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Review Article

Artificial Intelligence and Machine Learning in Pharmacovigilance

Jeeban Agnihotry*, Nityapriya Maharana, Biswa Bhusan Padhi, Chandrakanta Das, Sai Swagatika Das, Tushar Kanti Das

Pharmacy, Xavier Pharmacy College

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ABSTRACT

Pharmacovigilance (PV) is the systematic monitoring of medicines for the detection, evaluation and prevention of harmful drug reactions (ADRs) after market provision. Traditional PVs are based on spontaneous reporting and manual signal detection, and can be expensive and often slow. In recent years, artificial intelligence (AI) and Machine Learning (ML) methods have shown promising PVs by evaluating large and diverse data sources (clinical records, social media, scientific literature, etc.) much faster than humans. The AI/ML methods (including natural language processing (NLP) and deep learning) were successfully applied to the task as automated ADR detection, case report processing, and literary exams. These methods improve the sensitivity and locality of CAC signal detection, allowing personalized risk stratification in real-time security monitoring. However, AI-controlled PVs also face challenges related to data quality, interpretability and regulatory oversight. Current regulatory initiatives (e.g. EMAS AI Reflection Paper, Draft FDA Guidelines) highlight the need for AI tools to comply with the benefits, limitations and forward-looking statements of legal and ethical standards.

INTRODUCTION

Pharmacovigilance (PV) – “the technological know-how and sports regarding the detection, assessment, understanding and prevention of damaging consequences or another medicine-associated problem” – is vital for ensuring drug protection after marketing. Traditional PV structures depend closely on spontaneous reviews

(person case safety reviews, ICSRs) submitted through healthcare specialists and patients. These reviews feed databases (together with the FDA Adverse Event Reporting System) in which pharmacovigilance professionals manually evaluation and apply statistical algorithms (e.g. disproportionality analysis) to discover protection alerts. However, this reactive process is fundamentally gradual and incomplete: many

***Corresponding Author:** Jeeban Pradeep Agnihotry

Address: Pharmacy, Xavier Pharmacy College.

Email ✉: jaganagnihotry@gmail.com

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ADRs continue to be underreported and protection alerts often emerge most effective after sizable delay. Meanwhile, the healthcare atmosphere has generated vast volumes of virtual statistics (digital fitness records, medical notes, biomedical literature, affected person forums, social media, etc.) which can be in large part unstructured and past the capability of guide analysis. Advances in artificial intelligence (AI) and machine learning (ML) provide new possibilities to mechanically method and understand these heterogeneous statistics streams. In particular, herbal language processing (NLP) strategies can extract medical statistics from free-textual content narratives and social media posts, whilst pattern-popularity algorithms can standard astonishing ADR institutions in huge datasets. This evaluation surveys the principles of AI/ML for PV, current applications, dedications and limitations, regulatory perspectives, and destiny directions. Its objectives to introduce early-profession researchers and postgraduate college students to this evolving subject with enough technical depth and clarity.

OVERVIEW OF PHARMACOVIGILANCE:

Pharmacovigilance includes all activities carried out by the supervisory authorities and manufacturers, monitoring the safety of the drug after acceptance. Core tasks include collection of ADR reports (from clinicians, patients, and the literature), coding symptoms using standardized vocabulary (e.g. MedDRA), and identification of the statistical associations of signal detection-drugs and unwanted outcomes that can indicate new security systems. For example, if a drug with a particular event is reported disproportionately compared to other events, it could be a test. ICSR is the most common data source for PVs, but is plagued by bias and sub reports. Underreporting is a major issue. Not all patients and physicians report on unspeakable, particularly frequent or

expected side effects. Furthermore, ICSR data often lack detailed clinical context and are submitted in free textual narratives that require manual interpretation. These limitations can delay actual ADR knowledge and generate false leads (for example, due to report distortion). To complement ICSR, PV practitioners are increasingly considering sources of other sources of real-world data (RWD). Electronic health Records (EHRs), insurance claims, and aggressive surveillance studies can help quantify ADR prevalence. The biomedical literature can report new ADRs in clinical practice or research. Generated patients (forums, social media) can demonstrate the experience of the consumer. However, extracting reliable safety signals from these sources requires an extended data processing method. While traditional PVs focus on statistical monitoring of structured data, the increase in big data and AI/ML provides tools for entering supported information and recognizing complex patterns. To understand these AI/ML methods, you need A brief -Primer for those core principles (next section) depending on your research into how they apply to PV challenges.

BASICS OF AI AND ML RELEVANT TO DRUG SAFETY:

Artificial intelligence (AI) refers to computer systems that perform tasks that require intelligence, such as humans. Machine learning (ML) is a subset of AI where algorithms automatically learn predictive models from data, instead of being explicitly programmed for all tasks. The classic definition of ML is "a field of research, which gives computers the opportunity to learn without being explicitly programmed" (Samuel, 1959). The most important ML paradigms include:

Supervised Learning;

Models (e.g. collection trees, random forests, support vector machines, neural networks) are



educated on ancient facts in which the appropriate output (e.g. “ADR present” vs “no ADR”) is known. The educated version can then be expecting ADR presence in new facts. For instance, a classifier may be educated to flag affected person statistics or social media posts that point out unique ADRs. Unstructured facts, supervised fashions like random forests were famous for ADR detection. In unstructured textual content, deep neural networks (specifically deep learning models) have accomplished state-of-the-artwork consequences for NLP obligations.

Unsupervised Learning;

Here the set of rules reveals styles in unlabelled facts. Clustering or anomaly-detection strategies may be used to institution comparable reviews or perceive reviews that deviate from the norm (potential novel ADR signals). However, unsupervised strategies require careful interpretation through professionals.

Deep Learning and NLP;

Deep getting to know refers to neural networks with many layers (e.g. Convolutional or recurrent networks, transformers). Notably, transformer-primarily based totally language fashions (e.g. BERT, GPT) permit state-of-the-art NLP on clinical textual content. NLP strategies convert unstructured textual content (ICSR narratives, scientific notes, tweets) into numerical functions or semantic representations that ML models can process. Common NLP steps consist of tokenization, vector embedding, sequence modelling (e.g. LSTM, transformers), and entity recognition. For example, an NLP pipeline may identify mentions of medication and detrimental activities in a discussion board publish and classify the textual content as containing an ADR. Recent large language models (LLMs) (e.g. GPT-) may even generate or summarize medical text, that's rising for obligations like literature screening.

Model Evaluation;

AI/ML fashions are normally assessed through metrics along with sensitivity (recall), specificity, precision, and F1-rating on held-out check facts. In pharmacovigilance, excessive recall (locating as many authentic ADRs as possible) is frequently prioritized, even as controlling fake positives. Model training often calls for enormous, excellent categorized datasets; one annoyance in PV is the paucity of publicly labelled ADR corpora, though efforts exist to annotate ICSRs and social media posts.

In summary, AI/ML brings a spectrum of computational tools—category algorithms, neural networks, and NLP strategies—that could system heterogeneous facts. These strategies fluctuate in complexity and interpretability: rule-primarily based totally approaches (the use of expert-curated regulations and ontologies) are greater transparent but restricted in scope, even as deep getting to know fashions are effective however frequently “black boxes.” Explainable AI (XAI) is an evolving location that pursuits to make models' reasoning greater understandable. The relaxation of this evaluates will illustrate how those AI/ML strategies were implemented to unique PV obligations, and what blessings and limitations were observed.

CURRENT APPLICATIONS OF AI/ML IN PHARMACOVIGILANCE:

ADR recognition from spontaneous reporting (ICSRs);

AI/ML can automate some of the traditional case presses. For example, duplicate report detection is a critical workload, allowing ML classifiers to replicate ICSRs for manual review. Similarly, the NLP model can automatically code text in standard terms, and flag reports (probably serious or newer ADRs) can flag them. -frontier experts include early AI deployment in PVs that allow you to focus on "simpler" tasks that require talent. ICSR triage, classification and deduplication. The



research prototype applies ML to ICSR data. For example, a fairy-trained algorithm has been proposed to testify on prediction metrics. Many pharmaceutical companies that study AI for signal management (e.g., by automating case narrative analysis), have limited peer review results. Nevertheless, in the near future, ML-enhanced monitoring of the report database can be expected to improve signal detection speed and consistency.

Social Media and Patient Forum Mining;

Unstructured patient Generated Data (Twitter, Health Forum, Online Review) contains extensive information about real drug experiences. In some studies, NLP/ML pipelines were installed to identify ADR crews for such texts. For example, Roosan et al. developed the A Context-Conscious Tool (a Tarantula) using fast text embarrassment and a patient-reported ADE lexicon to mine posts about the anticoagulant warfarin on patient forums. Your model reached a sensitivity of 84.2% and a specificity of 98% in the detection of the well-known warfarin-address. Similarly, Dong et al. trained a BERT-based model on Twitter data and achieved an F1 value of 0.81-0.98 to extract the ADR clamp width from the tweet. Bing and Li (2022) improved classification of ADR tweets by context-related NLP using attention-based LSTMs and large data records from Twitter posts. They concluded that "social media can have a reliable data source for collecting ADRs" covering many known ADRs. These applications show that AI ADR signals can be harvested from noisy text. Mining patients whose social chat can cover is underestimated or focused on patients (for example, discuss online that patient side effects may not be reported to a doctor). However, the challenges include informal language, short contexts of tweets, and sample distortions (users are not in a random patient population). Models often struggle with generalising new drugs and can record false signals (e.g. jokes or news re-posts labelled as ADRs).

EHR analysis (electronic health records);

EHR contains longitudinal clinical data (clinical results from clinicians, diagnosis, regulation, conclusive comments), and actual ADRs occurring. Golder et al. (2025) investigated seven studies and found that NLP/ML significantly improves detection of underreported events and security signals with a free-text EHR note. For example, a system that combines rule-based filters with statistical and deep learning methods can identify ADR cups. This revealed coding movements and revealed the signal. Other work applied ML to structured EHR fields (such as Laboratory values or billing codes) to record temporary patterns indicating ADR. A recently conducted JMIR check reported most studies of AI+RWD on ADR recognition (64% of studies) using the classifier of EHR-Data records (mainly random forest 94%). This research regularly displays better sensitivity than rule-primarily based totally search, however reveal issues: EHR records are heterogeneous (one-of-a-kind hospitals use one-of-a-kind formats) and regularly require massive preprocessing. According to Dimitsakiet al., simplest a minority of EHR-primarily based totally AI research put up their code or check models in actual scientific settings, so replicability is limited. In practice, AI gear can sift thru tens of thousands and thousands of EHR statistics to flag sufferers with viable ADRs (e.g. uncommon lab adjustments post- medication) for professional assessment. These structures have the gain of wealthy clinical context (age, comorbidities) that can customise signal detection, however additionally they call for stringent privacy safeguards.

Biomedical Literature and Document Screening;

The clinical and regulatory literature is every other supply of ADR information (case reviews, cohort research, warnings). Traditional PV safety reviews involve manually scanning tremendous numbers of publications. AI (particularly NLP and LLMs)



is an increasing number of explored for literature surveillance. For example, an assessment of GPT-3.5 and comparable LLMs confirmed that with cautiously crafted prompts, those fashions can automate preliminary literature screening for PV, achieving “excessive sensitivity and reproducibility” in retrieving applicable research whilst filtering out many beside the point papers. In practice, which means an AI-pushed literature evaluation ought to quick spotlight new case reviews or indicators in posted trials, saving researchers’ time. Some groups are already the usage of text-mining pipelines to test journals and protection reviews. The Vision is that during future, non-stop AI pipelines ought to routinely feed insights from the modern-day courses into PV databases. Again, human evaluation stays essential, however AI can dramatically boost up the preliminary triage of literature.

Other Emerging Applications;

AI is likewise being carried out to hybrid records sources. For example, ML models had been evolved to investigate affected person registry records or coverage claims for long-time safety signal detection. There are paintings on the usage of wearables and virtual biomarkers (heart rate monitors, smart pills) to hit upon physiological anomalies that would imply ADRs, with anomaly detection algorithms. In the sphere of regulatory submissions, NLP can automate the drafting and checking of protection summaries. As a concrete example, AI-primarily based totally structures had been piloted to extract MedDRA codes from clinical narratives or to auto-populate elements of case report forms. Collectively, those programs illustrate the breadth of AI/ML roles in PV – from front-line records screening to back-quit case processing.

ADVANTAGES OF AI/ML IN DRUG SAFETY MONITORING:

AI and ML offer several potential profits for pharmacovigilance:

Scalability and efficiency:

AI systems can be incessant and much faster than human teams. They are not subject to fatigue or cognitive limitations, permitting some data flows to monitor some data at hours. For example, NLP pipelines cannot be manually. This means the previous security issue (minimizing delay between events and recognition). Improved Signal Detection and Sensitivity: ML models are categorized to recognize subtle patterns in the data. Statistics can discover associations that can avoid standard methods. For example, Study shows that NLP/ML was applied to previously overlooked unstructured data. It has been found that EHR text was identified when mining "unknown security signals that were not displayed only by structured data." Similarly, the social media mining algorithms not recorded in formal reports. In general, AI/ML uses contextual information and learning to increase sensitivity, which is the actual ADR case.

Multi-Source Integration:

AI/ML methods can easily combine heterogeneous data (ICSR, EHRS, OMICS, social media, etc.) than rule-based systems. For example, the hybrid model can analyse genomic risk factors and reported symptoms in, patients to access personalized drug risk. The editorial of Zou et al. climaxes that exploiting “multiple modalities” (ICSRs, biochemical data, RWD, social media, etc.) through integrated AI models is a key upcoming trend Such a multi-modal analysis can view signals (reflecting the ADR trends and social media of EHR) to verify the trust.

Personalized Risk Stratification:

Advanced AI can adapt security surveillance to individual factors. For, ML subgroups (based on genetics, demographics, and comorbidities) can be identified with a higher ADR risk. The editor predicts that AI will allow for "personalization of

drug safety measures based on, individual genetic profiles." In practice, this means that AI helps prioritize monitoring of, patients who are most likely to develop rare responses and improve the general health impacts of public health.

Resource Optimization:

By transforming tasks at a low level, AI reduces manual workloads and costs at distances. A preliminary cost-benefit analysis shows that NLP support reports coding and signalling can reduce the working needs of the PV department. Over time, these efficiencies can enable only limited PV resources to be implemented through strategic analysis and regulatory measures.

CHALLENGES AND LIMITATIONS:

Despite its promise, AI/ML in PV also faces significant challenges;

Data Quality and Bias:

AI models are just as good as training data. In PVs, data is often sparse and loudly biased at. For example, social media users are not representative of the general patient population, and their contributions may include slang, misconduct, or misinformation. EHR -Data suffers from incomplete documentation and variations between systems. Machine -Learning Models are trained on limited or unstable data records, with no real ADR (false negative) and generates false signals (FALSE alarms). As stated in terms of PV, the data record covering all relevant conditions is "a lack of robust and effective training.

Interpretability and Explainability:

Additionally, many of the AI studies in PV may not be retrospectively generalized. Prediction. In regulated environments such as PVs, the lack of explanation is a problem. Regulators and clinicians should trust the security signal of the AI flag to be trusted and trust based on medical justification. For example, neuronal networks can mark a particular pair of drugs without an obvious causal pattern. This makes verification difficult.

This raises questions about confidence in the AI decision: Can you check these algorithms? The latest CIOMS draft recommends a human supervision and a risk-based approach, as unconfirmed AI conclusions can be misleading or miss out on key factors for the Regulatory guidelines also emphasize that people's reviews are still needed-AI supports experts and does not replace them.

Privacy, Ethics, and Consent:

Use of ML patient data (non-identified form) includes data protection risks. Mining on social media and patient forums is ethically sensitive. The post contains personal health information that is not intended for use in the research. If AI systems analyse such data, there is a risk of new identification or abuse. As highlighted by the clinical review, data is used without consent raises "ethical concerns." Thorough data protection management techniques (e.g. federal learning, discriminatory privacy) are required, but complicate implementation. Furthermore, transparency is ethically defined by the use of AI. Regulation and Verification Hurdles:

PV AI tools must meet high proof standards and reliability before accepting official acceptance. Most AI applications are currently located on the PV Academic prototype, not on the verified product. Only a small fraction of published studies publishes code or models in real clinical settings, making independent verification difficult. Regulation bodies (FDA, EMA) require robust verification. For example, FDA AI instructions require a "risk-based reliability framework" that provides a rigorous documented model performance. Wide range of acceptance remains until the standardized verification protocols and quality standards of PV AI are standardized.

Operational and technical obstacles:

Implementing AI solutions requires technical organization (computer performance, software integration) and qualified staff. Many PV



organizations may not have a data science team or have budgets for advanced analytics platforms. Even if the tools exist, integration into legacy PV databases and workflows can be complicated. Continuous model maintenance of this also required. If new drugs enter the market or languages are developed and continuous resources are needed, the AI model should be updated.

Regulatory Accountability and Legal Questions: Who is responsible for whether the AI-based PV decision is incorrect remains unknown. For example, if AI tools do not characterize important ADRs or generate false alarms, is controversial. Regulations such as the EU AI Act (2024) classify medical AI as high risk and set strict requirements for documents and human. Navigation of these legal landscapes is not trivial for PV developers. In practice, these challenges mean that AI/ML in PV is not a turnkey solution. Careful design, rigorous evaluations, and an in-loop approach are essential. The investigation repeatedly warns that "full automation of PV systems" without transparency and verification of is "misleading and inaccurate". "Ongoing research focuses on the development of explanatory models, data protection bonds, and the criteria to address these limitations.

REGULATORY PERSPECTIVE:

Regulators are aware of the potential of AI in drug safety, but they emphasize attentiveness. In July 2023, European Medicines Agency (EMA) in the Pharmaceutical Life Cycle released a draft of a reflection paper on AI. This EMA Guideline explicitly states that AI/ML tools can support PV tasks (for example, automating management reports and signalling unwanted events). Reflection paper supports a "human-centric" approach. AI should expand the decision of experts. For example, all AI systems that possibly affect drug profile use are suggested.

In a similar way, the FDA is dynamically involved in AI and PV. In early 2025, FDA released the AI/ML Guide Drag Lifecycle (covering non-device products). These guidelines suggest a risk-based frame for AI reliability assessments and inspire sponsors to document the development, validation and supervision of the model. It is significant that the FDA does not use AI for monitoring after stamping existing requirements. In another word, AI is a way to support PVs, but does not oversee and change the legal challenges of pharmaceutical companies to ADR. Form an international working group to determine best practices. For example, AI CIOMS Group in PV develops guidelines on topics such as explanations and human supervision (focusing on where regulatory quality processes need to adjust AI equipment). The new EU artificial intelligence law (effective 2024) classifies healthcare as "high risk" and imposes strict requirements for data governance, transparency and surveillance. AI systems used in pharmacovigilance will likely fall under such guidelines. Means that developers need to establish performance, equity and risk management.

FUTURE DIRECTIONS:

The use of AI/ML in pharmacovigilance is expected to raise quickly, driven by new technologies and data. Several significant trends are predictable.

Advanced Natural Language Models:

The Rise of Large-scale Language Models (LLM) transforms text analysis. Experts assume that the scalability in processing unstructured data in PVs will make LLM and associated NLP tools a major way. Future systems may use finely tuned style models in medical texts to summarise case reports, translate foreign language reports, and generate security counts. For example, LLMS can continue to read the global literature and determined security concerns. However, this requires careful



instantaneous design and vigorous domain adjustment to ensure honest precision.

Hybrid and Explainable AI:

A promising paradigm is "hybrid AI." It combines Data-Controlled ML with symbolic or knowledge-based components. In PV, this means integrating formal medical ontologies (e.g., SNOMED, MeSH) into neural networks so that estimates from AI models can be combined with concepts that humans cannot understand. Such a hybrid model can improve the explanation of the, permitting regulators to track how signals are recognized. There is growing interest in developing AI. This offers estimates of realistic or uncertainty in addition to spending, and facilitates regulatory authority norms.

Multi-modal Data Integration:

Future PV systems will likely take part some modes of data and analysis. For example, a combination of Honor data and pharmacogenomic monitoring of genomic information (identification of ADRs in genetically sensitive subpopulations) may support. The AI construction can also process text, images (such as radiation reports on drug effects), lab values, and environmental data. This multi-source approach, "big data," can lead to extensive security of acquaintance, but requires sophisticated data links and harmony standards.

Federation and Privacy-Preserving Learning:

When privacy is growing, learning and other distributed AI technologies allow joint PV models through raw data less institutions. For example, various hospitals or regulators can collaborate on ADR prediction models from the exchange of model updates instead of confidential records. Early research on the Healthcare System shows that federation models protect patient privacy at the same time as central concert. Coordination of these methods to PVs could promote a global monitoring network, while instantaneously respecting data sovereignty.

Real-time and Automatic Monitoring:

The long-term goal is continuous, automated security monitoring. Instead of regular manual checks, the AI Pipeline can monitor voluntary reports, clinical data feeds, and internet sources in real time. This means that if an anomaly is created, a warning will be raised immediately. Once this is achieved, integration into trusted AI models, real-time data pipelines, and regulatory workflows is required.

Human-Machine Alliance:

In the future, PV workflows will likely be redesigned by, people. Machine learning assistants can use literature in advance cases or in front of screens, but humans handle, experts with interpretation and conclusions. The consensus is that human supervision is still crucial. AI does not replace PV experts, but it expands. The Training program must have Pharmacovigilance employees with data science capabilities to operate the AI tools.

Overall, the future of PVs is amplified surveillance automation, intelligence and breadth. AI/ML innovations promise extraordinary efficiency and insights, but they are advanced through iterative research, validation, and regulatory feedback. As the limitations are esteemed, it is clear that "using AI to support PV/PE for the next few years remains an active research and development field", and all new progress (e.g., better models, new data sources) will open up further options to ensure drug trustworthiness.

CONCLUSION:













Pharmacovigilance is a new era equipped with artificial intelligence and machine learning. AI/ML Techniques - in particular NLP learning and deep learning - have already demonstrated the ability to extend the traditional PV by extracting ADR signals from a variety of unstructured data sources. These methods can improve the speed, sensitivity and scope of security monitoring, possibly allowing early intervention and more



personalized risk management. At the same time, AI/ML faces complex challenges with PV, ensuring data quality, maintaining patient privacy, maintaining transparency and meeting regulatory standards. Current efforts by the supervisory authorities (EMA, FDA, CIOMS) lay the foundation for safe and effective integration of AI in PVs.

For early care researchers and students, this field offers many exciting opportunities. It deals with better algorithms for text mining, AI models validation of real data, designable AI and, legal/ethical questions. Achievement relies on interdisciplinary collaboration between, pharmacologists, data scientists, clinicians and supervisory authorities. Ultimately, the goal is a more proactive, data-controlled pharmacovigilance system that protects patients more accurately than ever before, without losing the critical human judgment and supervision that controls drug safety.

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