RESEARCH PAPER

Artificial Intelligence in Pharmacovigilance: An Imminent Paradigm Shift for Innovative Intelligibility

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Abstract
Adverse drug reactions play a pivotal role in assessing the risk-to-benefit ratio of drugs. Pharmacovigilance (PV) is essentially involved in the timely detection of these risks in terms of adverse effects that are novel by their own virtue. The cornerstone of this process is the scientific acumen of the PV domain expert. However, extracting the essential data, which is deeply embedded in a pile of data that consists mostly of noise, is arduous and challenging. These challenges are difficult to avoid with traditional PV methods. Artificial Intelligence (AI) allows machines to learn, interpret, perform data mining and provide the ability to predict impending adverse effects, which is nearly impossible with traditional methods. This leads to the constant and diligent shift of focus in drug development. However, the paradigm shift is not as smooth as it seems. The present review will highlight the transformation of challenges from conventional PV to AI based PV by understanding the role of AI in PV.

Keywords Pharmacovigilance, Artificial Intelligence, Regulatory framework, Adverse drug reactions effects
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1. Introduction

Pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It is an important aspect of healthcare that ensures the safety and efficacy of drugs, particularly after they have been approved for use in the market [1]. The history of PV can be traced back to the 1960s when thalidomide, a drug used to treat morning sickness in pregnant women, caused a global disaster, resulting in thousands of babies born with severe birth defect [2,3]. This incident highlighted the importance of monitoring and reporting adverse drug reactions (ADRS) and led to the establishment of PV systems worldwide for assistance in the systematic drug vigilance [4]. Since then, many other drugs have been withdrawn from the market due to serious ADRS, such as Vioxx, a painkiller that was linked to an increased risk of heart attack and stroke [5]. Moreover, after several years of PV Practice still world is witnessing pharmaceutical tragedy despite of rigorous PV programs. Recently, The Gambia has experienced a tragic event due to a contaminated cough syrup, resulting in pediatric mortality is an adverse effect of certain off limit excipient [6-8]. This event serves as a traumatic reminder of the importance of PV in safeguarding public health. By closely monitoring and evaluating the safety of medicines, including identifying and evaluating adverse reactions or side effects, we can help prevent such tragedies from occurring [6]. The identification and reporting of ADRS have also led to changes in drug labeling and regulatory policies, aimed at improving patient safety[9]. A summary of the PV development from past to present is depicted in **Figure 1** (2)

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Figure 1 *Road map of current PV*

The significance of addressing drug-related safety in companies cannot be overstated. PV plays a crucial role in enhancing the safety and utility of new drugs over their predecessors. Regulatory aspects of PV are crucial for ensuring drug safety and protecting public health [10]. Organizations such as the United States Food and Drug Administration (FDA) and the European

Medicines Agency (EMA) have set forth guidelines and requirements for PV activities that companies must adhere to in order to obtain and maintain marketing authorization for their products [11]. Key elements of PV regulations encompass reporting requirements, safety monitoring, risk management, inspections and audits, and collaboration and communication. Pharmaceutical companies are directed to report adverse drug reactions (ADRs) to regulatory agencies and have systems in place to gather, analyze, and report this information [12]. Additionally, companies must continuously monitor the safety of their products, update safety information accordingly, and conduct post-marketing studies. To reduce risks associated with their products, companies must establish risk management plans, which might involve changes to product labeling, sharing information with healthcare professionals, or enforcing limitations on product use [13]. Regulatory authorities may inspect or audit companies' PV systems to verify compliance with regulations. Lastly, efficient PV necessitates collaboration and communication among regulatory authorities, pharmaceutical companies, healthcare professionals, and patients, with regulatory authorities working hand-in-hand with these stakeholders to ensure a coordinated and effective approach to PV [14].

Key areas covered by PV include quantifying drug-related harm to patients, where potential harms are identified, and solutions are strategized. However, improving drug safety is the primary goal of PV, and enhancing the quality of ADR data remains a significant challenge because of its volume. Hence, future advancements in PV will depend on the capacity to process vast amounts of information for better ADR data quality [15]. Active surveillance is vital for gathering ADR data, which entails monitoring patients' real-time responses to specific drug therapies. PV introduces tools for this purpose, empowering clinicians with valuable insights on patient specific ADRs [16]. New drug development and drug repurposing focus on improving drug safety, with PV assisting in identifying the mechanistic basis of ADRs, ultimately leading to increased drug efficacy and reduced toxicity [17]. These application areas target ADRs to ensure safer drugs, providing clinicians with the necessary tools to cater to individual patient needs. Despite the numerous benefits and applications of PV, there are limitations to the traditional approach [18].

1.2 Challenges of Traditional PV solutions

High quality ADR reports are essential for improving the patience outcomes. That leads to sharp rise in the expenditure. Data gathering, data mining and analyzing the gathered data are the foundation for high quality reports. For the same, pharmaceutical organizations are investing a hefty amount to implement such techniques to generate required complacent data. Thus high quality report making will costs enormous potential in terms of administrative as well as expenditure to analyse cumbersome large rush of patient-specific ADR data. The exponentially rising number of available data points is another challenge for traditional PV. There will be an exponential increase in ADR-related data inflow because of the growing global population. Unfortunately, methods used in traditional PV are not suitable to handle such an enormous amount of data. In other words, traditional PV is expected to cost more while not processing all the upcoming data. While in the process of finding the alternatives, Artificial Intelligence (AI) and Machine Learning (ML) emerged to seemingly offer solutions to the challenges traditional PV [19]. Communication of drug risk is centered on population risk with PV testing and providing clinicians the necessary tools to convey drug risks to individual patients. Heterogeneity of patient response is another aspect where PV experts investigate drug therapy response variations, supplying essential information to clinicians for selecting the best treatment. Patient-focused risk communication involves PV finding novel methods for creating patient-specific management solutions for adverse drug reactions (ADRs). Comparing diverse ADR reports leads to greater accuracy in patient-specific risk information and reduces ADR incidence[20]. **Figure 2** shows an overview detailing the challenges associated with PV.

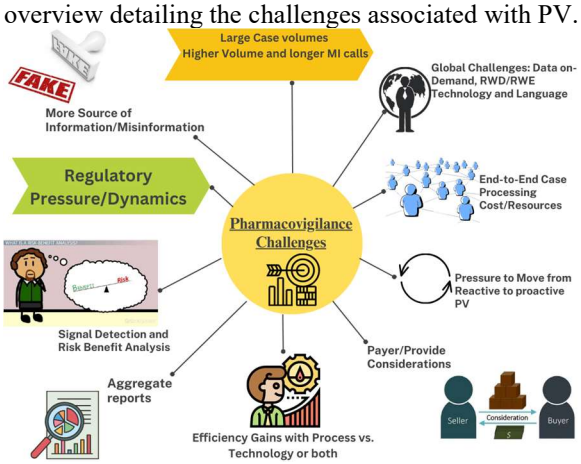

Figure 2 An overview detailing the challenges associated with PV.

2. RECENT CHALLENGES OF PV

With developing time the traditional challenges were augmented by the huge technological based modern recent challenges that need to understand to come up with reliable solutions. And there recent challenges are listed in **Figure 2** and are discussed as follows:

2.1. Technological Challenges

PV faces several technological hurdles, such as data integration and management, which involves combining and handling information from numerous sources like electronic health records, clinical trials, and social media. Ensuring data quality, privacy, and security is essential to avoid errors, inconsistencies, and unauthorized access [21]. Scalability poses another challenge as PV systems must accommodate the increasing volume of data. Interoperability is crucial for efficient collaboration across different organizations and systems, while interpretability and explain ability of AI and machine learning algorithms' output remain a concern for healthcare professionals. Addressing these challenges necessitates a collective effort from industry stakeholders, regulators, and technology providers, with collaboration and partnerships being vital in finding innovative solutions and maximizing technology's potential in PV [21,22].

2.2. Customer Based Challenges

PV primarily aims to ensure the safety and effectiveness of drugs and medical devices, but it also faces customer-based challenges that must be tackled in order to engage patients and healthcare professionals in these activities. Among these challenges are the lack of awareness, as many individuals are unfamiliar with the significance of PV and proper adverse event reporting, potentially causing underreporting and delayed identification of safety concerns. Additionally, language and cultural barriers can hinder participation in some regions or countries. The trust and confidence in PV systems and the pharmaceutical industry may be lacking for some, limiting their willingness to report adverse events. Busy healthcare professionals might also face time constraints, preventing them from reporting events or staying updated with the latest information. Lastly, obstacles in accessing up-to-date PV data can impede patients and professionals alike. To address these challenges, a comprehensive approach is needed that encompasses patient and healthcare professional education on PV's importance, fostering trust in systems, offering user-friendly reporting tools, and enhancing information accessibility. Engaging both patients and healthcare professionals is vital for the success of PV endeavors, and efforts to raise awareness and involvement in these activities are essential [23].

2.3. Market Challenges

PV encounters numerous market challenges that influence its efficiency and effectiveness. Some of these challenges include increasing complexity as more drugs and medical devices enter the market, making it difficult for PV systems to manage the volume and diversity of products. Resource constraints also pose a challenge, as PV activities necessitate significant investments in human resources and technology. Limited resources can hinder the capabilities of PV systems to effectively collect, analyze, and report adverse events.

Constantly evolving regulatory requirements can be difficult to comply with, particularly for smaller companies with limited resources. The globalization of the pharmaceutical industry also complicates matters as PV systems must function across various regions and countries, encountering differences in regulatory requirements, languages, and cultures. The highly competitive nature of the industry can sometimes result in a lack of focus on PV, potentially endangering patients. To address these market challenges, collaboration among the pharmaceutical industry, regulatory agencies, and other stakeholders is essential. Possible strategies include the development of more robust and standardized PV processes, leveraging technology for increased efficiency, and investing in training and education for PV professionals. By tackling these challenges, PV will play a crucial role in ensuring the safety and effectiveness of drugs and medical devices [24].

2.4. Regulatory Challenges

The ever-changing nature of regulatory framework makes it difficult for PV to maintain compliance, especially for smaller organizations with limited resources. As the pharmaceutical sector operates globally, PV systems must be adaptable to varying regional and national regulations, which can complicate the implementation of successful PV initiatives. Moreover, data privacy is a crucial concern, and strict rules dictate how patient information is collected, stored, and utilized. These regulations can hinder the effective gathering and analysis of adverse event information. Furthermore, ensuring the quality of adverse event data in compliance with regulatory guidelines can be difficult, particularly in an international context.

Collaboration between stakeholders is mandated by regulatory authorities to guarantee the efficacy of PV systems. However, aligning priorities between diverse stakeholders can be problematic. Tackling these regulatory challenges demands a joint effort from regulatory bodies, the pharmaceutical industry, and other parties involved. Potential solutions include implementing more standardized PV procedures, utilizing technology for enhanced efficiency, and investing in training and education for professionals in the field. By overcoming these hurdles, PV can serve as a vital component in ensuring the safety and effectiveness of drugs and medical devices [25-27].

Regulatory aspects of PV are crucial for ensuring drug safety and protecting public health. Organizations such as the United States Food and Drug Administration (FDA) and the European Medicines

Agency (EMA) have set forth guidelines and requirements for PV activities that companies must adhere to in order to obtain and maintain marketing authorization for their products [28]. Key elements of PV regulation encompass reporting requirements, safety monitoring, risk management, inspections and audits, and collaboration and communication. Pharmaceutical companies must report ADRs to regulatory agencies and have systems in place to gather, analyze, and report this information. Additionally, companies must continuously monitor the safety of their products, update safety information accordingly, and conduct post-marketing studies [26]. To reduce risks associated with their products, companies must establish risk management plans, which might involve changes to product labeling, sharing information with healthcare professionals, or enforcing limitations on product use. Regulatory authorities may inspect or audit companies' PV systems to verify compliance with regulations. Lastly, efficient PV necessitates collaboration and communication among regulatory authorities, pharmaceutical companies, healthcare professionals, and patients, with regulatory authorities working hand-in-hand with these stakeholders to ensure a coordinated and effective approach to PV [10,26,28].

2.5. Confidentiality & IPR Based Challenges

One of the major constraints of new technological innovative processes is the Intellectual property rights (IPR) challenges. IPR present various obstacles to PV activities, particularly concerning the exchange and utilization of adverse event data. Confidentiality issues arise as pharmaceutical firms may view adverse event data as sensitive information, complicating data sharing with regulators and other interested parties. Ownership complications can emerge when multiple entities partake in a drug or medical device's development and marketing, making adverse event data ownership complex. Data sharing concerns arise due to apprehensions regarding IPR violations and possible legal altercations between stakeholders when sharing adverse event data. Data usage restrictions may arise from IPR concerns, potentially hindering regulatory bodies from effectively analyzing the data. Data access limitations may occur as a result of IPR aspects, constraining researchers and other stakeholders' ability to examine the data. Addressing these IPR-associated challenges demands a cooperative approach between the pharmaceutical sector, regulatory authorities, and other participants. Potential strategies include creating concise guidelines for data sharing and utilization, forming standard operating procedures for adverse event reporting, and utilizing technology to enhance efficiency and security in data sharing. By tackling these issues, PV can fulfill a crucial function in guaranteeing drug and medical device safety and effectiveness, while concurrently safeguarding IPR [29,30]

3. ARTIFICIAL INTELLIGENCE (AI) AS NOVEL METHODS FOR IMPROVING PV

The impact of PV on various factors made the development of newer strategies crucial. AI stands for Artificial Intelligence. It refers to the development of computer systems that can perform tasks that would normally require human intelligence, such as learning, problem-solving, decision making, and language understanding [31], AI can be broadly categorized into two types based on the complexity of work they can perform: weak AI and strong AI. Further detail of its types are showed in **Error! Reference source not found.**. AI is to analyze vast amounts of data from various sources (electronic health records and social media), followed by enabling the identification of potential adverse events and drug interactions [32].

Pharmaceutical Industries which were lately more inclined towards the traditional methods of recording PV data, is now also witnessing an organic shift to newer and novel, AI empowered methods. Recent NDA submission from Abilify Mycite, by Otsuka Pharmaceutical Ltd. and Proteus Digital Health (Proteus) gained attention due to its AI interventions. Abilify Mycite is a prescription medicine for the treatment of schizophrenia, bipolar I disorder, and depression in adults. It is a drug-device combination product that incorporates an ingestible sensor in the tablet linked with the wearable patch, a mobile app, and a web portal. Abilify Mycite incorporates the most emerging and challenging breakthrough in PV i.e. AI, that can improve medication adherence, detect adverse events in real-time, and potentially improve patient outcomes [33]. However, It is not known if Abilify Mycite, can improve how well you take your aripiprazole or for changing your dose of aripiprazole. Some factors, such as a bad connection or reception, or not having your smartphone, may impact the consistency and reliability of data being detected, collected, and transmitted. Only functions related to tracking drug ingestion have been evaluated or approved by FDA.

Artificial intelligence (AI) algorithms can analyze the data collected by the system to identify patterns, predict adverse events, and provide personalized treatment recommendations. Moreover, AI can analyze activity levels and self-reported mood to identify potential triggers for relapse in patients with schizophrenia. It can also identify patients who may benefit from a dosage adjustment or a change in treatment based on their medication adherence patterns [34]. Other advantaged are presented in **Figure 4**.This benefits healthcare providers and regulators by allowing them to swiftly address safety concerns, which in turn improves patient well-being and results.

Patient-reported outcomes provide valuable insights into the efficacy and safety of medications [35].
Gathering information directly from patients allows healthcare providers and regulators to better comprehend medication usage and its impact on patient health. AI enabled mobile based application for software program further penetrate deep into the patient population due their outreach and helps as an important PV tool to monitor medication compliance and reporting any side effects. The personalization is another aspect of these apps that works best to counter the heterogenicity of the patient population [36]. Wearable devices are popular gadgets that prove out to be useful in tracking patient health and medication adherence, generating real-time data to spot potential adverse events and drug interactions [37]. Though, the monitoring by this technique is quite diffuse and bothersome.
However, it is essential to ensure that the use of AI in PV is carefully monitored and validated. AI models must be rigorously tested to ensure their accuracy and effectiveness in predicting adverse events and providing personalized treatment recommendations [38]. Additionally, patient privacy must be protected, and the use of data must be transparent and compliant with relevant regulations [39].

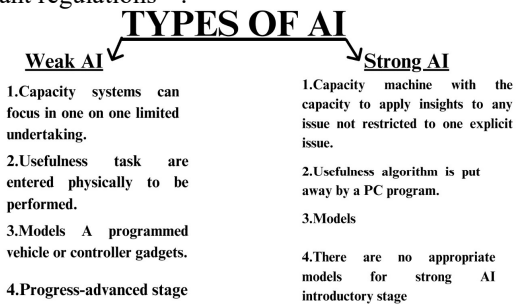

Figure 3 Types of AI (Artificial Intelligence)[40].

3.1. Transforming PV with the Power of Artificial Intelligence

In developing nations PV is an idea with low preferences bringing up the issues into framework to screen drug safety profile. However, reporting of ADRs is principally done through unconstrained revealing[41], by pharmacoepidemiologic (PE) strategies, and is also done by Adverse Drug Reaction Monitoring Centre's and Marketing Authorization Holder (MAH) businesses to tackle arising issues, record signals, and impart to limit or prevent harm [10]. The main activity in PE industry is identification and reporting of ADRs, coding of AI in specialized terms, getting ready for security individual reports, appraisal of seriousness, and relationship with suspected medication [42]. However, the worldwide accessible information is huge to such an extent that it can't be dissected physically. As of today, despite safety databases, significant components of PV operations are effort-intensive and spreadsheet-driven. The industry lacks integrated solutions that combine activities such as case prioritization and processing, aggregate reporting, and signal detection. So, the automation offers significant operational and strategic benefits, but full transformation entails a multi-year journey leveraging various technologies as outlined in this transformation roadmap [43] (**Error! Reference source not found.**). Simulated intelligence strategies like AI assume a critical part in the space of medication plan and recognizable proof of AEs of drug items [44,45]. Moreover it will be interesting see how advancements in the AI can offer a low cost-effective way to achieve the purpose of data handling[46,47]. There are several potential solutions that AI offer in PV which is illustrated in Figure 6 [48].

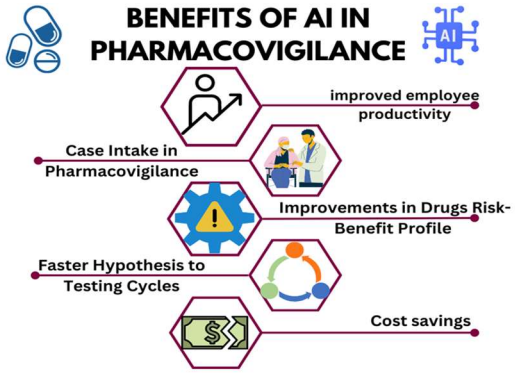

Figure 4 *Benefits of AI in PV.*

Firstly, they can lower the costs significantly. Secondly, it can enhance data analysis in PV by collecting and analyzing vast amounts of data while eliminating human factors. Free-form text data is widespread in the pharmaceutical and healthcare industries, making AI even more efficient options. Thirdly, the incorporation of AI leads to increase automation in repetitive and routine tasks, freeing up valuable resources and allowing professionals to concentrate on more significant goals [49]. Later, AI can improve risk-benefit assessment by aiding in the detection of potential drug-related events associated with specific populations, enhancing the evaluation of new and existing drugs' risk-benefit profile. Lastly, AI-driven PV can expand its outreach not only to healthcare resources but also to social media, news articles, and other public domain information. [50] This approach will increase the accuracy of Adverse Drug Reaction (ADR) predictions and provide real-world insights that contribute to the improvement of personalized medicine.

3.2. The Process of Using AI in PV

Utilizing AI in PV, the scientific practice of overseeing drug effects post-approval, generally encompasses several stages which are shown in **Figure 5**. Initially, data collection takes place, where information from Electronic Health Records (EHRs), patient reports, and other effects-related sources is gathered to train and test the AI system. After collecting the data, it undergoes preparation to be used in the AI system. This may involve data cleaning, preprocessing, and formatting to make it compatible with the AI's requirements.

Subsequently, the AI model is trained with the prepared data by inputting it into the system and fine-tuning the model parameters for optimal performance. The next step is to evaluate the trained model's accuracy and performance using metrics such as precision and recall, or possibly by testing it with a separate dataset. If the evaluation yields satisfactory results, the model can be deployed for PV purposes by integrating it into a larger system or utilizing it for real-time data analysis.

Lastly, the AI system's performance must be consistently monitored and assessed to detect potential issues and opportunities for improvement. Overall, incorporating AI into PV involves data collection, preparation, AI model training, evaluation, deployment, and continuous performance monitoring [51,52].

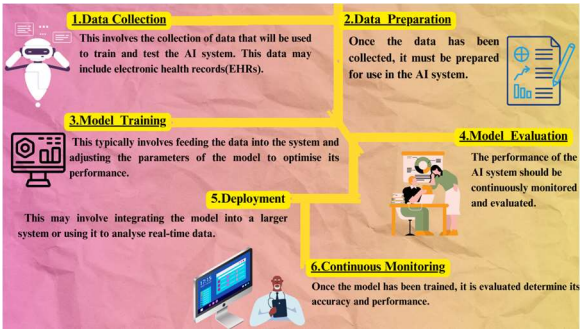

Figure 5 *Process of using AI in PV.*

4. BARRIERS OF ARTIFICIAL INTELLIGENCE IN PV WITHIN HEALTHCARE

The implementation of AI within PV brings numerous benefits, but also poses significant challenges illustrated in **Figure 6**. To achieve optimal results, several prerequisites need to be considered. Firstly, managing complex and unstructured data requires proper **data governance** methods. Although AI can process the data, they still require programming by humans. [53] Secondly, recruiting data science professionals to integrate AI and ML within healthcare and pharmaceutical businesses is imperative. However, this requires allocating resources for hiring experts well-versed in these technologies. Thirdly, **data protection** is crucial, particularly when handling sensitive patient information. Adhering to data security standards and guidelines is essential, and measures must be updated and fine-tuned as AI become more integrated [54]. Lastly, **intellectual property rights** are a significant concern, and existing case laws need to be revised to ensure AI driven biotech and pharmatech inventions do not fall through the gaps of current intellectual property legislation.

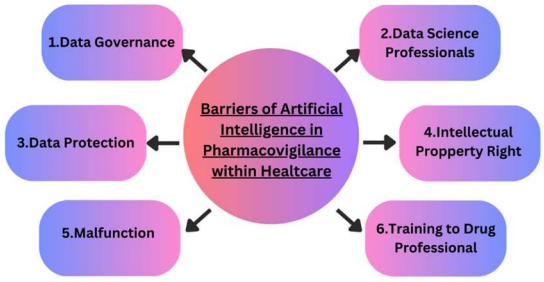

Figure 6 *Challenges of AI in PV*

Incorporating new and innovative AI technologies in the field of PV is necessary to meet growing demands. However, numerous constraints and obstacles must overcome to comprehend the complexities of these technologies completely. A significant limitation is the amount of data required to develop AI algorithms using sensitive health information. Interpreting PV data involves complex medical jargon, requiring thorough programming to ensure accurate translation of data to AI models**. Malfunctions** can occur, necessitating the creation of new support roles for identifying and resolving flaws in the AI algorithms [55]. Another challenge is the availability of structured and curated data to train AI software. Large amounts of data are required for AI algorithms to learn and make accurate predictions regarding PV-related factors. However, this data is often scattered across different sources and not readily available in a structured format, making it difficult to train algorithms accurately. **Privacy concerns** are also significant, as using AI to analyze sensitive patient data raises concerns about potential misuse for other purposes without individual consent. Lastly, drug safety professionals must be **trained** to work effectively with new and advanced AI technologies to implement them effectively. Increased effort and time must be invested in training personnel for effective implementation.) .[56]

5. FUTURE OPPORTUNITIES FOR ARTIFICIAL INTELLIGENCE IN PV

Smarter ICSR Collection is a major issue in PV, as their analysis is an even greater challenge. The World Health Organization (WHO) database holds over 20 million ICSRs, which could grant vital insights on drug safety and ADRs. With the introduction of AI into the ICSR collection process, PV is made smarter.

By 2030, ICSR reporting is predicted to be much more advanced due to AI-based tools such as Natural Language Processing (NLP)[57], which can analyze massive amounts of unstructured ICSRs text within fraction of time. Cloud-based computing, when combined with AI and Machine Learning can improve the cost-efficiency, scalability, and simplicity of PV. Social media networks are trusted by a majority of people and thus, social media could extend the scope of PV experts, and AI can translate this trust into improved drug production. Personalized medicine, in collaboration with AI, could analyze thousands of markers to better predict how drugs will affect specific individuals and thus help in improved PV. Using nanomedicine and drug delivery, implantable nanorobots are also being developed to improve drug delivery with AI tools such as neural networks, fuzzy logic and integrations [58]. Though AI and machine learning integration in pharma and healthcare is growing, there are challenges associated with the technology that need to be considered. Predictive analytics, real-time monitoring, natural language processing, and personalized medicine are some of the areas of focus. Despite of the growing concerns, it is expected that AI in PV will continue to nurture in the coming years [53,59,60].

6. CONCLUSION

Man-made intelligence-based investigation can present curiosity at each level of drug development, yet it is difficult to instrumentalise the conventional PV especially for the vast and variable PV data. Besides, prediction of adverse drug reaction by contemplating the data is another massive task with several challenges with respect to end to end case processing, large case volume processing, complex regulatory dynamics and difficulty in processing benefit-to-risk ratio. Simulated intelligence is arising as an answer for addressing key difficulties and to give new freedoms related to various parts of PV. Artificial Intelligence emerged as a refuge for PV to supersede the traditional manual PV hurdles. Integration of AI in traditional AI is itself a very intricate process and is filled with lots of knowledge outsourcing. Furthermore, new processes come with their own pro and cons. A drug safety professional may not have extensive AI training to implement new technologies effectively. In the digitalized world, data protection with patient confidentiality is another challenge to face. However, AI tools will be beneficial in retaining the faith of medical professionals and patients. Besides, prompt adverse effect prediction of AI tools will be a linchpin in PV success.

7. Key Points

- Pharmacovigilance (PV) is an essential tool for timely detection of adverse drug reactions.
- In new age era, role of PV has intensified with more inflow of real time data, data collected from clinical care throughout the drug development cycle.
- These need newer tools to sense, pool and analyze the data to detect potential adverse effects.
- Artificial intelligence (AI) algorithms can analyze the data collected by the system to identify patterns, predict adverse events, and provide personalized treatment recommendations.
- The advantages come with new challenges, which need to be addressed before paving the way for AI in PV.

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