



Artificial Intelligence Is Changing Face Of Pharmacovigilance.

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Abstract: Pharmacovigilance (PV) plays a pivotal role in ensuring drug safety by identifying, assessing, and preventing adverse drug reactions (ADRs) and other medication-related problems. This review aims to explore the evolving landscape of pharmacovigilance, highlighting key aspects such as ADR detection, the role of technology, post-marketing surveillance, and future challenges. The incorporation of artificial intelligence (AI) and machine learning (ML) into PV systems offers promising advancements in signal detection, case intake, and data mining. These technologies enable more efficient management of vast data sets, potentially improving patient safety outcomes. However, challenges persist, including underreporting, data quality, and the complexity of analyzing extensive PV data. Furthermore, global regulatory disparities and the need for a standardized approach remain key obstacles in realizing the full potential of AI in pharmacovigilance. This review discusses the benefits, current challenges, and future opportunities of PV technologies, proposing a more integrated approach for enhancing drug safety.

Index Terms – Pharmacovigilance, Signal Detection, Machine Learning, Artificial Intelligence, Adverse Drug Reaction.

I. INTRODUCTION

Pharmacovigilance

Pharmacovigilance is a subfield of pharmaceutical research that includes all scientific and data-gathering efforts related to the detection, assessment, understanding, and prevention of adverse events in medications and medical devices.

In theory, pharmacovigilance entails recognizing and assessing safety indicators. Once a signal has been found, it needs to be further evaluated to see if it poses a concern to public safety and if additional action is necessary.

The term "adverse drug reaction," or "ADR," refers to a response to a medication that is unpleasant and unexpected and that happens at doses that are typically used for the prevention, diagnosis, or treatment of disease, or for the alteration of physiological function. Pharmacovigilance is especially concerned with ADRs. Pharmacovigilance science also bears several other considerations:

- Poor quality medications;
- Medication mistakes;
- Absence of efficacy reports;
- Drug abuse and misuse;

- Reports of both acute and chronic poisoning;
- Evaluation of drug-related mortality;
- Adverse interactions between medications and chemicals, other medications, and food.

NEED OF PHARMACOVIGILANCE

1. It could be necessary to keep an eye on a drug's effects both during and after clinical trials and once it hits the market.
2. Unfavorable outcomes may occur both during clinical studies and following product introduction.
3. Keep an eye on medication quality.
4. Recognize the health hazards associated with administering specific medications.
5. Avoid hurting people.
6. Examine how effective medications are

AIM OF PHARMACOVIGILANCE

The primary objectives of pharmacovigilance for human medications have been established (Stephens, 2000), and they are easily transferable to veterinary medications:

1. The identification and measurement of adverse medication reactions that was previously unknown. .
2. Identification of patient subgroups based on physiological status, underlying disease, age, gender, breed, species, and other characteristics that put them at a higher risk of experiencing adverse medication reactions. .
3. Ongoing evaluation of a product's safety in each species for which it is approved, to make sure that the advantages outweigh the dangers. This ought to involve expanding monitoring to encompass new species and signals.
4. Examining the adverse reaction profile within and between species in comparison to production the same therapeutic class.
5. The identification of improper prescriptions and their administration; in the case of the latter, monitoring of the public or farmers as particular groups may be necessary.
6. Additional research into the toxicological, pharmacological, or microbiological characteristics of a medication or product in an effort to comprehend, if feasible, the mechanisms driving Unfavourable drug reactions.
7. Drug-drug interaction detection. This is especially crucial for newly developed medications that are given in combination with already-marketed goods or even other novel medications.
8. Giving veterinarians and other healthcare professionals who treat animals, such as farmers and other animal owners, the proper information on adverse medication reaction data and drug-drug interactions.
9. Adverse effects of veterinary pharmaceuticals on the environment and surrounding organisms.
10. The use of veterinary medications in animal-derived foods, such as meat, milk, and honey, in excess of the allowed residual levels.

Benefits and Role of Pharmacovigilance Technology.

A fundamental tenet of the pharmaceutical industry is the notion that randomized clinical trials can determine the safety and efficacy of a medication. The US Food and Drug Administration's (FDA) approval procedures and clinical trial processes may not offer a perfect assurance of safety for all potential customers in all situations.

It is acknowledged that the pharmacovigilance technology's clinical data mining and signal detection capabilities may be advantageous in offering the following:

- Methods those are practical, automated, and systematic for screening big datasets.
- Greater use of the extensive safety databases that the World Health Organization (WHO), the FDA, and other organizations maintain.
- Increased effectiveness by concentrating pharmacovigilance efforts on significant reporting relationships
- Benefits to public health by spotting possible safety concerns earlier and/or more precisely than with conventional pharmacovigilance techniques.

SCOPE OF PHARMACOVIGILANCE

Adverse Event Reporting. The gathering and examination of adverse event reports is one of the main duties of pharmacovigilance. These reports are filed by patients, healthcare providers, and pharmaceutical corporations when they believe a drug may have harmed someone or resulted in an unanticipated reaction. These reports are essential for spotting possible problems with safety.

Signal Detection

Experts in pharmacovigilance employ statistical and analytical methods to identify signals, or patterns or trends in adverse event reports that can point to a safety issue that has not yet been identified. Prioritizing additional research is made easier by identifying signals.

Risk Assessment: Pharmacovigilance specialists carry out comprehensive evaluations to ascertain the risk benefit profile of a medicine if a possible safety concern is detected. This entails assessing the seriousness of side effects and balancing them with the medication's therapeutic advantages.

Post-Marketing Surveillance: Before being approved for usage, medications are subjected to extensive testing in clinical studies. However, pharmacovigilance continues after a drug's approval, monitoring its safety in real-world contexts. This is essential because certain side effects could be uncommon or manifest only after prolonged use.

Future opportunities of Pharmacovigilance

The difficulties in effectively managing medication safety and complying with regulatory requirements give the strong impression that pharmacovigilance will inevitably be widely adopted. Pharmacovigilance, as a tool for change, possesses qualities that make it appealing to a wide range of stakeholders in a health care system that is politically and economically divided and beset by seemingly intractable issues with quality and cost as well as post marketing clinical studies.

- Does a contemporary pharmacovigilance technology system provide a multitier web application with minimal behind-the-scenes modifications? This certainly presents a challenge call to pharmacovigilance technology vendors to partner with pharmaceutical firms and health care providers to offer flexible, configurable, scalable, and interoperable pharmacovigilance technology solutions to meet the future pharmacovigilance needs in:
 - a. Increasing globalization;
 - b. Web based sales and information;
 - c. Broader safety concerns linked to the patterns of drug use within society;

d. A cooperative approach to working amongst central laboratories, insurance payers, biopharmaceutical companies, regulatory bodies, standards consortiums, and health care providers.

- Pharmacovigilance provides methodical assurance; but, in order to facilitate coordinated efforts, comparability, and interoperability, some standardization must be satisfied in terms of definition, range, threshold determination, or data mining statistical approach related to alert or signal triggering.
- Collaboration and contributions from a variety of stakeholders are needed to reach the goal. Of these, clinical safety science and statistical modeling subject matter specialists will continue to play crucial roles in guaranteeing deliverability and impartiality.

Challenges Of Pharmacovigilance

- The analysis and interpretation of freely supplied data involving various medications, health conditions, and occurrences per report are recognized to present inherent problems when done without the advantages of a research methodology, randomization, and a control group of participants receiving a placebo.
- There exist other challenges such as persistent underreporting, infrequent instances of over-reporting and misreporting due to publicity or legal action incomplete and missing data, and variations in reporting and naming/coding procedures throughout time. Furthermore, there is a great deal of uncertainty about the accuracy and completeness of the data in each field, such as dosage, formulation type, exposure timing, exposure duration, and follow-up, as well as in estimating the background rate of adverse events and corresponding product exposure. There are several obstacles to overcome in order to extract meaningful information from this database, such as organizing, storing, querying, and analyzing such a vast volume of data as well as fixing issues with the event and medication dictionaries and data miscoding.
- In order to appropriately balance the concerns for excessive signaling and accounting for background noise, analytical methods that are capable of routinely screening this database to discover potential major adverse events of concern in such a noisy backdrop are required.
- Determining the conditions under which an alarm should be sent, when a signal should be heightened to indicate a possible safety risk, and when a signal is likely enough to be real to merit follow-up will all be difficult decisions.
- When data on a drug-event link accrue, even after adjusting for repeated testing, statistical significance may become apparent if data mining analysis is carried out on data for millions of patients using thousands of drugs.

Utilizing data from the Swedish Drug Information System, the methodology to calculate the information component (IC) value for drug-event combinations chemical (ATC) classes of the nervous system, musculoskeletal system, and cardiovascular system (number of reports = 51,270) where only the suspected drug was considered as well as where both concomitant and suspected drugs were considered signaled a higher proportion of “type C” reactions when compared to when suspected drugs only were taken into consideration.

Artificial Intelligence.

Pharmacovigilance (PV) is using artificial intelligence (AI) more and more. The subject of artificial intelligence in pharmacovigilance, or AIPV, is expanding quickly, according to a MEDLINE search conducted with the phrases “artificial intelligence” and “pharmacovigilance.”

AI Terms:

Artificial intelligence is more challenging than defining intelligence itself. Legg and Hutter. examined seventy definitions, eighteen of which came from researchers in AI.

Approximately eight substantially autonomous intelligences, including verbal-linguistic, logical-mathematical, bodily-kinesthetic, visual-spatial, and interpersonal intelligence, are thought to exist in humans, according to psychologist Gardner⁶. These intelligences might be appropriate for specific AI activities including automated driving, image processing, and machine vision.

Methods

Artificial intelligence (AI) is a large field of computer science that encompasses machine learning (ML), which in turn includes deep learning (DL) and other ML forms, also referred to as traditional ML, as well as non-ML types of AI, sometimes called “good old-fashioned AI (GOFAI)”. ML can be considered from the standpoint of generic ML tasks, particular methods, and types of learning (e.g., supervised, unsupervised, and reinforcement learning).

Tasks

“The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem” is a commonly used definition of PV.¹⁸ When we think of PV, we frequently see committed experts laboring over progressively bigger individual case safety report (ICSR) data sets, periodic summary reports, risk management, signal identification and assessment, and product labeling. All of these duties fall under the purview of good PV practice for businesses having statutory or

Sources of Information and Data Sets:

Modern PV is a comprehensive procedure that seeks both clinical and preclinical data, particularly for signal evaluation with convergent lines of evidence from many data streams. Potentially relevant data span a wide range of levels, from molecules to humans, and come from reputable sources including preclinical toxicity data, spontaneous reports, electronic claims and medical records, registries, and clinical studies. User-generated material is one of the other information sources.

AIPV Definition of Scope

The aforementioned PTCs assist in determining the parameters of AIPV and offer an introduction to the fields of AI and PV. Drawing from these definitional PTCs and taking Wang’s⁷ criteria into account, we believe that a definition of AIPV’s scope would probably center around the following components: creation, investigation, and application of computerized algorithms and related technologies; assistance with and/or execution of operational and scientific PV duties; enhancement of PV knowledge discovery and process precision.

AI in PV health care

AI/ML has the ability to affect PV at every stage of its lifecycle, and this is being investigated. In general, ML in PV can be divided into three categories: duties pertaining to data intake, activities related to signal detection, and thirdly, other applications.

A variety of data ingestion (case intake or processing) tasks have been demonstrated to benefit from AI/ML, including the assessment of reported causation in individual case safety reports, anomaly identification as an alternative method to quality assurance and duplication detection

ML has been investigated and applied for signal analysis and detection at a significant point in the PV lifespan. Basic machine learning has been applied in the form of association rule analysis, also known as disproportionality analysis in PV.

Additionally, ML has been used to carry out various predictive modeling jobs and to find complicated patterns (syndromes) in safety data.

What could happen?

As techniques advance, ML's task performance should also increase and it may eventually be employed frequently in PV. The mere notion of AI/ML technology evokes an air of creativity and progress, making it an enticing technology.

Applying this cutting-edge technology to current PV systems with little to no adjustments to system governance and procedure is an alluring idea. Although some steps might become faster or more efficient as a result, total improvements might only be somewhat enhanced. More importantly, adding AI to current PV systems could appear innovative on the surface but really add to the amount and complexity of work that has to be done.

When AI/ML may help give solutions that lessen the effort, complexity, or cost associated with PV, it should be applied in PV. This will allow resources to be used more effectively and be directed towards the areas that are most crucial for guaranteeing patient safety. If not, this can lead to inconsistencies in the PV system, erode public confidence, and compromise patient safety.

ICSR processing is costly and requires a lot of physical labor. According to GSK's 2021 forecast, the average cost per processed case report was US\$33. It is alleged that other pharmaceutical companies incur significantly higher costs. Because of its high processing cost, ICSR processing is highly automatable

Even though implementing new technological solutions can be expensive at first, automation has a strong allure. However, if new processes are implemented carelessly or low-cost tasks are eliminated, this could lead to increased complexity and overall costs without enhancing patient safety.

The interaction between the pharmaceutical business that markets a product, the holder of the market authorization, and the regulatory bodies (such as the US Food and Drug Administration or the European Medicines Agency) is crucial to the use of AI/ML in PV. The absence of uniform PV regulations among regulatory bodies and legal countries poses a difficulty for entities gathering safety information pertinent to prescribers and patients, irrespective of their location.

Currently, it is challenging to analyses and share bigger amounts of data quickly without having the ability to assess their veracity and, consequently, the possible negative effects on decision-making and its consequences. This is separate from collateral consequences, such the possible influence on employee morale that can arise from less-than-ideal introduction of technologies that affect work practices.

What should happen?

It may seem from the previous section that AI/ML and large-scale automation-driven transformation are not appropriate for PV.

AI/ML systems must take into account in order to learn from previously analysed data while retaining the capacity to recognize unexpected results. They also must link learnings and requirements across the PV lifecycle with ease, effectiveness, and speed, from signal detection and data ingestion to sharing PV knowledge at the point of care.

We require a solution that can smoothly connect inputs and outputs from various data systems. In the end, such a system might provide information for an interactive continuous learning solution that helps stakeholders, prescribers, and patients understand the benefits and risks of medications and vaccinations.

Organizational, professional, and patient factors that affect AI adoption in healthcare were found in a recent comprehensive review.

Psychosocial aspects were important concerns for patients and healthcare providers. These factors included perceived ease of use, performance or effort expectancy, and social impact.

The adoption of AI is impacted by structural issues such as workflow, security, training, and organizational scale. Notably, the adoption of AI was adversely correlated with perceived risks to autonomy.

Patients and their healthcare providers are more likely to recognize the value of sharing their own healthcare data in order to provide greater PV insights for others, themselves, and those close to them if they believe that sub-population or population-level data will benefit their individual healthcare journey. The data quality accessible in PV systems will rise as the value of data sharing is increased through improved visibility on impact for patient safety. This will cyclically enable a stronger impact on patient safety.

Machine learning

Due to its ability to recognize patterns, solve problems, and make decisions, artificial intelligence (AI), a broad subject of computer science, has attracted a lot of interest from the medical community. Within the field of artificial intelligence

Computers' ability to take in information, learn from it, and arrange the data they are processing by modifying algorithms is the focus of artificial intelligence (AI) and machine learning (ML). Due to the abundance of large clinical picture collections available for machine interpretation and training, dermatology has a clear advantage when utilizing ML. In fact, studies have already demonstrated that ML is capable of accurately classifying and diagnosing skin diseases, such as eczema, psoriasis, onychomycosis, and skin cancer, at least as well as board-certified dermatologists. In artificial intelligence, machine learning teaches algorithmic models to perform certain tasks by finding and ingesting patterns from the data they come across, rather than relying on explicit computer code written by a human expert.

This technique can be approached in three different ways: supervised, semi-supervised, and unsupervised. The method that is most frequently utilized is supervised. When an algorithm system is intended to identify a new, unknown data point after learning via training using a labeled dataset, this is known as supervised learning. For example, to differentiate benign from malignant skin lesions, the computer system might display a number of images of skin lesions that have already been identified as either benign or malignant.

History of Machine learning

The history of machine learning is an intriguing journey through time, replete with noteworthy occasions, innovative thinkers, and game-changing discoveries. In this piece, we'll go further into the fascinating history of machine learning and acquire a better grasp of the technology that is transforming society.

Sr no	year	Evaluations
1	2006	National institute of standards and technology accede popular face recognition algorithm
2	2012	A Google x lab unsupervised neural network trained to detect cats in YouTube video
3	2014	Deep face was created.
4	2015	Google voice recognition Programme improved
5	2016	lip net recognizes lip-read phrases video

6	2017	Way men begin testing self-driving vehicles
7	2019	Virtual assistant market in united state
8	2020	Recursive belief based learning developed
9	2021	Google announced switch transformed

The Top 10 frequently used Machine Learning (ML) Algorithms are listed below:

1. Linear regression
2. Logistic regression
3. Decision tree
4. SVM algorithm
5. Naïve Bayes algorithm
6. KNN algorithm
7. K-means
8. Random forest algorithm
9. Dimensionality reduction algorithms
10. Gradient boosting algorithm and adaboosting algorithm

Machine Learning Algorithm Types

1. Supervised Learning

When labeled data is used to train supervised learning systems, it indicates that the input data has been correctly annotated with the output. These algorithms seek to discover a mapping between inputs and outputs so that new data can be predicted. Typical algorithms for supervised learning consist of:

- a. Linear Regression:** For the purpose of forecasting continuous outcomes, use linear regression. By fitting a linear equation to provided data, it describes the connection between a dependent variable and one or more independent variables.
- b. Logistic Regression:** For binary classification tasks (e.g., yes/no outcome prediction), logistic regression is utilized. It makes use of a logistic function to estimate probabilities.
- c. Decision Trees:** Based on basic decision rules deduced from the data attributes, these models forecast the value of a target variable.
- d. Random Forests:** A collection of decision trees that are usually used for regression and classification to increase model accuracy and reduce overfitting.
- e. Support Vector Machines (SVM):** Primarily utilized for classification, SVM may also be applied for regression and is particularly effective in high-dimensional spaces.
- f. Neural network:** Strong models that are capable of capturing intricate non-linear interactions are neural networks. Applications for deep learning make extensive use of them.

2. Unsupervised Learning

Data sets lacking labeled replies are utilized with unsupervised learning methods. Deducing the inherent structure from a collection of data points is the aim here. Typical methods for unsupervised learning include:

- a. Clustering:** A collection of objects is grouped by algorithms such as K-means, hierarchical clustering, and DBSCAN so that the objects in the same group are more similar to each other than to the objects in other groups.
- b. Association:** These algorithms look for patterns, like market basket analysis, that characterize significant chunks of your data.

- c. **Principal Component Analysis (PCA)** is a statistical technique that transforms a set of observations of variables that may be correlated into a set of values of variables that are linearly uncorrelated by applying an orthogonal transformation.
- d. **Auto-encoders:** A unique class of neural networks designed to efficiently learn how to code unlabelled data.

3. Reinforcement Learning

Algorithms using reinforcement learning are trained to make a series of decisions. The algorithm gains the ability to accomplish a task in an unpredictable, maybe complicated environment. In reinforcement learning, an agent chooses what to do by adhering to a policy, and it gains knowledge from the results of these decisions by receiving rewards or punishments.

- a. **Q learning:** Q-learning is a method for model-free reinforcement learning that determines the worth of an action in a specific state.
- b. **Deep Q learning:** With the help of deep neural networks and Q-learning, deep Q-Networks (DQN) enables the method to directly learn effective policies from high-dimensional sensory inputs.
- c. **Policy Gradient Methods:** Unlike action value estimation, these methods directly optimise a policy's parameters.
- d. **Monte Carlo Tree Search (MCTS):** A decision-making technique that plays out scenarios to discover the best option; most famously employed in games like go.

A general summary of the most prevalent kinds of machine learning algorithms may be found in these categories. Each has optimal use cases and strengths that make them more appropriate for some activities than others.

Popular Algorithms for Machine Learning:

1. Linear Regression

Imagine how you would arrange random wood logs in increasing order of weight to get an understanding of how linear regression works. But there's a catch: you can't weigh every log. Visual analysis requires you to estimate the weight of the log based only on its height and circumference, then arrange the log according to a combination of these observable dimensions. In machine learning, linear regression works similarly to this.

Through the process of fitting them to a line, a relationship between the independent and dependent variables is established. The linear equation $Y = a * X + b$ represents this line, which is also referred to as the regression line.

Within this formula:

Y-dependent variable

a-slope

X-independent variable

b-intercept

By minimizing the sum of the squared differences in distance between the data points and the regression line, the coefficients a and b are obtained.

2. Logistic Regression

From a set of independent variables, discrete values (often binary values like 0/1) are estimated using logistic regression. It uses a logit function to fit data, which aids in predicting the likelihood of an event. Another name for it is logit regression.

The following techniques are frequently applied to enhance logistic regression models:

Incorporate terms of interaction

Omit features

Regularization methods make use of a non-linear model.

3. **Decision tree:**

One of the most often used supervised learning algorithms in machine learning today is the decision tree method, which is used to classify issues. It performs effectively when classifying dependent variables that are continuous or categorical. The population is divided into two or more homogenous sets using this method according to the most important characteristics or independent variables.

4. **SVM:**

Plotting raw data as dots in an n-dimensional space (where n is the amount of characteristics you have) is how the SVM algorithm performs classification. Classifying the data is made simple by assigning a coordinate to each feature's value. The data can be divided into groups and plotted on a graph using lines known as classifiers

5. **Naïve Bayes Algorithm:**

A Naïve Bayes classifier makes the assumption that a feature's presence in a class is independent of any other feature's presence.

When determining the likelihood of a specific result, a Naïve Bayes classifier would take into account each of these attributes separately, even if they are related to one another.

Building a Naïve Bayesian model is simple, and it works well with large datasets. It's easy to use and has been shown to beat even the most complex categorization techniques.

6. **KNN (K- Nearest Neighbours) Algorithm:**

Problems involving regression and classification can both be solved with this technique. It seems to be more frequently utilized in the Data Science sector to address categorization issues. A straightforward technique is used to store all examples that are accessible and classify any new cases by determining the majority vote of their k neighbors. After that, the case is allocated to the class with which it shares the greatest similarities. This calculation is done via a distance function.

KNN is easily comprehensible when compared to actuality. For instance, it makes sense to speak with a person's friends and coworkers to learn more about them!

Before choosing the K Nearest Neighbors Algorithm, take the following into account:

KNN requires a lot of computing.

Higher range variables may skew the algorithm; so, variables must be normalized.

Pre-processing of the data is still necessary.

7. **K- means:**

It is an approach for unsupervised learning that resolves clustering issues. Data sets are categorised into a certain number of clusters (let's call that number K) so that every data point within a cluster is different from every other data point in a cluster but is homogenous overall.

How do K-means clusters?

For every cluster, the K-means algorithm selects k centroids, or points. With the nearest centroids, each data point forms a cluster known as a K cluster. These days, it builds new centroids from the members of the current cluster.

Each data point's closest distance is found using these updated centroids. Until the centroids remain unchanged, this process is repeated.

8. Algorithm of Random Forest

A Random Forest is an ensemble of decision trees. Each tree is assigned a class based on its attributes, and then the tree “votes” for the class that best fits the object. The forest chooses the classification with the most votes (over all the trees in the forest).

Every tree is cultivated in the following ways:

A random sample of N cases is selected if the training set has N cases. The training set for the tree's growth will be this sample. In the event that there are M input variables, a number $m \ll M$ is given so that, at each node, m variables are arbitrarily chosen from the M , and the node is split using the optimal split on this m . Throughout this procedure, the value of m is kept constant.

Every tree is grown to the greatest degree that is practical. Pruning is not done.

9. Dimensionality reducing Algorithm

In the modern world, corporations, governmental bodies, and research institutions store and analyse enormous amounts of data. As a data scientist, you are aware that there is a wealth of information included in this raw data; the task at hand is to find important patterns and variables.

You can locate pertinent details with the aid of dimensionality reduction algorithms such as Decision Tree, Factor Analysis, Missing Value Ratio, and Random Forest.

10. The AdaBoosting and Gradient Boosting Algorithms

Gradient and AdaBoosting are two types of boosting techniques that are employed while handling large amounts of data in order to produce highly accurate forecasts. Boosting is an ensemble learning approach that enhances robustness by combining the predictive power of many base estimators.

To put it briefly, it builds a strong predictor by combining several average or weak predictors. These boosting algorithms consistently do well in data science contests such as Crowd Analytics, AV Hackathon, and Kaggle. These are currently the most popular machine learning algorithms. Utilize them in conjunction with R and Python codes to produce precise results.

Conclusion

Pharmacovigilance remains a critical component in safeguarding public health by ensuring the continuous monitoring of drug safety throughout the life cycle of medicinal products. The integration of advanced technologies like artificial intelligence and machine learning into pharmacovigilance practices has the potential to revolutionize signal detection, data processing, and post-marketing surveillance. These innovations can enhance the efficiency and accuracy of identifying adverse drug reactions, ultimately leading to improved patient safety and more informed healthcare decisions.

However, significant challenges persist, including inconsistent global regulations, data quality concerns, and the complexity of large-scale data analysis. To overcome these hurdles, a collaborative and standardized approach among regulatory authorities, pharmaceutical companies, and healthcare professionals is essential. Addressing these challenges and fully leveraging AI/ML capabilities will ensure that pharmacovigilance evolves to meet the growing demands of modern healthcare systems while continuing to protect patients from potential medication risks.

This review highlights the need for ongoing advancements in PV technologies and practices, underscoring the importance of collaboration and innovation in creating a safer, more responsive drug safety monitoring system.

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