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AI-DRIVEN PHARMACOVIGILANCE: THE EVOLUTION FROM RULE-BASED SYSTEMS TO GENERATIVE LARGE LANGUAGE MODELS

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ABSTRACT

Pharmacovigilance has progressed from systems that relied heavily on people to intelligent systems that rely heavily on artificial intelligence (AI) technology and use artificial intelligence (AI) technology to improve safety in monitoring drugs postmarketing within the current healthcare systems. This paper describes how Generative artificial intelligence (AI), particularly large language models, are transforming key pharmacovigilance processes such as generating individual case safety reports (ICSRs), reviewing literature, and detecting signals through automation of these processes. Compared to traditional practices, artificial intelligence (AI) supported systems have higher sensitivity, less likelihood of generating false-positive results, and increased time efficiencies. The incorporation of global surveillance data and regulatory requirements provides additional support for assessing safety and compliance. While challenges exist such as issues with data quality, regulatory validation processes, and workforce-related shortages when utilizing artificial intelligence (AI) technologies, there has been the development of scalable and more precise solutions using AI technologies within pharmacovigilance. Generally, this shift in pharmacovigilance procedures marks a move from reactive, data-based drug safety management to a more proactive approach, which is expected to enhance patient outcomes and the efficiency of regulation within the growing complexity of the healthcare system.

KEYWORDS: Pharmacovigilance, Generative AI, ICSR, Signal Detection, Drug Safety

1. INTRODUCTION

The Transformative Role of Pharmacovigilance in Contemporary Healthcare Generative artificial intelligence is driving the evolution of pharmacovigilance activities. Ramcharran et al. (2025) found that large language model (LLM)-generated individual case safety report (ICSR) narratives produce an F1 score at or above 0.94 and therefore meet applicable regulatory standards [1]. Technologies such as IQVIA's Vigilance Detect are helping overcome some of the manual processing constraints by extracting adverse event-related data from social media and electronic health records (EHRs). The usage of natural language processing (NLP) technologies has decreased the time to review an adverse event to only 81% of the time spent if the review were completed manually [2]. The evaluation of safety signals using machine learning can confirm the existence of these signals 3.2 times faster than traditional disproportionality analysis, while also reducing the rate of false positives by 41% [3].

1.1 The Emergence of Artificial Intelligence in Drug Safety Surveillance

The field of literature screening that incorporates AI has become quite robust. GPT-4 and Claude 2 have demonstrated sensitivity rates of 97% and reproducibility rates of 93% through the use of N-shot and chain-of-thought reasoning for classifying abstracts from biomedical literature related to pharmacovigilance. Li et al. demonstrated that GPT-3.5, GPT-4, and Claude 2 achieved an overall sensitivity of 97.2%, compared to a mean sensitivity rate of 78.4%, when analyzing 10,000 peer-reviewed articles. In contrast, human reviewers took up to three times longer to complete their assessments. Additionally, Claude 2 attained a reproducibility rate of 93.4%, which significantly surpasses the coefficient of inter-reviewer agreement (ranging from 0.65 to 0.78) typically observed in panels utilizing traditional review methodologies [4].

1.2 Core Automation Applications in Pharmacovigilance Practice

The use of natural language processing (NLP) with generative AI helps extract information regarding adverse events and patient demographic information (as well as clinical symptoms) from unstructured data, generating automated narratives that comply with regulatory standards in much less time [5]. The ability of AI to detect safety signals is enhanced through context validation that cannot be provided through statistical validation [3]. The literature monitoring function has also demonstrated the ability of GPT-4 to accurately identify relevant literature with 97.2% sensitivity across 10,000 abstracts in PubMed [4]. Finally, safety signals can be identified through methods superior to traditional analysis methods [6].

These capabilities will continue to improve as data increases and the complexity of regulations continues to increase for companies operating on an international level [4, 5].

1.3 Pharmacovigilance Foundations and Global Regulatory Infrastructure

The World Health Organization (WHO) established an international program for drug monitoring (or pharmacovigilance) following the 1968 conference in Uppsala that defined the discipline as the process of identifying, assessing, and preventing the occurrence of an adverse drug reaction (ADR) [7]. The major global repository for adverse drug reactions, referred to as VigiBase, has received reports from over 148 countries. Actually, during the months between February and May 2021, COVID-19 vaccine safety reports submitted to VigiBase increased from just over 25 million to more than 26 million. Supporting nations that have developed pharmacovigilance systems (for example, India's developing system) will help facilitate greater geographic diversity with the types and number of reports submitted into VigiBase. All adverse drug reactions are encoded in MedDRA terminology and linked with a WHO product code, allowing for the possibility of comparing cross-regional safety profiles on the basis of similar geographical characteristics [8, 9].

Table 1: Global Drug Safety Surveillance Systems and Their Relationships to Regional Areas.

System	Location	Main Characteristics
US FAERS	USA	OpenFDA API: Quarterly Output through Data Extraction Available [10].
EU EudraVigilance	27 Members of EU+EEA	15-Day ICSR Notification when reporting to EudraVigilance (XEVMPD) and Integration of XEVMPD [11].
India PvPI	India	Inclusion of the CDSCO (Central Drugs Standard Control Organization) as a regulatory authority in VPI and recognition of some of its requirements regarding patient safety [12].
Japan JADER	Japan	Predicting injury caused by a drug using machine learning within the database maintained by the PMDA [10].

1.4 Regulatory Signal-Digital: Model, Parameters, and Regulatory References

Drug safety through normal pharmacovigilance includes validated disproportionality analyses as the PRR and ROR which are determined from an analytic method of 2x2 Contingency Tables, in combination of the EBGM model statistically derived from the Multi-Item Gamma-Poisson Shrinkage algorithm (EBGM). For sparse datasets, the IC lower bound (IC025) is used to determine conservatively-based signal estimates in the WHO VigiBase [10]. ICSR Process Standards, defined in Section 3.3 of GVP Module VI, address

demographic data of the patient, identification of the drug, description of the clinical event, and the qualification of the reporter [11]. ICSR submission timelines; Serious AE reports - 15 calendar days; non-serious AE reports - 90 calendar days; material follow-up reports - 15 calendar days (expedited) [11, 12]. Workflow components must comply with 21 CFR, Part 11 under GCP, including; MedDRA coding, E2B (R3) XML submissions, and causality assessments [12, 13, 14]. Periodic Safety Documents include DSUR (per ICH E2F) and PBRER (per ICH E2C(R2)) [15].

1.5 Evolution of Pharmacovigilance Automation: Switching from Rule-Based Systems to Machine Learning

In the early automation stage (approximately 2000-2015), deterministic rule-based logic was used for various duplication detection, serious/regulatory assessment, and MedDRA coding tasks [16, 17], As the volume of cases in FAERS continued to increase, coupled with the significant amount of information available on social media sites, the development of automated tools that relied solely on deterministic rules (e.g., Argus v6.0) were no longer satisfactory [18, 19, 20]. Between 2015 and 2022, adaptive algorithms that are capable of identifying potential adverse events from textual data in both unstructured narratives and social media were developed [21, 22, 23]. ArisGlobal has operationalized automated pipelines for quality assessments and case completeness scoring by applying machine learning models as part of these automated pipelines for kinds of technologies [24]. BioBERT was developed to be the first pre-trained biomedical language model applicable to both the biomedical domain and the general domain and achieved +0.62% f-value for named entity recognition and +2.80% f-value for relational extraction against the general-domain baselines [25, 26]. Additional details can be found in Table 2.

Table 2: Signal Identification Transformation Measurement.

Process	Traditional rule-based method	Machine learning methods	Net gain in performance
False Positive Rate	High baseline [22]	Low false positive rates due to machine learning automation	Very significant decrease
Rare Event Detection	Limited sensitivity [21]	Improved ability to recognize patterns	Major increase in quantity of cases being identified as rare events [25]
Cost of Processing Cases	100% manual processing	Automated first-pass sort of cases	Major saving over previous method [22]

2. Transition from Rule-Based Systems to AI

2.1 Phase 1 (2000–2015): Deterministic Rule Engines

Hard-coded if/then rules and keyword matching dictionaries that were used by early pharmacovigilance platforms to detect duplicates of adverse event records and to classify the severity of the events were set up in case management tools such as Argus v6.0 [16, 27]. At that time, however, there was too much manual configuration to make this system sustainable at scale [18]. Additionally, the number of reported adverse events to the FDA via the Adverse Event Reporting System (FAERS) rose so quickly that rules could not be maintained manually [19], and the volume of unstructured clinical narratives set forth in social media far exceeded the capacity of keyword matching tools to handle such narratives [20]. The temporal reasoning that was absent from early pharmacovigilance systems prevented the creation of longitudinal profiles of patients, which ultimately made it impossible to differentiate between pre-existing conditions and newly developed adverse effects of products given to patients [20].

2.2 Phase 2 (2015-2022): The Statistical ML Era

The move to statistical ML (machine learning) significantly reduced false-positive rates, automated core processes in pharmacovigilance, and improved sensitivity to find rare adverse events [21, 22]. Custom-engineered ML-derived features have consistently outperformed traditional methods in identifying complex event pattern configurations across disparate data sources [23, 28]. ArisGlobal's change from human-initiated quality checking to ML-driven scoring for case completion has resulted in over a 60% increase in efficiency of operations [24]. The use of BioBERT, a language model designed for the biomedical domain, has improved performance for Named Entity Recognition (F1 +0.62) and Relation Extraction (F1 +2.80) compared to standard BERT [25, 26].

2.3 Phase 3 (2022–2024): Development of Domain-Specific Models Based on Transformer Architecture

There have been great advancements in the use of transformer-based models, for example, PubMedBERT and ClinicalBERT, since they allow for accurate extraction of information from biomedical/clinical corpuses through their ability to provide context and understand words appropriately [29, 30]. Diligent use of ICH E2B(R3)-compliant automation for reporting serious adverse events via Oracle Clinical One has improved compliance with regulatory agencies in addition to maintaining the integrity of data throughout the workflow for managing adverse events [31, 32]. High-dimensional embedding representations (for example, 1,024-D) for data representation/aggregation have provided support for

semantically meaningful case aggregation as well as improving signal detection in pharmacovigilance by evaluating document similarity across multiple documents [33, 34].

2.4 Phase 4 (2025–2026): Generative Artificial Intelligence and Large Language Models

The contemporary GenAI and LLM platforms trained on a corpus of one trillion tokens allow for the automation of the end-to-end lifecycle of the ICSR process and can now perform signal detection at the level of expertise exhibited through regulatory reviews [17, 35, 36]. The Navikenz GenAI system has been utilized to expedite the hazard assessment process as well as the initiation of global submissions to major regulatory agencies [6, 37]. Additionally, RAG infrastructure (Regulatory Analytics and Global Data Warehouse) has provided the capability to retrieve regulatory intelligence in real-time in collaboration with the FDA and EMA [38]. Oracle Argus is able to provide the required framework for oversight of risk management plans in accordance with GVP Module V requirements [39]. BaseLife Sciences has automated the processes for developing RMPs in compliance with existing EMA or FDA requirements [40, 41].

Table 3: Performance of Large Language Models in Pharmacovigilance [29, 30, 42, 43, 44].

Model	PV Benchmark	PV Performance
Claude 3.5 Sonnet	Safety Compliance	ASL-2 Safety Classification [43]
GPT-4o	ICSR Triage 80%	Reduction in time spent for triage [42, 44]
PubMedBERT	Biomedical Natural Language Processing Named Entity Recognition (NLP NER)	Biomedical Natural Language Processing Named Entity Recognition (NLP NER)
ClinicalBERT	Processing clinical texts	NER for clinical domain performance exceeds others [30].

3. Generative AI and Large Language Models in Pharmacovigilance

Unlike rule-based architectures, generative AI uses dynamic and context-specific methods to semantically parse natural language from different data sources. It changes unstructured clinical narratives into pharmacovigilance documents that can be used. The comparative analysis of GPT-4, GPT-3.5, and Claude 2 has demonstrated considerable potential for automating safety signal detection from the literature. The authors of the research paper "Pharmacovigilance monitoring of large databases with large language models" looked at how well large language models can do pharmacovigilance monitoring. Using AI and ML in pharmacovigilance allows for the automated processing of unstructured case documents [1,

45]. On the other hand, APA increases the time it takes to process each case while making sure that all regulations are followed [45, 46]. During triage, the built-in NLP pulls structured data elements like patient demographics, drug administration characteristics, and adverse event characteristics. It also gets rid of duplicate records. Contextual coding algorithms result in accurate MedDRA coding and the creation of regulatory-compliant narrative reports for submission to the sponsor and relevant authorities [46, 47]. With these tools, pharmacovigilance teams can move from reviewing data manually after the fact to proactive, data-driven risk management that speeds up aggregate safety reporting (ASR) and makes it easier to comply with regulations. Centralized data repositories and automated alerts make data more reliable by allowing people to work together. As the number of adverse drug reaction (ADR) reports grows, so does the use of cloud-based artificial intelligence (AI) around the world. Due to a lack of qualified workers around the world, the global pharmacovigilance software market is expected to grow to more than $24.69 billion by 2035. The EMA/FDA joint 2026 Guidelines for Good AI Practices require human oversight of all risk-critical decisions and continuous lifecycle monitoring for model drift to protect patients in a changing environment [41, 47, 48, 49].

4. Using AI to Automate Reporting Case Narratives

Large Language Models (LLMs) have replaced labor-intensive manual workflows for pharmacovigilance case narrative generation. Patient-level variables are systematically derived from unstructured source data; dosage regimens are compared against WHO standards, deterministic models assign adverse event seriousness [5, 50], and WHO-UMC causality is categorized into four levels: certain, probable, possible, and unlikely [49]. Multimodal ingestion employs OCR for PDFs and NLP for electronic communications [5, 45]; this architecture is exemplified by Genpact's PVAI platform, which provides lower cost and higher throughput than traditional methods [45]. Under GVP Module VI, drug identifiers are reconciled to the WHO-DD hierarchy and events encoded in MedDRA, as well as case chronologies reconstructed [26, 50]. This produces narratives that meet the ICSR requirements for source attribution, patient history, and cause-American ability assessment [5]. All PII has been redacted before E2B(R3) submission in keeping with GDPR and 21 CFR Part 11 [50]. AI is estimated to handle about 42% of the pharmaceutical software market, comprising ~14 million submitted ICSRs on a yearly basis [10, 46, 51]. EMA Annex 11 mandates lifecycle management and secure audit trails from 2026; unsupervised generative AI cannot issue final safety determinations without verified human oversight, as

stipulated in EMA Annex 22 [52, 53, 54]. Published benchmarks confirm these improvements; the 2018 Pfizer pilot achieved extraction accuracies of 72–74% across 12,000 ICSRs. ArisGlobal's LifeSphere system helped reduce work by a lot, 85% for 50 clients [55]. The FDA's Sentinel System was able to detect 92% of issues from 250 records [56]. A model using Bayesian methods was tested on over 8,500 cases. Did very well with a score of 0.955 [57]. Also, a RAG framework that included people validating the results kept errors under 1% [41, 58]. The next big thing in monitoring drug safety might be combining health trackers with medical imaging to get real-time updates [59].

5. AI in Signal Detection, Real-World Data, and Multimodal Inputs

Classical disproportionality methods for identifying drug-ADR relationships are outperformed by artificial intelligence methods. Rather than spending days calculating causality through expert-defined Bayesian networks, AI calculates the cause-and-effect relationship between a patient and drug/ADR while minimizing subjectivity and increasing efficiency to within hours of the patient's drug use [60]. Prediction through machine learning based upon both genomic and polypharmacy variables allow for identifying ADRs with precision along with VigiBase data having increased sensitivity versus classical disproportionality methods. Causal graph modeling successfully identified confounders from over 35 million case reports globally [57]. Additionally, AI uses Electronic Health Records (EHR), spontaneous reports, and social media to detect dynamic safety outliers. The FDA Sentinel System monitors safety signals by analyzing over 250 million patient records, combining insurance claims and EHR data, and identifying many high-risk outcomes (e.g., after eight days of opioid medication, the patient has over a 90% chance of experiencing some type of positive outcome) [61]. Analyzing real-world data yields AUCs >0.93 using gradient boosting tree algorithms on over 14 million annual submitted ICSRs (incident cases and related incidents) [62, 63]. Monitoring of real-time RWD with VigiLyze allows identification of reporting delays for serious events; these systems support explainable safety assessments while meeting CIOMS requirements [57, 59]. It is estimated that AI efficiencies will grow the pharmacovigilance market by more than $21 billion by 2035 [10]; however, the FDA and EMA require all regulatory decision-making with GenAI input to include human supervision and explainability audits (SHAPs) as a prerequisite to market launch [64, 65, 66].

6. AI in Regulatory Intelligence

AI is revolutionizing regulatory intelligence through real-time monitoring of legislative changes, assessment of compliance, and automation of regulatory reports (in aggregate) [67, 68]. Integrated QA-RAG pipelines (using FDA, EMA & CDSCO guidance) have demonstrated 15-25% improved performance over traditional RAG baselines for precision, recall & F1 measures of efficacy across a variety of clinical trials [69]. These frameworks also allow for monitoring regulatory variance across ~50 jurisdictions to harmonize clinical trials globally in real-time [70]. AI aids in drafting PSURs per ICH E2F Guidelines and helps to harmonize the multiple regulatory risk mitigation plans in different regions, speeding the preparation cycle by 60% [71]; this results in HAQ systems yielding a 99.7% recall rate & providing accurate answers in minutes 100% of the time [72]. The FDA's January 2025 draft guidance outlines a seven-step process in order to establish credibility via the following: Quality assurance for data safety; reducing bias potential in safety evaluations; post-marketing safety monitoring [66, 73, 74]. The 2026 GVP revisions from the EMA have recognized AI as a standard feature of pharmacovigilance systems [67, 68], particularly how AI can parse the EudraVigilance database and provide empirical evidence that risks associated with PSURs have been minimized [67, 68]. Safety organizations should adopt AI for multi-language literature reviews while also complying with the legal requirements outlined by the various countries [67], including the EMA Annex 11/22, CIOMS XIV, and 21 CFR Part 11, all of which will require Good AI Practices to be adhered to during the lifecycle management process [65, 75, 76].

7. Case Studies and Real-World Use Cases

The transition of conceptual artificial intelligence to regulatory standards as mandated by EMA GVP 2026 and Guidelines of the FDA has been validated through real-world deployments [68, 77]. In 2025, the USFDA used the ELSA AI tool to develop a catalog of complex adverse events, automatically generate database codes, and audit clinical trial safety datasets [78]. The MAH's are in the process of restructuring digital safety infrastructures to support ICH requirements and meet future GVP updates [67, 68] by transitioning from descriptive risk management plans to algorithm-based systems that demonstrate risk minimization through evidence-based methods in Periodic Safety Update Reports [67, 68]. IQVIA used a centralized quality management tool using AI technology across 89 countries [79]. The IQVIA Detect and IQVIA Collect tools and process social media and safety data in accordance with FAERS and EudraVigilance requirements, targeting a 50% reduction in cost

while achieving an overall quality performance of greater than 99% [79]. Navikenz's generative RAG pipelines autonomously decomposed complex pharmacovigilance-based legal contracts, resulting in a 20% reduction in legal processing effort as well as a significant improvement in the understanding of the AI-generated output [6]. All systems are validated through a rigorous independent assessment of AI compliance, providing for verified human oversight, secured audit trails, and vendor qualification in accord with GVP Module VI timelines [68], establishing AI as the scalable platform for processing 14 million individual case safety reports annually [77, 78, 80].

8. Considerations Related to Regulatory, Ethical, and Bias

The rapid evolution of generative artificial intelligence (AI) within the realm of pharmacovigilance has revealed numerous critical vulnerabilities, including algorithmic bias, model opacity, and the potential violation of patient data privacy [81, 82]. Generative models are predominantly trained on homogeneous clinical datasets (e.g., comprising individuals from one ethnic/racial group or age group); therefore, they inherently exhibit biased predictive heuristics. For example, generative AI models display 20%–40% lower sensitivity in identifying adverse drug reactions for Asian individuals compared with White populations and generate nearly complete failure to detect adverse drug reactions in both African cohorts and the elderly [81, 83, 84]. As a result of this bias, regulators will require the performance of demographic parity testing to ensure fair generalization of the models' outcomes [81]. Further, regulators have established a requirement that AI safety predictions must be reported in full transparency (e.g., using SHAP values). SHAP values demonstrate a 12% improvement over LIME in attributing clinical prediction factors and are required to be reported in compliance audits of pharmacovigilance activities [57, 85, 86]. AI systems that process clinical narratives must meet the regulatory requirements of 21 CFR Part 11 and Annex 11, including implementing tamper-proof audit trails, role-based access controls, and Excellent Clinical Practice (GxP)-validated data anonymization architectures [87, 88]. The Council for International Organizations of Medical Sciences (CIOMS) XIV 2025 Draft and the European Medicines Agency (EMA) Artificial Intelligence (AI) Act will require developers of AI systems to have human veto authority over high-risk computational decisions and will mandate that diverse training datasets be used for the development of AI systems [89, 90, 91]. With 22% of predictive healthcare-related models exhibiting clinically significant drift within their first year of operation, it is imperative that comprehensive

lifecycle protocols be implemented, which include extensive pre-deployment bias audits and post-market validation exercises [41, 92, 93].

9. CONCLUSION

The development of generative artificial intelligence has created an entirely updated global infrastructure for pharmacovigilance, with over 14 million individual case safety reports (ICSR) generated each year and over 38 million historical records stored in the VigiBase database [9, 10, 94]. The evolution of the field has progressed from the use of rule-based algorithms that achieved 71% medical accuracy to enterprises relying on large language models (LLM) to achieve greater than 96% medical accuracy [16, 25, 42, 43, 95]. For example, generative AI tools developed by Genpact PVAI have reduced the time necessary for compiling the patient narratives to approximately four minutes per record and meet or exceed 98% compliance with the European Medicines Agency (EMA) guidelines for good pharmacovigilance practices [6, 39, 96, 97]. For information technology companies, compliance with the requirements of the U.S. Food and Drug Administration (FDA), as stated in 21 CFR Part 11, and the European Medicines Agency's (EMA) published guidelines of GVP 2026/Annex 22 provides the framework for establishing and maintaining a validated system of human-in-the-loop monitoring with fully traceable decision-making audit logs [15, 50, 53]. The combination of the 37% shortage per country in the pharmacovigilance workforce and standardization of E2B(R3) coding in 148 countries creates an opportunity to achieve a global drug safety marketplace valued at $20.9 billion by 2035 [9, 10, 15, 80, 98, 99, 100]. As generative AI technologies evolve into explainable AI ecosystems and continue to integrate with real-world data, they will provide a proactive framework necessary to ensure maximum patient safety in the modern era of pharmaceutical medicine [1, 50, 67].

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