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Redefining Drug Safety: The Role of Artificial Intelligence in Pharmacovigilance

Toufique Ahmed Mollah[1], Mahmudur Rahaman Mallick[2], Subhodip Saha[3]

[1]*Vice President, International Life Science Association, Kolkata, West Bengal, 700001*

[2]*Calcutta Institute of Pharmaceutical Technology and Allied Health Sciences, Banitabla, Howrah, West Bengal, 711316*

[3]*NIMS University, Jaipur, Rajasthan, 303121*

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Abstract—

Background: The current state and forecast: Global Pharmacovigilance Market, which is expected to see a paradigm shift, reaching a projected market value - 25.37 billion USD with an annual growth rate - 42.81% within the AI market sector. According to estimates, the no. of ADR (Adverse Drug Reaction) reports is expected an exponential increase due to support organizations, various Social Media Platforms, and Electronic Health Records (EHR), making manual analysis impossible.

Objective: Our paper introduces an overview of current applications and implementations of Artificial Intelligence (AI) within the field of drug safety, from its statistical roots associated with data mining to the current methods utilizing Large Language Models (LLMs).

Scope: It covers various AI/ML technologies like, Natural Language Processing (NLP), its use within case intake automation, use and implementation of Machine Learning (ML) Models such as Random Forrest and Bayesian Networks within signal detection analysis, and proposes and explains current and potential applications for Generative AI within risk management documentation. Results: Industry cases and current implementation examples suggest that AI/ML contributes towards a reduction of up to 60% within case intake analysis and towards an increased sensitivity factor within signal detection compared with traditional disproportionality analysis methods.

Conclusion: The industry is undergoing a shift from the 'compliance-driven' PV function towards a 'data-driven' safety and risk management paradigm. However, implementing this on a global scale is facing important challenges and obstacles such as Algorithmic Explainability (XAI), Data Biases, and issues within regulatory acceptances.

***Keywords*—Pharmacovigilance, Artificial Intelligence, Signal Detection, Generative AI, PV.**

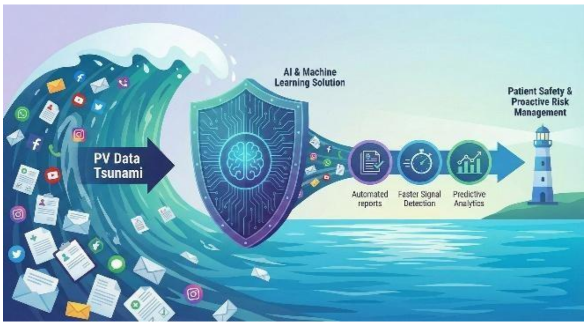
I. INTRODUCTION

1.1 The Fundamental Mandate

Pharmacovigilance (PV) is the spine of public health protection within the pharmaceutical product lifecycle. Pharmacovigilance is "the science and activities undertaken after World Health Organization (WHO) approval of a medicine to detect, assess, understand, and prevent adverse effects or any other possible hazards occurring due to this product," according to World Health Organization. The basic idea of this area of expertise was to wait until a person was harmed, a report was submitted, and sufficient reports had been collected to trigger an investigation by safety professionals. But this "wait-and-see," manual process is no longer a viable option for today's world [1].

1.2 "Data Tsunami" - Crisis of Volume

Currently, the industry is experiencing what is referred to as a "Data Tsunami." In the old days, the source of safety information included clinical trials and direct feedback from physicians. The information today has diversified and proliferated.



- Velocity and Volume: Every year, the WHO VigiBase accumulates approximately millions of Individual Case Safety Reports (ICSR). Currently, major EAE companies handle over 500,000 cases every year.

- The Variety Challenge: Data is no longer simply data in structured forms. It is streaming from patient support programs, legal actions, scientific literature, and even unstructured social media updates.
- The Burden: This requires a safety associate with expertise to spend at least 30 to 60 minutes processing a case manually. Because the volume increases annually by at least 10-15%, it is a linear approach to a growing exponential problem by trying to solve it by increasing staff [2].

1.3 The Algorithmic Imperative

When Artificial Intelligence is introduced in this ecosystem, it is not an improvement but a life-saving tool. This is because humans are very good at clinical decision-making but not at processing a large amount of data for complex patterns. AI performs this job better. By performing menial tasks like code and data entry and processing huge amount of data using Machine Learning in order to identify complex and non-linear patterns within this data, the PV function can transition from a "compliance-focused" data factory to a "patient-focused" safety strategy unit. This paper will discuss how Artificial Intelligence is changing this environment and turning the industry from a reactive compliance-based industry to a predictive risk manager industry [2].

Table 1: Executive Summary & Key Research Highlights

Metric	Statistic	Source / Context
Global PV Market Size	$8.3 Billion (2024) $\rightarrow$ $19.4 Billion (2035)	Transparency Market Research, 2024
AI in PV Market Growth	CAGR 21.5% (2025–2034)	Cervicorn Consulting, 2025
Data Volume (VigiBase)	>35 Million Reports (July 2023)	WHO Uppsala Monitoring Centre
Processing Efficiency	40–60% reduction in manual time	Industry Benchmark (Top CROs)
Cost Savings	~$20 (Manual) $\rightarrow$ <$5 (AI-Automated)	Operational Analysis
Accuracy Target	>90% for automated coding	MedDRA Auto-coding standards

Key Insight: The shift is from a linear staffing process (more manpower to handle more cases) to a non-linear technological process (use of algorithms, which is infinitely scalable).

II. HISTORICAL CONTEXT: THE EVOLUTION OF SAFETY SCIENCE

In order to clarify the future of PV, a technical evaluation of the past 60 years must be undertaken.

The Era of Awakening (1960s to 1990s): The Modern PV was born out of the Thalidomide Tragedy of 1961 [11]. "Spontaneous Reporting Systems" were developed as a result of the Thalidomide tragedy. For instance, the Proportional Reporting Ratio (PRR) was implemented to determine whether the medicine led to more adverse events than would be predicted by chance. The approach was entirely statistical.

The Data Mining Revolution (2000 to 2015): The quantity of "false alarms" resulting from basic math got overwhelming as databases grew in size, such as the FDA's FAERS database. Bayesian data mining emerged. The regulator used the MGPS (Multi item Gamma Poisson Shrinker) computer program as a "benchmark tool" [12]. The noise might be "shrinked" by the MGPS to make the signals about possible hazards more noticeable for the safety doctors to respond to.

The NLP & Big Data Pilots (2015 to 2020): The industry started to play around with unstructured data. There were initiatives such as the WEB-RDR pilot, a EU project, which aimed to tap into social media sites such as Twitter and Facebook to capture adverse reactions. Although these first efforts were fraught with slang language and sarcasm, they demonstrated safety information could be found outside of traditional clinical environments, paving the way for today's sophisticated Natural Language Processing.

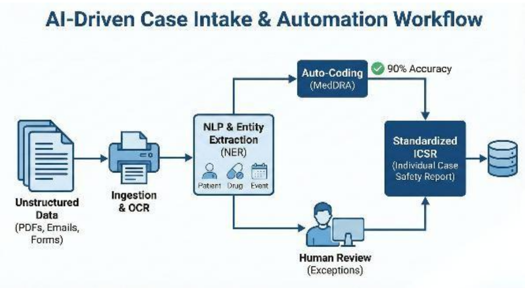
III. PRESENT CONTEXT: AI IN ACTION (2024 to 2025)

Today, AI is no longer conceptual in nature but is functional in three key pillars of the PV Workflow.

3.1 Pillar 1: Case Intake Automation

The study of ICSRs is currently the most common use of AI. This addresses the crucial "volume" problem since it affects patient care by

- The Technology: It makes use of a combination of Natural Language Processing (NLP) and Optical Character Recognition (OCR); BERT models optimized for biologic text have received special attention.



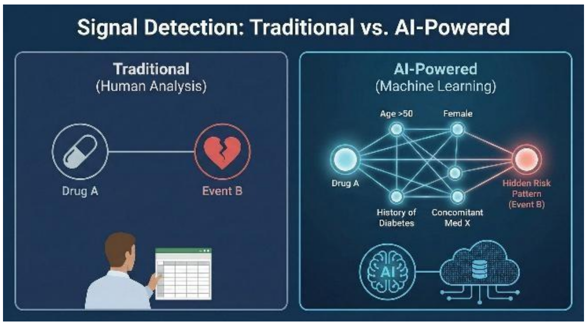
- The Workflow:
  - Ingestion: The system scans the PDF, fax, or an email
  - Entity Extraction: The four valid entities are extracted using Named Entity Recognition (NER), including an identifiable reporter, a patient, an alleged suspect drug, and an adverse event.
  - Auto-Coding: The system maps the verbatim text (e.g., "my head is pounding") to the standardized MedDRA term ("Headache") with >90% accuracy.

- Impact: This automation impacts the system positively in reducing human touch points by a minimum of 40 to 60 percent, meaning human case processors can only intervene in exceptional medical evaluations [5].

3.2 Pillar 2: Advanced Signal Detection

While humans seek "known" risks, AI systems search for the "unknown."

- Beyond Statistics: Conventional statistics look for Drug A + Event B. Large volumes of data with numerous variables (50+) can be processed using machine learning methods like Random Forest or Neural Network models.



- Pattern Recognition: For instance, the system recognizes that the adverse effect occurs only among female patients above the age of 50, who use Drug A, and previously had Diabetes—that is not easily recognizable from the one million-row data set, much less done manually by the human eye [6].

3.3 Pillar 3: Literature Surveillance

Monitoring medical journals is a regulatory requirement.

- Semantic Search: AI looks through databases such as PubMed. In contrast to keyword searching (where all instances of a particular drug are pulled), AI has context. This allows it to distinguish between "Drug X led to a rash" and "Drug X treated a rash," cutting in HALF the amount of irrelevant research results pulled, consequently cutting in HALF the amount of research required to review for literature review teams (Point 7).

IV. FUTURE OUTLOOK: THE PREDICTIVE FRONTIER

It is the beginning of the Era of Generative AI and Predictive Safety.

- Generative AI (GenAI) & LLMs: It is suggested to pilot the creation of Periodic Safety Update Reports (PSURs) using large language models (such as GPT-4 with medical data). Therefore, the AI system will synthesize safety profiles and benefit-risk statements in a first draft that will be validated to prevent "hallucinations" rather than a person taking a week to do so [16].

- Digital Twins: Thus, "Digital Twins," which might involve virtual copies of each patient's physiology, may be used in the upcoming years. Based on their genetic data, AI may be able to predict how their body will respond to the drug even before individuals take it, rendering PV "Personalized Safety" rather than "Population Safety."

V. OVERVIEW ON SYSTEMIC LITERATURE REVIEW

We live in the world of "literature" that is published every other day. The quantity of the "literature" that is presented to the "Safety Associate" after case intake is rapidly increasing and does not appear to lessen with time. "Literature" is apparent to possess an adequate quantity of "Safety Data" from across the world, and the automation of "literature" case intake does not appear to be far-off, particularly when the utilization of various "case intake" "AI" tools appears to be done on a daily basis. "Artificial Intelligence" seems to have the potential to be used to "various disease states" and is practical for managing "Large Data." "Automation" and "Machine Learning" models can "optimize pharmacovigilance procedures" and "provide an efficient method to 'analyze' data related to 'Safety." (Salas, et al., 2022)

The aim of the paper is to list the available "Open-Source" "Literature Review" "Tools," discuss the "workflow," list the "limitations" that each "tool" possesses, and then address the amalgamation of the above "technologies" into the "Pharmacovigilance" environment. We will, however, attempt to explain the "black box" of the "Systemic Literature Review" ("SLR") "tool" to the fullest capability available to us to remove the "lacuna." We will, however, refer to the "Intelligent Systemic Literature Review" ("ISLaR") "tool" that appears to be declared to be the "future" within the "literature" available to us. In the paper "Tools of the Trade—Not Just Buzzwords," Kelsie Cassell states, "Tools like ISLaR 2.0 combine systemic review workflows with AI support, suggesting the prospective use of "AI" "SLR" "tools" to "revitalize" "conventional" "practices" to "achieve "efficiency' and "decrease" the "workload'." (Cassell, et al., 2025)

Using a systematic technique, an SLR (Systematic Literature Review) is a form of investigation that allows researchers to compile, find, and critically assess previous research papers (such as articles, conference proceedings, book research papers, and doctoral theses). (Pati & Lorusso, 2018) Thus, it is a systematic and open manner of conducting research that aims to discover, choose, assess, and interpret existing findings on a specific question formed carefully. Literature review will aid in:

- knowledge needs
- To inform policy and practice
- Support evidence-based decision
- Adds a framework for future study

Systemic pharmacovigilance: In order to compile the gathered information into a safety report, a literature study is carried out in order to methodically track adverse events and ascertain the relationship between the medication and adverse event. One of the main sources for reports of adverse reactions to post-marketed medications is literature reviews. In order to guarantee patient safety and regulate marketed medications, an effective literature evaluation is necessary.

5.1 Systemic Literature Review Tools in Pharmacovigilance

Challenges:

Pharmacovigilance involves a precise process. If this automation gets out of hand, then serious contraindications can evolve. Hence, numerous hurdles exit that a basic free open-source systematic literature review aid could encounter: Being -

1. Firm regulatory demands on explainability and audit ability- The current tools in the SLR industry currently considered by regulators as black boxes and therefore challenging to audit and validate. Thus, companies feel that anything affecting the reporting of safety should be validated, auditable, and explainable, yet the current solution does not meet the criteria. (Kassekert, et al., 2022)
2. High computer system validation (CSV) and compliance effort- CSV is mandatory for any computerized tool that impacts ICSR submissions, with mandatory 21 CFR Part

11 compliance, audit trail, and data privacy functionalities in these tools. Generic SLR tools are typically designed for academic environments, which increases the cost of validation in PV studies.

3. Unstructured and highly narrative-style safety literature- Contrary to clinical trial literature, PV literature combines case reports, review reports, editorials, and abstracts of conferences. It has implicit ADR statements in which no uniform expression is used, and also lacks explicit statements on causality. SLR techniques are not appropriate for this kind of literature; hence human medical expertise is required. (Bota and others, 2022)
4. Fear of losing safety cases (and inspections)- In PV, lost cases within the literature may result in underreporting, signal delays, and penalties from inspections. Companies would thus rather lack efficiency than sensitivity in this process and would rather overdo it than potentially lose a case and completely rely on inefficient automatic Safety Literature Retrieval methods. (Gaikwad, 2025)
5. Integration problems with existing PV systems- The integration of SLR solutions with safety databases (Argus Safety, ARIS Global, Veeva Vault Safety), detection of signals, managing references and literature databases (Embase, PubMed, Google Scholar) is a challenge. Failure to achieve this integration gives rise to a non-integrated workflow system and therefore a lack of adaptability. (Yu, Beam, & Kohane, 2018)
   Human factors: resistance to change & trust
   - There is familiarity with searching using PubMed/EmBase, EndNote/Mendeley, or manual screening. There can be difficulties in these search types:
   • "Can I trust the algorithm's inclusion/exclusion?"
   • "Will this pass inspection?" (Sharma, 2024)

5.2 Currently Applied Tools:

Therefore, there is human reluctance, as well as barriers, both regulatory and technical, that are hindering the widespread adoption of SLR tools. However, this limited adoption is being witnessed as there are SLR tools being designed to adapt to the pharmacovigilance context. The major tools are:

1. Drug Safety Triages (Clarivate)- The system is validated for use within the GVP and is a pharmacovigilance literature review tool able to search and import, deduplicate, screen, and prioritize literature automatically using NLP to identify safety terms within the literature for pharmacovigilance professionals to identify and report on efficiently. (Quaderi)
2. Compier Literature Screening- AI-driven platform for abstract and full-text screenings, classification, and data extraction regarding safety information (patients, events, and products). Supports database connections for Embase/MEDLINE and safety systems, such as Oracle Argus Safety. (Techsol, 2023)
3. Tepsivo Literature Screening- Automated global and local literature search and monitoring system. It's useful for regular PV literature surveillance and reporting. (Tepsivo)
4. Freyr Solutions Literature Review Tool (IMPACT-L)- It is an in-house tool for the quick identification of PV literature articles and mentioned PV products. It is used to assist pharmaceutical companies in finding relevant literature publications.

Other such general systemic review management tools which may be applied for pharmacovigilance include-

- DistillerSR- Systematic review software designed for enterprises, which can be automated, has forms, templates, and audit trails, all very helpful in a PV literature review study.
- EPPI-Reviewer Web- Comprehensive research tool available that deals with search results management, screening, coding, meta-analysis, and graphics.
- Rayyan- A free/low-cost tool for screening title/abstract using AI power. May be useful for initial screening of large sets of literature before thorough screening for PVs.
- Abstrackr, SWIFT-Active Screener, RobotAnalyst- The tools are designed for semi-active screening and prioritization of search results utilizing machine learning.
- Colandr, JBI SUMARI, SyRF- Full

processing systematic review support for screening, assessing, and reporting of findings. (Cowie, Rahmatullah, Hardy, Holub, & Kallmes, 2022)

5.3 Typical Workflow of these tools: Pharmacovigilance: After formation of a research strategy in databases such as PubMed and EMBASE, a literature search is followed by importation of results into management systems to filter and sort results according to a certain criterion. After thorough scrutiny of studies identified by those criteria, quantitative data regarding studies is extracted. Pharmacovigilance systems are used to classify signals and create reports. The quality of a study is determined according to its methodology, and synthesis of results is performed according to a structured procedure described below:

1. Develop search strategy- Determining the study's findings question is the first step in the systematic review process, followed by the development of the search strategy. Among other factors, researchers determine the terms (MeSH terms, phrases, and synonyms) associated with the drug, adverse events, plus the target population. PICO/PEO is utilized to determine the specific research question, which is relevant to the clinical field. The search is conducted on various scientific databases, including PubMed, Embrace, among others, to get the most relevant clinical studies available without biases related to publication.

2. Import results to review management tool- The selected citations are exported using either RIS/BibTeX formats and then imported into specific review management software such as Covidence or DistillerSR. These help with:
   • organize citations
   • review editor assignations
   • keep an audit trail
   • standardize screening and extraction processes. This enables replication and transparency. Schmidt et al. (2025).

3. Deduplicate and screen titles/abstracts- Deduplicate findings can be eliminated both automatically and manually because an article may appear in multiple databases. The titles and abstracts are then screened according to inclusion/exclusion criteria. It is possible to efficiently prioritize likely relevant studies without compromising accuracy by using tools such as Rayyan or ASReview. After that, studies that might be pertinent are chosen for full-text screening. (Cleo et al., 2019)

4. Full-text review, extraction, and coding- For articles that remained, full texts of those articles are obtained, and articles are assessed carefully. Researchers pick essential information such as:
   • Study design and population
   • Drug Exposure
   • Type and frequency of adverse events
   • Outcomes and conclusions

Tools such as Covidence or EPPI-Reviewer make it possible to have standardized forms for data extraction and coding to ensure data consistency.

5. Signal detection, categorization, and reporting- The retrieved data is examined for any safety signals in pharmacovigilance, including patterns that might suggest a connection between the suspected medication and a claimed adverse event. Pharmacovigilance uses specialized tools, like Compier or Drug Safety Triage, to promote in accordance with regulatory reporting requirements, categorize, and highlight medically noteworthy discoveries. This establishes a link between actual drug safety decision-making and the results of systematic reviews.

6. Quality/bias assessment with established checklists- Each included study is critically appraised using standardized tools (e.g., risk-of-bias checklists). It assists in determining the credibility of the findings and the uncertainties associated with them. The following regions would usually be considered:
   • selection bias
   • reporting bias
   • confounding
   • methodological flaws

7. Synthesize findings and report- Finally, results are synthesized:
    - narrative synthesis for descriptive data
    - meta-analysis if statistical pooling is appropriate (Sarkis-Onofre, Catalá-López, Aromataris, & Lockwood, 2021)

Results are presented according to PRISMA standards and include a PRISMA flow diagram with the following: numbers identified

- screened
- excluded
- included in the final review

This will enable clarity and transparency. (Page, et al., 2021)

5.4 Future Prospect:
The future of systematic literature reviews is undergoing dynamic changes due to the ever-increasing rate of scientific production, which is exponentially rising. The conventional systematic literature review is exhaustive, but it is also quite painstaking, time-consuming, and requires quite an input of resources. There have been indications that AI/ML technologies can greatly cut down the manual efforts required, quicken the process of screening, and also lead to greater consistency to the extent that the performance is comparable to that of human reviewers, particularly when it involves the extraction of data and its categorization. For instance, the protocols of the ongoing researches involve the direct comparison of the efficiency and accuracy that can be gained from the use of automated techniques to the use of systematic review procedures. Even abstract prioritization, relevance ranking, or the drafting of the systematic narrative is being explored through natural language processing and large language models. (Lieberum et al., 2025) (Marshall & Wallace, 2019) Literature screening in pharmacovigilance is a key function in the monitoring of published works to identify and assess the potential for adverse drug reactions (ADRs), safety signals in post-marketing data, and trends in published literature globally. With the use of AI technology, screening can be automated to provide key safety information with priority applications to reduce the workload and enhance the speed of signal detection. For instance, NLP technology can analyze thousands of published articles in a short while to provide structured safety information for quick potential safety signal detection compared to current methods. (Salas, et al., 2022) For the pharmacovigilance industry, the concept of intelligent SLR would involve making the shift from traditional periodic and manual reviews of literature to real-time or near real-time safety surveillance. A trend that aims to optimize compliance and make it possible to take immediate action on relevant evidence as it becomes available is the utilization of AI models that can compile information from various sources that are unstructured and structured. These sources include scientific literature and real-world evidence. (Algarvio, Conceição, Rodrigues, Ribeiro, & Ferreira-da-Silva, 2025) Furthermore, as advanced SLR tools evolve into intelligent approaches, they are likely to enable the development of diversified human-AI workflows, where large screening and processing of data are performed by automation, and interpretation, appraisal, and decision-making are performed by designated human experts. This would enable pharmacovigilance departments to easily expand their operations without having to employ more personnel, medical studies and international safety data. Despite issues like data quality, regulatory acceptability of automated results, and the need to develop understandable AI models, the incorporation of intelligent SLR solutions is poised to become standard industry practice and the norm of modern pharmacovigilance activities. (Nagar, Gobburu, and Chakravarty, 2025)

VI. EXAMPLES OF APPLICATION OF AI IN PHARMACOVIGILANCE

Despite AI-enabled automation's revolutionary promise, there are still a lot of challenges and limitations. Investments in computer power, infrastructure, and regulatory compliance are necessary for the application of AI technologies. Additionally, ongoing algorithmic validation, conservation, monitoring, and improvement efforts are necessary to guarantee the accuracy, dependability, and application relevance of AI-powered systems. Real-world examples have demonstrated how AI can enhance regulatory decision-making and pharmaceutical safety monitoring. Sentinel by the FDA, IBM Watson for Drug Safety, a product of Oracle Health Sciences' Argus Safety, Signal Mine of Advera Health Analytics, and pharmacovigilance solutions by system are a few examples of how AI may be used to transform pharmacovigilance procedures.

Table 2: Illustrations of AI use in pharmacovigilance

IBM Watson for Drug Safety	Watson for medication Safety, an AI-powered platform from IBM Watson Health, uses machine learning and natural language processing (NLP) to assess structured and unstructured data from several sources, facilitating medication safety monitoring and well-informed decision-making. Benefit: Increases the efficacy and efficiency of medication safety evaluations and judgments. A disadvantage is that it may be prone to algorithmic bias and demands a large upfront expenditure. Limitation: based on the reliability and accuracy of the data [36].
AstraZeneca's AI-Driven Pharmacovigilance System	To improve the process of finding safety signals and recognizing adverse medication responses, AstraZeneca employs artificial intelligence tools. To find patterns more quickly, these systems use machine learning and sophisticated data analysis. Benefit: Improves early detection of negative effects and guarantees improved adherence to legal standards. Disadvantage: Implementation requires significant infrastructure support and qualified specialists. Limitation: There is a chance that uncommon side effects will go unnoticed or that false alerts will be generated [36].
Advera Health Analytics' Signal Mine	Advera Health Analytics developed Signal Mine, an AI-powered tool that facilitates pharmacovigilance by making it easier to monitor adverse medication occurrences and assess possible hazards. Benefit: It improves the accuracy and efficiency of adverse event monitoring. A disadvantage of the platform is that it may not scale well and may have problems with system integration. Limitation: The completeness and quality of the data it processes have a significant impact on its efficacy [36].
Oracle Health Sciences' Argus Safety	Oracle's Argus Safety is a cutting-edge pharmacovigilance platform that makes it easier to record adverse events and identify safety signals by leveraging AI and machine learning. Benefit: Makes it possible to identify possible dangers and handle adverse event data automatically. The cost of implementation and continuing support is a drawback. Limitation: To guarantee accuracy and compliance, its algorithms require routine monitoring and revalidation [36].
FDA's Sentinel Initiative	Through the use of artificial intelligence and sophisticated data analytics, the FDA's Sentinel Initiative monitors medical products that fall under its purview electronically across the country. It makes it possible to identify adverse medication reactions and other safety concerns in real time by combining data from several healthcare databases. Benefit: Makes it possible to quickly identify and address emerging safety threats. A disadvantage is that it raises questions about data security and privacy. Limitation: Effectiveness depends on consistent data formats and seamless integration across systems [36].

VII. ADVANTAGES OF INTEGRATING AI IN PHARMACOVIGILANCE

- A large number of ADR reports can be

processed by the AI system, thereby decreasing the use of manual effort and the chances of errors. Such systems help in the extraction of valuable information from unstructured.

- It is possible for AI to examine data coming from different sources for novel signals or safety that would be impossible for traditional statistical analysis to accomplish.
- Natural Language Processing Tools are also used to interpret unstructured information such as social media comments and case submissions that may contribute to safety insights that could otherwise go undetected.
- Causality assessments for the adverse drug reaction (ADR) and the drug of interest can be done by AI models.
- Promoting the use of AI enables consistent, accurate MedDRA coding for adverse events.
- It facilitates the extraction of ICSR data from different published documents and electronic health records.
- It validates the duplicates, classifies reports as doctor reports or consumer reports, finds serious reports, and excludes nonserious reports.
- It picks out the ADRs and the data patterns in the structured and unstructured text.
- Time, efforts, and costs associated with case processing are reduced [27].

VIII. CHALLENGES IN INTEGRATING AI IN PHARMACOVIGILANCE

- AI has vast prospects of improvement in the process of medication monitoring and patient safety, which, when implemented in pharmacovigilance, is immensely valuable. However, certain challenges are keeping it from reaching its true potential. One of the foremost issues is the issue of data, which is a prerequisite for making AI-generated findings authentic, and is the most pressing concern currently [22]. It is extremely hard to conduct the kind of analysis and processing which is imperative for effective patient safety surveillance owing to missing and discrepant data, biases, and data silos [22].
- Although there is great promise for AI in improving PV, there are a number of issues that also need to be considered. The first of these is the fact that AI systems are dependent on the quality of available data for their effectiveness. Inefficient or even inaccurate ADRE may render ADR detection a challenge/O incorrect [22].
- The interpretation of PV data is yet again among those challenges that require action. Reporting in ADRs involves multiple decision-making cycles. Evaluation in individual case safety reports (ICSRs) is not normalized or even automatable because in many instances, human interpretation is required based on clinical presentation and alleged ADRs of patients. Even though AI algorithms exceed human interpretation in data processing in terms of their complexity, human analysis is critical in interpreting clinical data accurately [24].

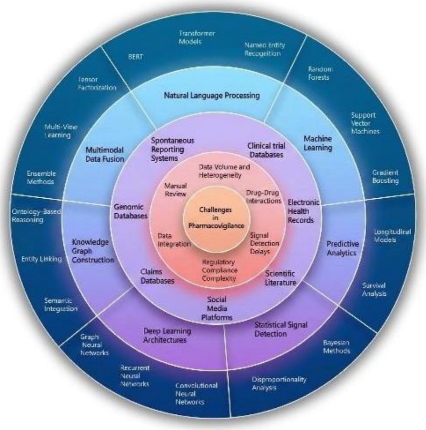


Figure: A comprehensive overview of state-of-the-art challenges in PV, sources of data, and the relevant AI technologies to address the challenges. AI, artificial intelligence; PV, pharmacovigilance. [A Nagar, J Gobburu et al.]

- The absence of research on this topic is a significant barrier as well. Although the popularity of this topic has increased, a lack of thorough research has been observed on the long-term effects of AI integration in PV [25].
- The lack of transparency in AI is also an important consideration here. Most advanced models are "black boxes" that produce an answer while not providing any rationale as to why certain decisions were

made [23].

- Availability of strong and valid training data sets containing all the diseases and therapeutic areas with enough examples to test accuracy and quality of performance of AI applications within a real-world scenario [26].
- Loss of high sensitivity algorithm would result in missed AEs of potential importance, while loss of proprietary algorithm would reveal spurious positive reports, generating background noise [31].
- Notational differences in the drugs and the diseases, description of side effects of the drugs, diversity and difficulties in local languages, ambiguities, and lack of necessary information may result in technical problems in data processing and labelling Privacy and ethical issues in using data in lack of consent from the individuals and violation of trust in doctor and patient relationships.
- Laws to facilitate validation and accuracy of the use of the AI tool, and strike a balance between the interests of technological companies and the health and well-being of patients [30].

IX. CONCLUSION

The incorporation of Artificial Intelligence in pharmacovigilance is a necessary development and anything but a indulgence. The industry will be able to allocate its most valuable asset: human expertise. The incorporation of Artificial Intelligence will enable such expertise to concentrate on complex medical analysis and risk minimization activities instead of focusing on repetitive analytically driven activities such as data management. The path ahead is clear: a predictive and automated pharmacovigilance pharmacological reality.

REFERENCE

[1] FDA. (2023). *Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products*. Discussion Paper.

[2] FDA. (2021). *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan*.

[3] EMA. (2023). *Reflection paper on the use of artificial intelligence in the lifecycle of medicines*. European Medicines Agency.

[4] WEB-RADR Consortium. (2017). *Recommendations for the Use of Social Media in Pharmacovigilance*. Drug Safety, 40(12).

[5] Trifirò, G., & Crisafulli, S. (2022). The role of natural language processing in pharmacovigilance: a systematic review. *Drug Safety*, 45, 477–491.

[6] Salas, M., et al. (2022). The Use of Artificial Intelligence in Pharmacovigilance: A Systematic Review of the Literature. *Pharmaceutical Medicine*, 36(5), 295-306.

[7] Bate, A., & Hobbiger, S. F. (2021). Artificial intelligence, real-world data and the future of pharmacovigilance. *Upsala Journal of Medical Sciences*.

[8] Danysz, K., et al. (2019). Artificial Intelligence in Pharmacovigilance: A Scoping Review. *Pharmacoepidemiology and Drug Safety*.

[9] McBride, W. G. (1961). Thalidomide and congenital abnormalities. *The Lancet*, 278(7216), 1358.

[10] Bate, A., et al. (1998). A Bayesian neural network method for adverse drug reaction signal generation. *European Journal of Clinical Pharmacology*, 54(4), 315–321.

[11] Algarvio, R. C., Conceição, J., Rodrigues, P. P., Ribeiro, I., & Ferreira-da-Silva, R. (2025). Artificial intelligence in pharmacovigilance: a narrative review and practical experience with an expert-defined Bayesian network tool. International Journal of Clinical Pharmacy , 47, 932–944.

[12] Bota, A., & co-authors. (2022). Natural Language Processing to Understand User-Generated Content for Pharmacovigilance: A Systematic Review. Pharmaceutics , 14, 266.

[13] Cassell, K., Ologunowa, A., Rastegar-Mojarad, M., Chun, B., Huang, Y. L., Wang, D., et al. (2025). Analysis of article screening and data extraction performance by an AI systematic literature review platform. Frontiers in Artificial Intelligence , 8, 1662202.

[14] Cleo, G., Scott, A. M., Islam, F., Julien, B., & Beller, E. (2019). Usability and acceptability of four systematic review automation software packages: a mixed method design. Systematic reviews , 8, 145.

[15] Cowie, K., Rahmatullah, A., Hardy, N., Holub, K., & Kallmes, K. (2022). Web-Based Software Tools for Systematic Literature Review in Medicine: Systematic Search and Feature

Analysis. JMIR Med Inform , 10, e33219.
[16] Gaikwad, C. (2025). Enhancing Pharmacovigilance with AI-driven Literature review. datacreds .
[17] Kassekert, R., Grabowski, N., Lorenz, D., Schaffer, C., Kempf, D., Roy, P., et al. (2022). Industry Perspective on Artificial Intelligence/Machine Learning in Pharmacovigilance. Drug Safety , 45, 439–448.
[18] Li, Y., Datta, S., Rastegar-Mojarad, M., Lee, K., Paek, H., Glasgow, J., et al. (2025). Enhancing systematic literature reviews with generative artificial intelligence: development, applications, and performance evaluation. Journal of the American Medical Informatics Association , 32, 616–625.
[19] Lieberum, J.-L., Toews, M., Metzendorf, M.-I., Heilmeyer, F., Siemens, W., Haverkamp, C., et al. (2025). Large language models for conducting systematic reviews: on the rise, but not yet ready for use—a scoping review. Journal of Clinical Epidemiology , 181, 111746.
[20] Marshall, I. J., & Wallace, B. C. (2019). Toward systematic review automation: a practical guide to using machine learning tools in research synthesis. Systematic reviews , 8, 163.
[21] 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.
[22] Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., et al. (2021). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. bmj , 372.
[23] Pati, D., & Lorusso, L. N. (2018). How to write a systematic review of the literature. HERD: Health Environments Research & Design Journal , 11, 15–30.
[24] Quaderi, N. Drug Safety Triager. Tech. rep., Clarivate.
[25] Salas, M., Petracek, J., Yalamanchili, P., Aimer, O., Kasthuril, D., Dhingra, S., et al. (2022). The use of artificial intelligence in pharmacovigilance: a systematic review of the literature. Pharmaceutical medicine , 36, 295–306.
[26] Sarkis-Onofre, R., Catalá-López, F., Aromataris, E., & Lockwood, C. (2021). How to properly use the PRISMA Statement. Systematic reviews , 10, 117.
[27] Schmidt, L., Cree, I., Campbell, F., & group, W. E. (2025). Digital Tools to Support the Systematic Review Process: An Introduction. Journal of evaluation in clinical practice , 31, e70100.
[28] Sharma, D. S. (2024). AI in Pharmacovigilance: The dawn of a data-driven safety revolution. Knowledge Bank .
[29] Techsol. (2023). Compier LIterature screening. Tech. rep., Techsol Life Sciences.
[30] Tepsivo. Prarmacovigilance Literature Screening. Tech. rep., Tepsivo.
[31] Yu, K.-H., Beam, A. L., & Kohane, I. S. (2018). Artificial intelligence in healthcare. Nature biomedical engineering , 2, 719–731.
[32] Desai MK. Artificial intelligence in pharmacovigilance – Opportunities and challenges. Perspect Clin Res 2024;15:116-21;118-19.
[33] Benjamens, S., Dhunnoo, P. & Meskó, B. The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database. *npj Digit. Med.* 3, 118 (2020). https://doi.org/10.1038/s41746-020-00324-0.
[34] Kaas-Hansen BS, Gentile S, Caioli A, Andersen SE: Exploratory pharmacovigilance with machine learning in big patient data: a focused scoping review. Basic Clin Pharmacol Toxicol. 2023, 132:233-41. 10.1111/bcpt.13828.
[35] Shukla, S., Bhatt, S., Gupta, D., Verma, S. Role of Artifical Intelligence in Pharmacovigilance. J. of Drug Disc. and Health Sci. 2024;1(4):230-238. DOI: 10.21590/jddhs.01.04.06.
[36] Swati Gaykar*, Ramdas Darade, Vikram Saruk, Manoj Garad, Anuja Ghaywat, Komal Gunjal, Bhure Priti, Applications of Artificial Intelligence in Pharmacovigilance: Emerging Trends & Future Perspectives, Int. J. Sci. R. Tech., 2025, 2 (10), 152-163. https://doi.org/10.5281/zenodo.17322642.