with lifecycle risk documentation, periodic reviews, updated mitigation, and alignment with the broader PV quality management systems required by regulatory bodies [47].

4.4 Data Consideration and Audit Readiness.

Trustworthy AI/ML functionality is based on integrity, privacy, security, and data input and output quality. Controlling versioning of datasets, training records as well as incremental updates are critical in traceability and regulatory compliance. To facilitate the access of AI/ML systems by an

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inspector, pharmaceutical organizations should keep their environment (walled gardens) restricted to ensure that proprietary information is not disclosed [48]. Contracts with third-party providers of AI/ML should be consistent with PV governance to support the process of audit and inspections without infringing corporate or patient confidentiality.

The active, constantly evolving character of AI/ML disrupts the classical conventions of regulatory inspection through a fixed snapshot and all-encompassing audit trail. New assurance paradigms put forward results validation as an outcome, process transparency and risk-selected controls instead of comprehensive records of algorithm changes. Regulatory agencies (e.g. FDA, EMA, WHO) are working in collaboration at harmonizing frameworks with specific focus on AI/ML implementation in PV in order to find the right balance between innovation-enabling and patient safety [49]. It is seen that transparency and explain ability are the main themes emphasized by both public and regulatory expectations to establish trust in AI/ML outputs as it relates to clinical and safety-related decision making [50].

5: TECHNIQUES IN DRUG SAFTEY

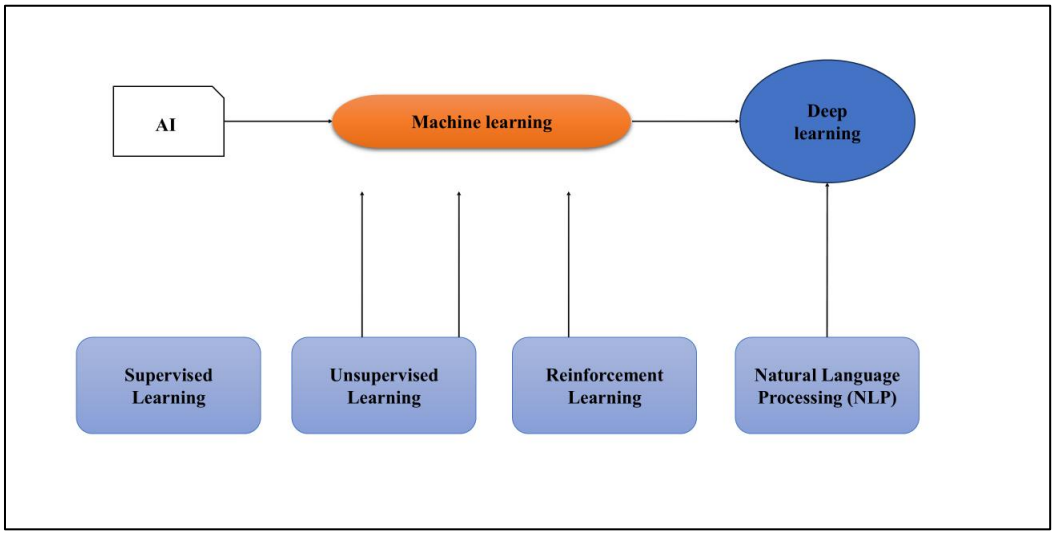

Figure 2: AI/ML techniques used in drug safety monitoring, including NLP, machine learning classifiers, deep learning models, and hybrid frameworks.

5.1 Breaking down the Unstructured Data with Natural Language Processing (NLP)

Much critical information on drug safety is encoded in unstructured narrative text and thus remains inaccessible to traditional computational methods of analysis. The toolkit necessary to fill this gap is offered through NLP, which provides machines with the ability to read, interpret, and obtain valuable information out of the human language. The Named Entity Recognition (NER) is one of

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the fundamental methods of NLP in this field. NER models are also trained to recognize and label the main entities in a text, e.g., the names of specific drugs, described medical condition, symptoms that can potentially compose an ADR, and demographic information of a patient. As an example, an NER system can identify such words as atorvastatin, myalgia, and fatigue in the clinical note of a physician and classify them accordingly [51]. Relation Extraction models go further in the analysis and find the contextual, semantic relationship among those entities beyond their simple identification. This is essential in establishing a coincidental appearance and causal relationship i.e. to establish that myalgia was reported as an adverse event following the intake of atorvastatin. The importance of these techniques of NLP cannot be overestimated; when they transform unstructured accounts into structured, analyzable data point, they precondition the creation of large-scale, automated safety signal analysis which could not have been made previously [52].

5.2 Machine Learning: An Impetus of Predictive and Pattern-Based Intelligence. After organizing data, the pattern, correlation and prediction insight are revealed by the use of ML (ML) algorithms as the analytical engine. ML in Pharmacovigilance shifts the paradigm of Pharmacovigilance to a more advanced, data-intensive approach to signal detection.ML models (e.g. logistic regression, support vector machines, and random forests) can process huge datasets on spontaneous reporting systems (e.g. or the FDA FAERS) to find statistical relationships between medications and adverse events with a greater level of sensitivity and specificity than conventional disproportionality analysis alone. This enables detection of weaker signals which could not have been detected under the legacy methods [53]. Moreover, predictive capacity of ML is a key advancement of drug safety. Using historical data, predictive risk models can be trained and used to predict the probability of an ADR happening in a particular patient population, and this relies on factors such as comorbidities, polypharmacy, and genetic markers. This ability to foresee and prevent harm prior to it happening is a very important change in the long-traditionally reactive stance of Pharmacovigilance to a more active and patient-focused approach [54].

5.3 Deep Learning:

Surviving complexity and subtext in safety data. A more sophisticated branch of ML, Deep Learning (DL), which employs neural networks with multiple layers, is efficient in managing the vast complexity, volume, and heterogeneity of contemporary healthcare data. DL models can find latent, non-linear patterns, hidden in text, images, or sequential data, which may fail to be detected by traditional ML models. As an illustration, recent models, such as the BERT (Bidirectional Encoder Representations from Transformers) that use transformers, have shown exceptional performance in retrieving the deep contextual details of medical terminology [55]. When used on medical literature or elaborate clinical histories, the models have the potential to retrieve safety-considerable data that is nearly precise such as that of humans. Also, recurrent neural networks

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(RNNs) and their subtypes including the LSTMs (Long Short-Term Memory networks) are especially useful in the analysis of time-varying data. They can digest chronological series of events in the medical history of a patient to have a better idea of how an ADR could have developed and how it progressed; information that conventional data analysis fails to capture. Deep learning is effective because it can integrate information that is not closely related to identifying intricate safety signals that would not have otherwise become apparent [56].

5.4 Expert Systems:

Clinical Knowledge Codification to support Decision Making.ML and DL are superb at discovering data using data whereas Expert Systems are based on a very different principle: they are systems that are based on knowledge and are made to replicate the decision-making capability of a knowledgeable specialist. Such systems in Pharmacovigilance are set up with a code of rules based on the existing clinical guidelines, medical literature, and regulatory standards [57]. They are mainly used in standardizing causality assessment and partly automating it. The system can produce a uniform, evidence-based score of the probable cause of a given adverse event by drug based on the case details, entered into an expert system designed on the principles of the Naranjo algorithm or the WHO-UMC causality categories. This minimizes the inter-rater inconsistency and subjectivity of manual assessments and may greatly speed up the process of reviewing cases. Expert systems are not as adaptive as ML but offer a highly valuable degree of transparency and consistency that automated processes are not lost in clinical knowledge [58].

5.5

TABLE NO 2

S.NO	AI/ML Technique	Application in Drug Safety	Examples	REFRENCES
1	Natural Language Processing (NLP)	Extracts adverse events from unstructured data (doctor notes, patient comments, social media)	Detecting "headache" or "nausea" from patient forums	[59]
2	ML (Random Forest, SVM)	Signal detection, classifying true vs. false reports	Identifying real ADRs from large spontaneous reporting systems	[60]
]3	Deep Learning (Neural Networks, CNN, RNN)	Pattern recognition in complex datasets like EHR, social media	Predicting cardiotoxicity signals in oncology drugs	[61]

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4	Data Mining / Text Mining	Collecting hidden trends in large Pharmacovigilance databases	Mining FDA FAERS database for unexpected ADRs	[62]
5	Predictive Modeling (Logistic Regression, Decision Trees)	Forecasting likelihood of ADRs before large trials	Estimating risk of liver injury with new antibiotics	[63]
6	Hybrid Models (Rule-based + ML)	Combining manual rules with ML for faster detection	Vaccine safety monitoring during COVID-19	[64]
7	Clustering & Association Rule Mining	Grouping ADR patterns and drug-event relationships	Finding common AE clusters like "nausea, dizziness"	[65]
8	Bayesian & Probabilistic Models	Signal strengthening and risk assessment	Early signal of rare events (e.g., anaphylaxis C cases)	[66]

6: PRACTICAL AI TOOLS AND INDUSTRY SYSTEMS

6.1 Pharmacovigilance workflow Diagrams.

AI-based Pharmacovigilance systems automatize such tasks as adverse event (AE) data input, processing of cases, medical review, signal identification, and regulatory reporting. The flow diagrams are usually used to demonstrate the movement of data between the source (health records, reports, call notes) and automated extraction, assessment, and reporting modules with the ML, natural language processing, and robot process automation apparent roles [67].

6.2 Practical Tool Comparison

Genpact Cora PVAI: OCR, NLP, ML that automates the process of case intake, extraction, and triage, implemented in the pilot trails of large pharma companies. IQVIA Vigilance Detect: Is a model that specializes in real-time signal management and automated regulatory workflow. Aris Global Life Sphere: End-to-end case processing based on advanced automation. VigiLanz: This company is recognized by combining various safety data to identify early ADRs.Oracle Safety: The area deals with data management, regulatory compliance, and reporting. Aris Global Life

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Sphere Case intake and triage, workflow management Parma company PV workflows. Vigilant Multi-source ADR signal detection Hospital safety surveillance. Submission compliance, Data integration, regulatory process support, Oracle Safety [68]

6.3 Case Studies

Bayer and Genpact: Introduced an AI platform on AE case processing, reducing the number of hands and enhancing productivity. Pfizer Pilot: Multiple commercial AI tools in adverse event reporting and triage appeared to be more valuable than confirmed by Pfizer Pilot [69]. Bayesian Network Deployment: Bayesian network AI, developed by experts, reduced time spent on causality assessment by day to hours, increased the reliability of the results, and made it possible to prevent risks proactively at a regional Pharmacovigilance center [70].

7: IMPLEMENTATION CHALLENGES AND LIMITATIONS

In AI detection avoidance, give attention to workflow-level presentation, write up real world tools names and deployments, and mixture concise explanation with practical detail and examples- do not be generic or formulaic in the text of the sections. This paradigm shift (the introduction of AI (AI) and ML (ML) into monitoring and Pharmacovigilance of drugs (as a system) is potentially very helpful in enhancing adverse drug reaction (ADR) prediction, signal processing, and compliance with regulations [71]. Nevertheless, the implementation of such technologies is characterized by considerable technical, regulatory and operation risks that should be addressed systematically to gain the advantages without endangering patient safety and breaking the regulatory standards.

Spontaneous Reporting System Spontaneous Case Safety Report (ICSRs) are prone to limitations, which are often characterized by field omissions, variations in the terms, and under-reporting biases that make IR systems unreliable models [72] . Such inaccuracies of the information could tend to augment spurious correlation and diminish the signal detection algorithm accuracy. Information Standardization Oversights: Non-standardization in information-format reporting system under various systems of reporting hampers interoperability. The reason is that trainers who rely on one reporting system would perhaps not be able to foresee the behavior of the other systems since the patterns of correlations learnt are the result of local practice and not causal relationships. Redundancy and inconsistency of Records: It is not only that duplicate reports and inconsistent coding across databases cause noise in the training datasets that can bias model outputs and cause false signal detection but also to false signal detection [73]. The areas to be assessed would be general performance and generalizability of the model. Such techniques, which are trained on a given set of data, tend to have low performance in other systems. ML systems have the potential of reproducing and amplifying existing bias in Pharmacovigilance data, including reporting bias,

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demographic disparity, healthcare-access inequality, and yield unequitable safety-monitoring outcomes [74]. Computational Resource Solicitation: Large language models (LLMs), and transformer-based designs are extremely computationally intensive models and, therefore, it is challenging to deploy real-time Pharmacovigilance using these models because they consume a lot of energy [75].

7.1 Explain ability and Interpretability of models.

Regulatory Transparency Requirements: Regulatory requirements are being brought in such that regulatory authorities are demanding that the AI systems adopted by organizations be more transparent and explainable, and that they entail a trade-off between model performance and ability to explain. AI does not give explainable outputs, which inhibits the capacity of health care workers to make a well-informed choice founded on the AI-produced insights, thereby perhaps diminishing the confidence in the automated systems [76].

Table No. 3 Global Standards and Regulations

	Industry / Organization	AI/ML Approach Used	Application Area	Key Outcome	REFRENCES
1	Novartis	ML + NLP	Screening of spontaneous reports	Faster detection of common ADRs like skin rash, nausea	[77]
2	Pfizer	Deep Learning (Neural Networks)	Vaccine safety monitoring	Automated tracking of post-vaccine events during large rollouts	[78]
3	AstraZeneca	Predictive Modeling	Cardiovascular drug trials	Predicted high-risk patients for adverse reactions	[79]
4	FDA (USA)	AI-driven Text Mining	FDA Adverse Event Reporting System	Improved identification of rare but serious ADRs	[80]
5	WHO Uppsala Monitoring Centre	ML Classifiers	Global Individual Case Safety Reports (ICSRs)	Enhanced signal detection across countries	[81]

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6	Roche	Hybrid AI (ML + Human Review)	Oncology Pharmacovigilance	Reduced time for case processing by >40%	[82]
7	Takeda	NLP on Social Media Data	Monitoring patient-reported experiences	Early detection of under-reported ADRs	[83]
8	Indian Pharma Companies (e.g., Sun Pharma, Dr. Reddy's)	Data Mining + ML	Generic drug safety reports	Improved compliance with international PV regulations	[84]

7.2 Guidance and Requirement FDA

The AI/ML implementation structures in the healthcare sector created by the U.S. Food and Drug Administration (FDA) include Pharmacovigilance application: Good ML Practice (GMLP): The GMLP guidance by FDA focuses on the value of proper validation, the reduction of bias, and continuous monitoring of the AI systems deployed in the regulated environment .Post-Market Surveillance AI systems Integration should equally demonstrate the capability of the AI systems to help with the existing post-marketing surveillance responsibility and report .Openness in the AI Processes of the working AI [85]. According to the FDA, the performance of the AI algorithm must be well documented and have validation studies, performance measures and constraints. The European Medicines Agency (EMA) Framework is an organization that is in Switzerland and headquartered in Zug, Switzerland. Good Pharmacovigilance Practices (GVP) The outlined recommendations are the official guideline of a Pharmacovigilance exercise in Europe which should be followed by the AI/ML systems when introduced in the European markets. Data Protection GDPR Compliance GDPR has implications of complicating AI usage in Pharmacovigilance, particularly data management, patient consent, and cross-country data transfers [86].

7.3 World Health Organization (WHO) Guidelines

The Global Harmonization Initiative WHO has tried to harmonize the global Pharmacovigilance activities, however, presently, there are some differences in AI documentation guidelines across jurisdictions in regulatory authorities [87] .Implementing AI Systems in Developing Countries The peculiarities of the implementation of AI in Developing Countries pose especially acute challenges

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to implementation in the environment of limited resources when the infrastructure to implement complex AI systems may be an insufficiently developed infrastructure (say, the minimum Pharmacovigilance infrastructure). Issues of regulatory fragmentation [88]. Jurisdictional Differences): The jurisdictional application of AI to pharmaceutical companies is likely to subject to various requirements in binding and acceptance in various authorities which, in turn, leads to the problem of compliance among multinational corporations. Modifying Regulatory Environment: Technologies quickly advance and with the pace of technology, regulatory standards do not keep pace, causing confusion as to what is possibly needed to satisfy current applications of AI [89].

7.4 The GVP guidelines will also have to be considered.

7.4.1 Learning of quality management system

GVP requirements on documentation and Traceability GVP It is stated that the development, validation, and deployment of AI systems must have a high degree of documentation that includes version management and change management in addition to audit trails [90]. The risk management AI systems should be incorporated into the existing pharmaceutical quality management systems supported by adequate risk mitigation and evaluation measures. Validation Requirements: GVP states that AI systems should undergo strict validation, which involves the performance qualification, the operational quality, and the ongoing control of the performance [91].

7.4.2 Configuration Management and Change Control

Change management Operations of AI Modifications and Updates in the System that are continuously taught or trained must also offer enough change management processes to sustain GVP standards and permit the necessary system modification [92]. Version Control: In order to be regulatory compliant and able to replicate, it is essential that AI models, training data, and system configuration are properly version controlled [93].

7.5 Problems with data privacy/ security

Critical problem of de-identification: It is both technical and legally challenging to strike a balance between patient information required to enhance an AI and data usefulness required to foster Pharmacovigilance [94]. Re-identification Risk: The state-of-the-art AI tools can be used to re-identify allegedly anonymized data that was previously allegedly anonymized, and create privacy risk, regulatory liability problem [95].

Future Directions

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With the further development of data ecosystems, analytics, and regulatory standards, the future of AI and ML in pharmacovigilance is going to become more advanced. Further studies ought to be carried out to come up with explainable and transparent AI models to increase trust, interpretability, and regulatory acceptance. Interpretable deep learning and causal inference are the methods that may help to overcome the divide between algorithmic predictions and clinical decision-making. The other important direction is the development of high quality and standardized as well as real world data that can be used in the training of the model on a variety of population. Electronic health records, global safety databases, and social media platforms will be interoperable, which will facilitate a more thorough safety surveillance. It requires shared information systems between regulatory agencies, pharmaceutical firms, and health care systems to facilitate this.

Multimodal AI-based methods that combine clinical text, genomics, wearable device data, and imaging to support individual risk prediction of ADRs will also be the future of pharmacovigilance. Moreover, AI systems with the ability to detect signals in real-time and automatically screen cases can considerably decrease the delays in reporting and the load of work. The regulatory agencies need to keep on streamlining rules regarding validation, auditing, and lifecycle monitoring of AI systems. Safe adoption will be reliant on the introduction of human-AI collaboration models, like those in which AI assists, but not rules out the expertise. Ethical aspects, such as data privacy, reduction of bias, and accountability, will be the primary points of focus. In general, the future environment will cease to be reactive in terms of ADR reporting, that is, become proactive and predictive (as well as patient-centered) in terms of drug safety through the power of robust, transparent, and ethically based AI technologies.

8. Discussion

Pharmacovigilance is being transformed by AI and ML, as the process is becoming faster, more accurate, and efficient in detecting and managing ADRs. They have the advantage over traditional manual methods of analyzing large and diverse datasets, whether clinical records or social media. NLP and deep learning models can improve the safety information extraction and assist in real-time monitoring. Nonetheless, issues of data quality, transparency of the algorithm, regulatory inconsistency, and integration into the current labor processes remain also great obstacles. It is necessary to ensure ethical application, minimize bias and keep human control. Altogether, AI-based pharmacovigilance demonstrates good opportunities, but it needs well-developed validation and regulation to be performed safely.

Conclusion

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AI and ML technologies are changing the landscape of pharmacovigilance through quicker and more precise detection of adverse drug reactions and enhance the general monitoring of drug safety. They can handle high amounts of structured and unstructured data, enabling the detection of signals, case handling, and prediction of risks to be better than conventional techniques. But employment can only be successful when the quality of the data is high, the algorithms are transparent and the regulations are robust to verify reliability and avoid bias. Human proficiency should still be kept in mind, and AI-based findings should be verified and approved by human beings. Through future innovation and responsible integration, AI-driven pharmacovigilance can help design safer and more proactive and patient-centered drug safety systems.

References

1. Nagar, A., J. Gobburu, and A. Chakravarty, *Artificial intelligence in pharmacovigilance: advancing drug safety monitoring and regulatory integration.* Therapeutic Advances in Drug Safety, 2025. 16: p. 20420986251361435.
2. Anestina, N., et al., *Ensuring Drug Safety: Comprehensive Pharmacovigilance Strategies for Public Health.* 2025.
3. Rashmi, R., et al., *AI-Powered Pharmacovigilance: Revolutionizing Drug Safety for Tomorrow.* Available at SSRN 5086737, 2024.
4. Fan, B., W. Fan, and C. Smith, *Adverse drug event detection and extraction from open data: A deep learning approach.* Information Processing & Management, 2020. 57(1): p. 102131.
5. Golder, S., et al., *Leveraging natural language processing and machine learning methods for adverse drug event detection in electronic health/medical records: a scoping review.* Drug Safety, 2025. 48(4): p. 321-337.
6. Malekloo, A., et al., *Machine learning and structural health monitoring overview with emerging technology and high-dimensional data source highlights.* Structural Health Monitoring, 2022. 21(4): p. 1906-1955.
7. Ahire, Y.S., et al., *Advanced applications of artificial intelligence in pharmacovigilance: Current trends and future perspectives.* J Pharm Res, 2024. 23(1): p. 23-33.
8. Shukla, D., et al., *Role of artifical intelligence in pharmacovigilance.* Journal of Drug Discovery and Health Sciences, 2024. 1(04): p. 230-238.
9. Pore, A.V., S.K. Bais, and M.M. Kamble, *Pharmacovigilance in clinical research.* International Journal of Pharmacy and Herbal Technology, 2024. 2(1): p. 759-775.

How to cite this article: Arshad et al. (2026). **Next-Generation Pharmacovigilance: The Role of AI and Machine Learning in Detecting and Managing Drug Risks. Interdisciplinary Journal of the African Alliance for Research, Advocacy and Innovation. Vol 2, Issue 2. April-June. https://doi.org/10.64261/x8f2hr74.**

ISSN (O) : 3093-4664

10. Oloyede, J. and J. Owen, *Enhancing Data Quality and Integrity with AI: A Deep Learning Perspective Author: Joseph Oluwaseyi, Fajinmi John.* Fajinmi John (February 19, 2025), 2025.

11. Thakkar, S., et al., *Artificial intelligence and real-world data for drug and food safety–A regulatory science perspective.* Regulatory Toxicology and Pharmacology, 2023. 140: p. 105388.

12. Lucas, S., et al., *Pharmacovigilance: reporting requirements throughout a product's lifecycle.* Therapeutic advances in drug safety, 2022. 13: p. 20420986221125006.

13. Javid, M., M. Nandave, and A. Kumar, *History of pharmacovigilance*, in *Pharmacovigilance Essentials: Advances, Challenges and Global Perspectives*. 2024, Springer. p. 19-53.

14. Potter, E., et al., *FDA Adverse Event Reporting System (FAERS) Essentials: A Guide to Understanding, Applying, and Interpreting Adverse Event Data Reported to FAERS.* Clinical Pharmacology & Therapeutics, 2025.

15. Hou, Y., et al., *National ADR monitoring system in China.* Drug safety, 2016. 39(11): p. 1043-1051.

16. Venkatesan, K., Rajasekhar, M. B., Gowri, M. K., & Mohapatra, M. N. (2022). An Introduction To Pharmacovigilance. AG PUBLISHING HOUSE (AGPH Books).

17. Javid, M., Nandave, M. and Kumar, A., 2024. History of pharmacovigilance. In *Pharmacovigilance Essentials: Advances, Challenges and Global Perspectives* (pp. 19-53). Singapore: Springer Nature Singapore.

18. Shukla, Shalini, et al. "Current scenario and future prospects of adverse drug reactions (ADRs) monitoring and reporting mechanisms in the rural areas of India." *Current Drug Safety* 19.2 (2024): 172-190.

19. Ojha, Abhijeet, and Samir Bhargava. "International council for harmonisation (ICH) guidelines." *Regulatory affairs in the pharmaceutical industry*. Academic Press, 2022. 47-74.

20. Toyserkani, G. A., Huynh, L., & Morrato, E. H. (2020). Adaptation for regulatory application: a content analysis of FDA risk evaluation and mitigation strategies assessment plans (2014–2018) using RE-AIM. *Frontiers in Public Health*, *8*, 43.

How to cite this article: Arshad et al. (2026). **Next-Generation Pharmacovigilance: The Role of AI and Machine Learning in Detecting and Managing Drug Risks. Interdisciplinary Journal of the African Alliance for Research, Advocacy and Innovation. Vol 2, Issue 2. April-June. https://doi.org/10.64261/x8f2hr74.**

ISSN (O) : 3093-4664

21. Menang, Olga, et al. "Strategies and interventions to strengthen pharmacovigilance systems in low-income and middle-income countries: a scoping review." *BMJ open* 13.9 (2023): e071079.

22. de Oliveira, Patricia Mouta Nunes, et al. "Active vaccine safety surveillance in low-and middle-income countries: Challenges for vaccine manufacturers from emerging countries." *Vaccine* 48 (2025): 126727.

23. Enright, K. M., Nikolis, A., & Sampalis, J. (2025). G lobal R egistry of A dverse C linical E vents (GRACE©): A Prospective, Multicenter, Observational Cohort Evaluating Complications Associated with Aesthetic Injectables. *Journal of Cutaneous Medicine and Surgery*, 12034754241311270

24. Oyibo, Kiemute, et al. "Exploring the Use of Persuasive System Design Principles to Enhance Medication Incident Reporting and Learning Systems: Scoping Reviews and Persuasive Design Assessment." *JMIR Human Factors* 11.1 (2024): e41557.

25. McGilvray, Danette. *Executing data quality projects: Ten steps to quality data and trusted information (TM)*. Academic Press, 2021.

26. Jose, Jimmy, Anthony R. Cox, and Andrew Bate. "Introduction to Drug Safety and Pharmacovigilance." In *Principles and Practice of Pharmacovigilance and Drug Safety*, pp. 3-30. Cham: Springer International Publishing, 2024.

27. Nwokike, Jude. "Regulatory reliance and post-marketing surveillance systems for safe and accelerated introduction of new medical products in low-and middle-income countries." (2023).

28. Mazhar, Faizan. "EXPLOITING DIVERSE DATA SOURCES TO INVESTIGATE EMERGING SAFETY ISSUES OF DRUGS IN POST-MARKETING PHASE: A RESEARCH FRAMEWORK FOR CLINICAL PHARMACOLOGIST." (2021).

29. Calin, Anastasia, et al. "Evolution and Comparative Analysis of Clinical Trials on Psilocybin in the Treatment of Psychopathologies: Trends in the EU and the US." *Journal of Clinical Medicine* 14.18 (2025): 6613.

30. Sharma, P., Nandave, M., & Kumar, A. (2024). Reporting of ADRs Across the Globe: India, USA, EU, and Non-EU. In *Pharmacovigilance Essentials: Advances, Challenges and Global Perspectives* (pp. 127-146). Singapore: Springer Nature Singapore.

31. Malahleha, M. A., & Ajam, T. (2024, March). *Enhancing the effectiveness of data management to improve data quality for evidence-based decision-making: A case study of*

ISSN (O) : 3093-4664

Pelonomi Tertiary Hospital.

32. Razzaq, K., & Shah, M. (2025). Machine learning and deep learning paradigms: From techniques to practical applications and research frontiers. *Computers*, *14*(3), 93.
33. Reis, Joe, and Matt Housley. *Fundamentals of data engineering*. " O'Reilly Media, Inc.", 2022.
34. Devore, Jay L., Kenneth N. Berk, and Matthew A. Carlton. *Modern mathematical statistics with applications*. Springer Nature, 2021.
35. Sarker, Iqbal H. "Machine learning: Algorithms, real-world applications and research directions." *SN computer science* 2.3 (2021): 160.
36. Taye, Mohammad Mustafa. "Understanding of machine learning with deep learning: architectures, workflow, applications and future directions." *Computers* 12.5 (2023): 91.
37. Key contributions/findings Promoting pedagogical core concepts that are repeated in multiple algorithms, instead of a comprehensive list of algorithms.
38. Serrano Segarra, María. "Problem-based learning: and effective teaching strategy to improve learning outcomes in commercial law."
39. Mosqueira-Rey, Eduardo, et al. "Human-in-the-loop machine learning: a state of the art." *Artificial Intelligence Review* 56.4 (2023): 3005-3054.
40. Lachner, Andreas, et al. "Learning-by-teaching without audience presence or interaction: When and why does it work?." *Educational Psychology Review* 34.2 (2022): 575-607.
41. Jiang, Ellen, et al. "Promptmaker: Prompt-based prototyping with large language models." *CHI Conference on Human Factors in Computing Systems Extended Abstracts*. 2022.
42. ÖZDEN, MUHAMMET YAŞAR. "Use of AI in Education: AI Competency Framework for Teachers." *Journal of Computer Education* 4.1 (2025): 1-17.
43. Ng, Davy Tsz Kit, et al. "A review of AI teaching and learning from 2000 to 2020." *Education and Information Technologies* 28.7 (2023): 8445-8501.
44. Sun, Dan, et al. "Block-based versus text-based programming: a comparison of learners' programming behaviors, computational thinking skills and attitudes toward programming." *Educational technology research and development* 72.2 (2024): 1067-1089.

How to cite this article: Arshad et al. (2026). **Next-Generation Pharmacovigilance: The Role of AI and Machine Learning in Detecting and Managing Drug Risks. Interdisciplinary Journal of the African Alliance for Research, Advocacy and Innovation. Vol 2, Issue 2. April-June. https://doi.org/10.64261/x8f2hr74.**

ISSN (O) : 3093-4664

45. Lieser, Ping, Steven D. Taff, and Anne Murphy-Hagan. "The webinar integration tool: A framework for promoting active learning in blended environments." *Journal of Interactive Media in Education* 2018.1 (2018): 7-7.

46. Shamir, Gilad. *Introducing machine learning in K-12 education for the advancement of computational thinking*. Diss. Tel Aviv University, Israel, 2023.

47. Pandey, R. P., Chang, C. M., & Raj, V. S. (Eds.). (2025). *Artificial Intelligence in Managing Antimicrobial Resistance*. CRC Press.

48. Shi, Yi, et al. "The diagnosis of tuberculous meningitis: advancements in new technologies and machine learning algorithms." *Frontiers in Microbiology* 14 (2023): 1290746.

49. Khan, Muhammad Raheel, et al. "Comprehensive Analysis of Cardiovascular Diseases: Symptoms, Diagnosis, and AI Innovations." *Bioengineering* 11.12 (2024): 1239.

50. Fu[1], L., Li, J., & Gong, S. (2023). comprehensive analysis of m7G methylation regulators in the. *Bioinformatics Applied to Neuroscience*, 147.

51. Gupta, N., Singh, H., & Singla, J. (2024). A comparative review on machine learning based medical diagnostic systems for Chikungunya and Zika virus. *Computational Methods in Science and Technology*, 343-348.

52. Sweidan, Kamal, et al. "The First AAU International Conference on Pharmacy and Biomedical Sciences." *BMC Proceedings*. Vol. 17. No. 16. 2023.

53. Ahire, Yogesh S., et al. "Advanced applications of artificial intelligence in pharmacovigilance: Current trends and future perspectives." *J Pharm Res* 23.1 (2024): 23-33.

54. Johnson, Stephen B., et al. "An electronic health record based on structured narrative." *Journal of the American Medical Informatics Association* 15.1 (2008): 54-64

55. Chen, Brian K., and Y. Tony Yang. "Post-marketing surveillance of prescription drug safety: past, present, and future." *Journal of Legal Medicine* 34.2 (2013): 193-213..

56. Dimitsaki, S., Natsiavas, P., & Jaulent, M. C. (2024). Applying AI to structured real-world data for pharmacovigilance purposes: Scoping review. *Journal of Medical Internet Research*, *26*, e57824.

57. To detect and describe the most widespread AI methodologies used today in the Pharmacovigilance field, as well as ML algorithms, natural language processing, deep learning, and Bayesian networks. To assess the accuracy, speed, and scalability of AI-based

ISSN (O) : 3093-4664

Pharmacovigilance systems against traditional methods in terms of their performance measures and effectiveness.

58. Nagar, A., Gobburu, J., & Chakravarty, A. (2025). Artificial intelligence in pharmacovigilance: advancing drug safety monitoring and regulatory integration. *Therapeutic Advances in Drug Safety*, *16*, 20420986251361435.
59. Ahire, Yogesh S., et al. "Advanced applications of artificial intelligence in pharmacovigilance: Current trends and future perspectives." *J Pharm Res* 23.1 (2024): 23-33.
60. Taylor, James. *Decision management systems: a practical guide to using business rules and predictive analytics*. Pearson Education, 2011.
61. Yang, J., & Li, F. (2025). The Impact of Technological Progress on Pharmacovigilance. *Pharmacovigilance-Facts, Challenges, Limitations and Opportunities: Facts, Challenges, Limitations and Opportunities*, 43.
62. Ajmal, C. S., et al. "Innovative approaches in regulatory affairs: leveraging artificial intelligence and machine learning for efficient compliance and decision-making." *The AAPS Journal* 27.1 (2025): 22.
63. Ahire, Yogesh S., et al. "Advanced applications of artificial intelligence in pharmacovigilance: Current trends and future perspectives." *J Pharm Res* 23.1 (2024): 23-33.
64. Salas, Maribel, et al. "The use of artificial intelligence in pharmacovigilance: a systematic review of the literature." *Pharmaceutical medicine* 36.5 (2022): 295-306.
65. Ahire, Yogesh S., et al. "Advanced applications of artificial intelligence in pharmacovigilance: Current trends and future perspectives." *J Pharm Res* 23.1 (2024): 23-33.
66. Ahire, Yogesh S., et al. "Advanced applications of artificial intelligence in pharmacovigilance: Current trends and future perspectives." *J Pharm Res* 23.1 (2024): 23-33.
67. Korade Payal, B., et al. "Pharmacovigilance: A Pillar of Modern Drug Safety." *Asian Journal of Pharmaceutical Research and Development* 13.5 (2025): 60-68.
68. Ahire, Yogesh S., et al. "Advanced applications of artificial intelligence in pharmacovigilance: Current trends and future perspectives." *J Pharm Res* 23.1 (2024): 23-33.

ISSN (O) : 3093-4664

69. Sardella, Marco, and Lucia Costanzo. "The 7th European Pharmacovigilance Congress: speaker abstracts."

70. Ahire, Yogesh S., et al. "Advanced applications of artificial intelligence in pharmacovigilance: Current trends and future perspectives." *J Pharm Res* 23.1 (2024): 23-33.

71. Beninger, Paul. "Signal management in pharmacovigilance: a review of activities and case studies." *Clinical therapeutics* 42.6 (2020): 1110-1129.

72. Watson, Richard T. *Data management, databases and organizations*. John Wiley & Sons, 2008.

73. Signal Management is the continuous review of safety-related data to identify trends or indications of the reported adverse incidents

74. Tieu, Carolyn, and Christopher D. Breder. "A critical evaluation of safety signal analysis using algorithmic standardised MedDRA queries." *Drug safety* 41.12 (2018): 1375-1385.

75. The application of benefit-Risk Management involves the continuous assessment of the positive effects of a drug against the risks

76. Butler, Dianne, et al. "Regulatory experience of handling risk management plans (RMPs) for medicinal products in the EU." *Expert Opinion on Drug Safety* 20.7 (2021): 815-826

77. WILSON, LAUREN. "Enhancing Safety Surveillance during Clinical Trials: The Development of a Safety Data Review Handbook to Support Pharmacovigilance Clinicians." (2024)..

78. Benson, Chizubem, et al. "The impact of interventions on health, safety and environment in the process industry." *Heliyon* 10.1 (2024).

79. Schurer, Maximillian Juan. *Towards the interoperability of spontaneous reporting systems in pharmacovigilance: A maturity model approach with a sociotechnical system focus*. Diss. Stellenbosch: Stellenbosch University, 2020.

80. Ukoba, Kingsley, et al. "Optimizing renewable energy systems through artificial intelligence: Review and future prospects." *Energy & Environment* 35.7 (2024): 3833-3879.

81. Wang, Yue, and Sai Ho Chung. "Artificial intelligence in safety-critical systems: a systematic review." *Industrial Management & Data Systems* 122.2 (2022): 442-470.

How to cite this article: Arshad et al. (2026). **Next-Generation Pharmacovigilance: The Role of AI and Machine Learning in Detecting and Managing Drug Risks. Interdisciplinary Journal of the African Alliance for Research, Advocacy and Innovation. Vol 2, Issue 2. April-June. https://doi.org/10.64261/x8f2hr74.**

ISSN (O) : 3093-4664

82. Sen, Debarshi, et al. "Data-driven semi-supervised and supervised learning algorithms for health monitoring of pipes." *Mechanical Systems and Signal Processing* 131 (2019): 524-537.

83. Smith, Jordan, and Martha Logan. "Reinforcement Learning-Based Hospital Workflow Optimization During Crises." (2024).

84. Abi, Roland. "Ethical and Explainable AI in Data Science for Transparent Decision-Making Across Critical Business Operations."

85. Ebbevi, David, et al. "Boards of directors' influences on occupational health and safety: a scoping review of evidence and best practices." *International Journal of Workplace Health Management* 14.1 (2021): 64-86.

86. Glaser, Michael, and Rory Littlebury. "Governance of artificial intelligence and machine learning in pharmacovigilance: what works today and what more is needed?." *Therapeutic Advances in Drug Safety* 15 (2024): 20420986241293303.

87. Barbieri, Maria Antonietta, et al. "Artificial intelligence in pharmacovigilance signal management: a review of tools, implementations, research, and regulatory landscape." *Expert Opinion on Drug Safety* (2025): 1-16.

88. Puchakayala, Praneeth Reddy Amudala. "Data Quality Management for Effective Machine Learning and AI Modelling, Best Practices and Emerging Trends." *International Research Journal of Innovations in Engineering and Technology* (2022).

89. Duggineni, Sasidhar. "Impact of controls on data integrity and information systems." *Science and technology* 13.2 (2023): 29-35.

90. Khurram, Minahil, et al. "Artificial Intelligence in Manufacturing Industry Worker Safety: A New Paradigm for Hazard Prevention and Mitigation." *Processes* 13.5 (2025): 1312.

91. Rajendran, Gowthamraj, Reiko Raute, and Cedric Caruana. "A Comprehensive Review of Solar PV Integration with Smart-Grids: Challenges, Standards, and Grid Codes." *Energies* 18.9 (2025): 2221.

92. Nastoska, Aleksandra, et al. "Evaluating trustworthiness in AI: Risks, metrics, and applications across industries." *Electronics* 14.13 (2025): 2717.

93. Okare, P., et al. "A conceptual version-control and data lineage framework for agile financial reporting pipelines." *Gyanshauryam: International Scientific Refereed Research Journal* 6.3 (2023): 154-169.

How to cite this article: Arshad et al. (2026). **Next-Generation Pharmacovigilance: The Role of AI and Machine Learning in Detecting and Managing Drug Risks. Interdisciplinary Journal of the African Alliance for Research, Advocacy and Innovation. Vol 2, Issue 2. April-June. https://doi.org/10.64261/x8f2hr74.**

ISSN (O) : 3093-4664

94. Glaser, Michael, and Rory Littlebury. "Governance of artificial intelligence and machine learning in pharmacovigilance: what works today and what more is needed?." *Therapeutic Advances in Drug Safety* 15 (2024): 20420986241293303.

95. Panda, Swarup. *Scalable Artificial Intelligence Systems: Cloud-Native, Edge-AI, MLOps, and Governance for Real-World Deployment*. Deep Science Publishing, 2025.

How to cite this article: Arshad et al. (2026). **Next-Generation Pharmacovigilance: The Role of AI and Machine Learning in Detecting and Managing Drug Risks. Interdisciplinary Journal of the African Alliance for Research, Advocacy and Innovation. Vol 2, Issue 2. April-June. https://doi.org/10.64261/x8f2hr74.**

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