Post-Market Surveillance & Pharmacovigilance in the Age of Big Data and AI: Emerging Models and Regulatory Implications

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Abstract

In the age of big data and artificial intelligence (AI), post-market surveillance and pharmacovigilance face previously unheard-of difficulties. The 94% median underreporting rate and delayed signal detection are two major drawbacks of traditional pharmacovigilance systems that rely on spontaneous adverse drug reaction (ADR) reporting. This analysis looks at how pharmacovigilance procedures are changing along the whole value chain, from data collection to regulatory reporting, as a result of AI and machine learning (ML) technology.

Every one of the four main types of big data analytics—prescriptive, exploratory, descriptive, and predictive—brings special skills to pharmacovigilance activities. Beyond signal detection, AI is used in industrial quality control, medicine repurposing, and resource allocation optimisation. Significant obstacles still exist, though, such as problems with data quality, privacy, standardisation, and the requirement for human monitoring in the "human-in-the-loop" method.

This review examines international regulatory strategies and talks about the moral ramifications of pharmacovigilance powered by AI. In this revolutionary age of healthcare innovation, future perspectives place a strong emphasis on combining human expertise with cutting-edge technology to improve public health protection and advance international drug safety standards.

Key Words: Pharmacovigilance, Post-market surveillance, Artificial intelligence (AI), Big Data analytics, Regulatory frameworks.

1. Introduction:

Post-market surveillance (PMS) is a critical process for ensuring patient health and safety after a medical device, including in vitro diagnostic medical devices, has been launched on the market . Pharmacovigilance (PV) is a data-driven process to identify medicine safety issues at the earliest by processing suspected adverse event (AE) reports and extraction of health data. In pharmacovigilance systems - the science revolving around the safety of drugs - significantly impacts patient safety by obscuring the true incidence and nature of adverse drug reactions (ADRs). ADRs are estimated to account for 2.7–15.7% of hospital admissions and occur in approximately 17% of hospitalized patients. The median underreporting rate is alarmingly high, around 94 %, which affects the ability to detect safety signals and make informed public health decisions. In the early 1970s, “Big Data” established its relevance as a distinct branch of science. AI is a branch of computer science. AI system contains a database of facts and uses an algorithm to make machines to imitate human behavior that requires understanding, creative composition, speech recognition, and decision-making. To obtain true benefits through big data, all the data is processed in an intelligent manner hence an integration of “Artificial intelligence” with big data started. The convergence of AI, Big Data, and drug development occurs in each stage of the developmental lifecycle of a drug. The traditional methods of adverse drug reaction (ADR) detection and drug safety monitoring are being challenged. AI and machine learning (ML) technologies, including natural language processing (NLP) and deep learning, offer promising solutions to automate and enhance pharmacovigilance processes. The Human AI search utilized advanced caching techniques and a natural language processing system to identify relevant reports. Searches were conducted on PubMed and PubMed Central. The number of identified relevant reports, precision rates, and time requirements for each approach were analyzed. Artificial intelligence (AI) refers to technology capable of mimicking human cognitive functions and has important applications across all sectors and industries, including drug development. The objective of PV is to reduce the incidence and the risk associated with the use of medicines at the earliest by processing suspected adverse reaction reports and extraction of health data to identify drug safety signals. It delves into the notable benefits and challenges encountered in advancing data analytics of the early 21st century.In many countries, Post-marketing surveillance of drug safety relinquishes on a systematic analysis of spontaneous using Generative artificial intelligence (AI) to overcome gaps in the present PV ecosystem is critical to maintaining an uninterrupted record of

security and effectiveness within healthcare analytics, data mining techniques, predictive analytics, and the emergence of scientific fields like bioinformatics and health informatics are empowered by Big Data. The Uppsala Monitoring Centre (UMC), which manages the World Health Organization (WHO) global database of ICSRs (VigiBase), has imple mented notable machine learning tools to enhance PV processes. Their vigiMatch algorithm repre sents one of the earliest applications of machine learning in routine PV, efficiently detecting dupli cate case reports by processing approximately 50 million report pairs per second

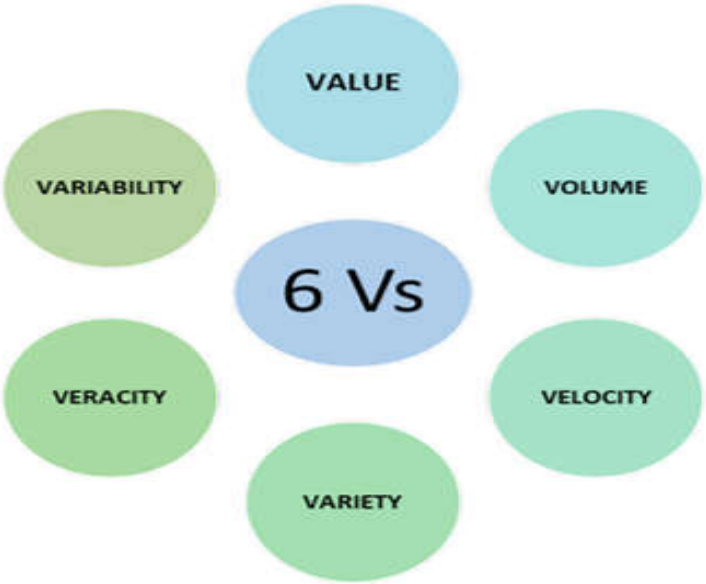


Fig. 1. Characteristics of big data.

1.1 Traditional vs. Modern Pharmacovigilance Systems:

AI/ML has been shown to be useful for multiple aspects of data ingestion (case intake or processing), such as duplicate detection anomaly identification as an orthogonal approach to quality assurance and for assessment of reported causality in individual case safety reports (ICSRs). In a study published by Celgene and IBM, deep-learning approaches to evaluate ICSR processing exceeded the 75% accuracy rate threshold, demonstrating the potential of AI to improve reporting efficiency and the consistency and quality of data.

1.2 Traditional Pharmacovigilance Systems:

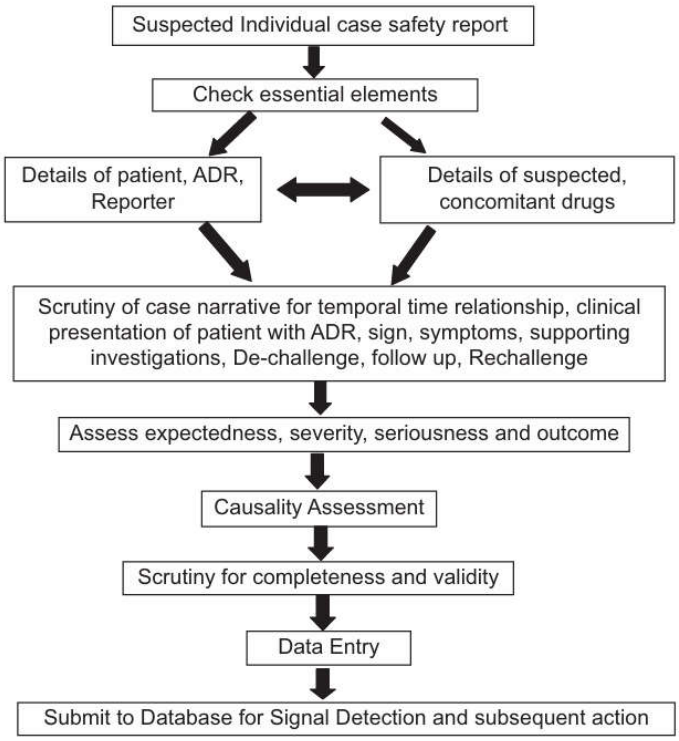
Pharmacovigilance practice during the past exclusively performed post-market tracking through spontaneous adverse drug reaction (ADR) reporting systems. The reporting procedure primarily depended on data from healthcare professionals as well as patients and pharmaceutical businesses. The safety monitoring approach proved necessary to find safety related problems yet its slow pace and extensive work requirements and delayed or insufficient information made it difficult to manage. Pharmacovigilance operated through conventional methods of accepting information through paper forms as well as phone conversations and in-person meetings.

Underreporting proved to be an enormous challenge because pharmacovigilance captured a small portion of adverse events during analysis which mainly focused on post-issue responses.

1.3 Modern Pharmacovigilance Systems:

AI and ML technologies are shaping the entire value chain in PV, from data collection through information extraction, analytics, insights, and regulatory reporting to actionable intelligence. AI helps identify, classify, and prioritize relevant information from disparate sources, such as EHRs, medical literature, and social media, con tributing to a more efficient and robust data collection process. Terminology evolution has brought pharmacovigilance into the digital era to conduct advanced real-time monitoring that leverages big data together with AI technologies. The integration of machine learning and natural language processing techniques with predictive analytics now allows systems to examine enormous electronic health records alongside clinical trials data together with social media content and wearable device outputs. Using this approach safety signals become detectable at earlier stages before reaching broad scale occurrences.

Modern artificial intelligence systems can evaluate large data sets to find information patterns which escape human surveillance. The proactive methodology speeds up adverse events discovery while boosting safety evaluations while enabling rapid regulatory action.



2. Types of big data analytics:

Big data entails formulating hypotheses, which can be influenced by experiential observations and the occasional discovery of connections between variables, sometimes by chance. There are four primary categories of big data analytics. They are

Descriptive Analytics: Scatter diagrams and pie charts are essential tools in descriptive analytics, which visually represent data in a comprehensible format. These tools provide insights into the significance of past events, often referred to as dashboards. For instance, a population census data can be presented, categorizing it based on factors such as gender, age, education, income, and population density. These tools help visualize and understand the data's significance.

Exploratory or Discovery Analytics: Discovery Analytics is a method that uses data from various sources to uncover unexpected relationships among variables. It helps companies to identify

customer behavior patterns through feedback, social media posts, and blogs. By predicting customer actions like subscription renewals or cancellations, companies can create attractive offers to influence their customers. This approach is particularly useful in the context of customer behavior, such as social media and sales trends.

Prescriptive Analytics: Prescriptive Analytics is a method that uti lizes massive volumes of data to recommend optimal decision- making alternatives to capitalize on the expected future. To accom plish this, it integrates the predictive analytics output and employs artificial intelligence, optimization algorithms, and expert systems in a probabilistic setting to give versatile, robotic, limited, time- varying, and best-suited choices.

Predictive Analytics: Predictive analytics has gained prominence, enabling organizations to adopt proactive, forward-thinking ap proaches and this is an advanced analytics subfield that uses statis tics, data mining, machine learning, and artificial intelligence to forecast future events. It combines information technology, business modeling, and management to anticipate trends and behavior pat terns. Predictive analytics is particularly useful in marketing, helping businesses understand customer needs and preferences, and enhancing customer engagement and decision-making.

3. List of Software used in big data analytics

Software used in big data analytics.

Software	Significance	Versions
Apache Hadoop	Distributed storage & processing framework	3.x, 2.x, 1.x
Apache Spark	In-memory processing	3.x, 2.x
Apache Kafka	Distributed event streaming platform	3.x, 2.x
Elastic search	Real-time distributed search & analytics	7.x, 6.x
MongoDB	NoSQL database for big data	5.x, 4.x
Microsoft Azure HDInsight	Managed Hadoop, Spark, and more on Azure	Various
IBM InfoSphere	Data integration & governance	11.x, 10.x
Snowflake	Cloud-based data warehousing	Latest
Data bricks	Unified analytics platform	Latest
SAS	Analytics & business intelligence	9.4, Viya
Tableau	Data visualization and analytics	2022.4, 2021.x
Google BigQuery	Serverless highly scalable enterprise data warehouse	Latest

4. **AI/ML Applications in Pharmacovigilance**:

- Effective integration of machine learning models with EHRs can increase the volume of accessible data.
- Applications of AI, such as random survival forecasting, an exten- sion of RF, are well suited to support projections of new drug appli- cation (NDA) submissions, which informs the optimization of resource allocation and workload inside regulatory agencies.
- Application of AI in drug repurposing was exemplified by Manczinger et al 51 , who described a ML algorithm (i.e., Support Vec- tor Machine Learning algorithm) that demonstrated the ability to select for drugs that were already in clinical assessment studies for psoriasis and were further validated by in vitro and in vivo studies.
- The application of AI tool to PV system has potential benefits to minimize the burden of manual workload and boost efficiency
- The application of AI can also be noted in post-market safety monitoring, drug repurposing, manufacturing, and pharmacovigilance, which all play a critical role in the drug development lifecycle.
- Currently, the drug development pipeline determines the probability of technical and regulatory success of a drug by assessing historical estimates driven by the current status of the development program and the specific disease under investigation. This information is then combined with insights from key opinion leaders and statistical analyses performed by drug sponsors to provide projections of the likelihood of a successful drug launch.
- The insilico models are an example of a favored MIDD approach that is currently utilized in the industry for the preclinical stages and includes subtypes such as quantitative structure-activity relationship (QSAR), non-compartmental analysis (NCA), physiology-based pharmacokinetic (PBPK modelling), and pharmacokinetic/pharmacodynamic (PK/PD) models, computer systems based on QSAR like DEREK, TOPKAT, COMPACT, MUL- TICASE, HazardExpert, and OncoLogic.
- current AI systems still require human oversight to ensure ADR detection and signal evaluation quality and accuracy. This "human-in-the-loop" approach is necessary to mitigate errors and validate findings, which can limit the scalability and efficiency of AI applications in pharmacovigilance

- Pharmacovigilance supported by AI can be seen through applications such as the Web Crawler utilized by the Singapore Health Sciences Authority to monitor active alerts regarding product defects and potential adverse drug reactions (ADRs), which assist the agency in minimizing potential defective products from affecting the local market.

Table 1 Common machine learning algorithms for predicting adverse drug reactions and drug-drug interactions

Algorithm	Application	Strengths	Limitations
Random Forest	Early detection of ADRs (e.g., drug-induced liver injury)	High accuracy; can handle missing data	Computationally intensive; prone to overfitting
Decision Trees	Predicting ADRs based on patient data and drug properties	Easy to interpret; fast execution	Less effective with noisy data
Neural Networks	DDIs prediction through pattern recognition	High flexibility; can model complex relationships	Requires large datasets; less interpretable
Support Vector Machines	Classifying ADR risk based on structured data	Effective for high-dimensional datasets	Difficult to tune; sensitive to parameter choices
Deep Learning	DDI prediction using molecular and biological data	High accuracy; capable of modeling intricate relationships	Requires extensive data; computationally expensive

ADRs Adverse drug reactions; *DDI* Drug-drug interactions

5. Global Regulatory Approaches

Challenges and Ethical Concerns:

The combination of big data analysis with AI for early risk identification creates various drawbacks that specifically relate to data quality and privacy and interpretation difficulties. The use of poor quality data materialized through incomplete records or data inconsistencies along with inaccuracies results in both false outcomes and lost safety detection opportunities. Data harmonization plus standardization become more difficult due to inconsistent data entry methods used in combined electronic health records and wearable devices systems.

Future Perspectives

Big data and AI harnessing will lead to advanced and accurate pharmacovigilance operations. The industry stands ready to protect public health while raising global drug safety through advanced technology implementation with human expertise support. A transformative period begins now that emphasizes safety prevention alongside advanced patient security as the leading frontier of modern innovation.

AI techniques while leveraging their potential to improve the pharmacovigilance workflow. The performance of AI models is highly dependent on the quality and quantity of data available. Inadequate or poorly curated databases can lead to inaccurate or incomplete detection of ADRs.

These may help prioritize and accelerate manual assessments by pharmacovigilance experts. These models must be validated and standardized to ensure reliability and interoperability within pharmacovigilance frameworks.

Conclusion:

The monitoring, evaluation, and assurance of drug safety have undergone a radical change with the incorporation of Big Data and Artificial Intelligence into Pharmacovigilance and Post-Market Surveillance. Real-time adverse event identification, predictive risk profiling, and ongoing benefit-risk assessment are made possible by these technologies at a scale that was previously unachievable with conventional methods. But these developments also have significant regulatory ramifications, such as the requirement for uniform international standards, algorithmic transparency, data privacy issues, and data standardisation. In order to create reliable, moral, and compatible surveillance frameworks in the future, industry, regulatory agencies, medical practitioners, and technology developers must cooperate together. By doing this, the healthcare industry will be able to fully utilise AI and Big Data to protect patients, improve medication safety results, and increase public confidence in the regulatory system.

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