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INFLUENCE OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

Sankara Narayanan K., Asha Sree Kumari, A. K, L.V. Vigneshwaran*, M. Senthil Kumar

Sree Abirami College of Pharmacy, Coimbatore-21.

***Corresponding Author: L.V. Vigneshwaran**

Sree Abirami College of Pharmacy, Coimbatore-21.

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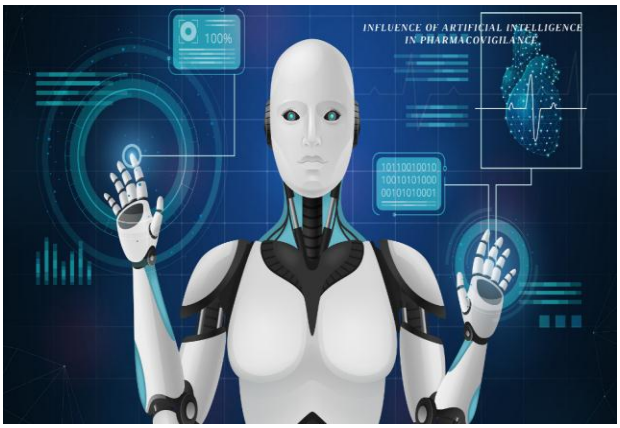
ABSTRACT

Pharmacovigilance is the science and practice of detecting, assessing, comprehending, and preventing pharmacological side effects and other drug-related issues. PV collects a lot of data daily all around the world, and processing all of that data is a difficult effort. Artificial intelligence (AI) has the potential to lower case processing costs and boost PV activity. PV was created to ensure the safety of patients who are only exposed to therapeutic medications in clinical trials and research. Bringing novel medications to market poses a significant challenge in terms of drug safety. Future toxicity and safety issues, including rising polypharmacy and patient diversity, will put these established techniques to the test. Artificial intelligence and robots in health care are rapidly evolving, particularly for early detection and diagnostic applications. Artificial intelligence and robots in health care are rapidly evolving, particularly for early detection and diagnostic applications. Because there are advantages in the process, the future of AI in health care is not entirely hopeful. The application of AI in the world's healthcare system suggests that present rules are in favor of it. It has been demonstrated that the norms of technology development and health technology product development may be established and used in medical care.

KEYWORD: Artificial Intelligence, Pharmacovigilance, Healthcare, Drug Safety, Adverse Drug Reaction.

INTRODUCTION

Pharmacovigilance is the weapon for Drug Safety research and practices are connected to the identification, assessment, understanding, and prevention of adverse effects or any other drug-related problem. Pharmacovigilance requires a foundational research model for the future that would give clarity in scope and direction, as well as identify areas where further work would be beneficial.[1] Pharmacovigilance systems were first used in the biomedical field fifty years ago and have since played an important role in drug safety monitoring. Pharmacovigilance researchers have been looking for a real-time, continuous, and prospective strategy for a long time.[2] In pharmacovigilance, artificial intelligence (AI) is increasingly being applied (PV). Artificial intelligence (AI), a multidisciplinary field, is becoming more prevalent in pharmacovigilance (PV). The field of Artificial Intelligence in Pharmacovigilance (AIPV) is quickly increasing, according to a MEDLINE search for the phrase artificial intelligence and pharmacovigilance.[3] Automation may serve as a viable scalable option for ICSR (Individual Case Safety Report) intake and processing for a biopharmaceutical business to satisfy its commitments to patients and regulatory authorities about the safe use and distribution of its medicines. The goal of augmented intelligence isn't to replace pharmacovigilance professionals, but to aid them in making consistent decisions so that, over time, a more reliable and cleaner dataset is available for more robust and timely signal detection, which will better inform the actions taken in response to those signals. Automation is just the beginning of a shift in medication safety that will lead to greater product control, more proactive pharmacovigilance, and a better knowledge of the risk-benefit profiles of medical goods for improved patient safety.[4]



ARTIFICIAL INTELLIGENCE INFLUENCES IN HEALTHCARE

"Intelligence is defined as the capacity to solve problems or generate products that are valued in one or more cultural contexts".[5] Technology plays a critical part in today's world. Technology has a role in making human

jobs easier and more efficient. In addition, technology plays an essential role in the health industry in reducing mistakes caused by human error.[6] To apply this modern technology of Artificial Intelligence to pharmacovigilance would require substantial effort in terms of not only technology development and implementation but also change management to attain the advanced form in the Healthcare system.[7]

PRE-CLINICAL DRUG SAFETY

AI techniques have been shown to play an important role in pre-market drug safety, especially in the area of toxicity evaluation. Drug toxicity determination is the main step in drug design and involves identifying the AEs of chemicals on humans, plants, animals, and the environment.[8] Pre-clinical evaluations are a necessity for preventing toxic drugs from reaching clinical trials. Despite this, high toxicity is still a major contributor to drug failure accounting for two-thirds of post-market drug withdrawals and one-fifth of failures during clinical trials. Thus, accurate toxicity estimates are necessary for ensuring drug safety and can help reduce the cost and development time of bringing new drugs to market.[9] Animal studies have historically been the most conventional approach taken to assess toxicity.[10]

BENEFITS OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

With the rise of AI in PV, PV experts may be concerned about their career prospects. A brief study of PV specialists at a pharmaceutical business indicated a generally positive view on AI in PV, such as that it will allow humans to shift from high-volume, highly routinized labor to more meaningful, high-value work.

PV experts achieve nearly 100 percent accuracy/compliance in critical areas, which is difficult for a machine to match, highlighting the necessity to carefully set operational goals for AI in PV, such as reducing the median time for human-in-the-loop during ICSR case processing.[7] Without the need for humans, AI algorithms gather data from adverse drug event forms and assess case validity.

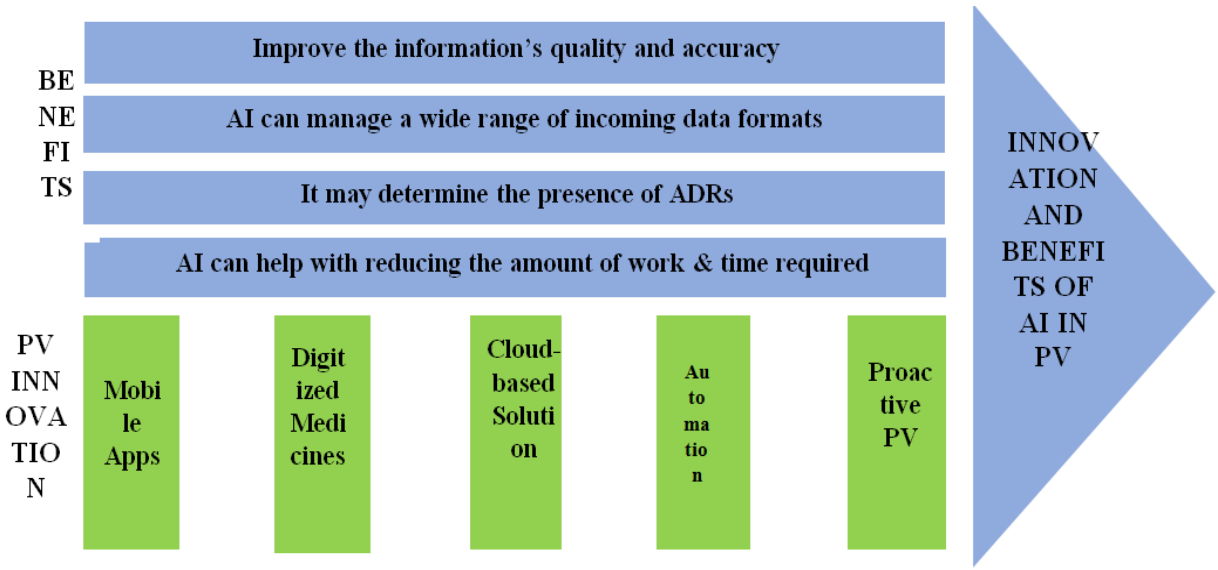


Fig. No. 1: Innovation and Benefits of AI In Pharmacovigilance.

The approval of life-saving treatments like anticancer, antitubercular, and antiretroviral therapies is based on a fast-track system so that these drugs may be quickly accessible to patients, and PV is in charge of assessing, communicating the risk, and performance of these medications. There are several AI applications in PV, and it is certain to have a financial influence on the industry.

I. Error-free reporting promptly:

Artificial intelligence is a fantastic application for automating monotonous chores. Direct annotation of source documents, which is time-consuming and expensive, may be automated and owing to rigorous guidelines, human mistakes can be eliminated.

II. Patient experience is improved:

Patient safety is the ultimate aim of all pharmacovigilance activities. The use of machine learning to monitor the PV process improves medication safety and treatment accuracy. More rapid identification of safety signals helps to the most effective use of medicines and improve patient safety. Risk-mitigation techniques might be implemented more quickly and with greater precision.

III. Safety insights based on data

The growing size of data sets and sources makes it hard to handle pharmacovigilance data only through expert labor. The demand for streamlining is enormous, and data science solutions may help by automating the analysis, offering intelligent, meaningful insights, and making forecasts.[11]

DEFECTS OF ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

There are adverse effects, warnings, and precautions when using AI in PV, just as there are with medications and gadgets. It's not uncommon for research to be skewed among peer-reviewed, grey, and commercial publications. The amount of potential real-world deployment is limited.[12] Security difficulties and AI implementation duties in clinical settings, as well as a lack of transparency for some, AI algorithms and privacy issues for data utilized for AI model training. Some of the ethical issues that AI clinical applications encounter are listed below.[6]

Fig. No. 2: Ethical issues that AI clinical application.

THE FUTURE OF PHARMACOVIGILANCE

Teams in charge of drug safety are under a lot of pressure to accomplish more with less. To be more conscientious and make certain that the highest standards are reached. Pharmaceutical companies are being forced to rethink pharmacovigilance as the number of safety incidents continues to climb at an exponential rate and the amount of data that must be analyzed expands.

Artificial intelligence has already been established in the business and shows enormous potential for safety and pharmacovigilance. Automation, artificial intelligence, and machine learning technologies offer an opportunity to move the pharmacovigilance role away from data collection and reporting and toward improving product quality, treatment regimens, cost reduction, and patient safety. Digitalization, artificial intelligence analytics, and patient-centered data collecting are the future of pharmacovigilance, and they will almost certainly improve overall medication safety. The PV sector has been looking for a long-term solution to untenable ICSR (Individual Case Safety Report) quantities, and by adopting AI, we can enhance our approach to PV and aim for excellence in our operations for the benefit of our patients.[13]

FOCUS ON PHARMACOVIGILANCE THROUGH AI

The first thing to keep in mind is that the types of data that need to be processed and evaluated in PV operations are quite diverse and vary substantially in terms of "number" and "quality." On one end of the "data spectrum," we have PV data from clinical studies, where all reports are rigorously monitored and every data is examined, monitored, and validated. Furthermore, broad use of these novel sources will necessitate a significant rethinking and reshaping of many detection and management procedures inside a MAH's (Manufacturing Authorization Holders) PV system.

Medical Literature Monitoring (MLM), which is peer-reviewed, is another important source of safety data, and the peer-review method should assure the data's credibility. The data collected with the use of new PV applications, which are becoming increasingly popular in developing nations, is of comparable quality, if not slightly higher. The WEB-RADR (Web-Recognizing Adverse Drug Reactions) Consortium has done some work in this area.[14]

IDENTIFY DRUG SAFETY DURING DRUG DEVELOPMENT

The use of neural networks to assess multifocal electroretinograms for early diagnosis of hydroxychloroquine toxicity is one example of AI's possible uses in this area. Automating processing processes applicable to ICSRs, where natural language processing and machine learning are already being utilized to extract ICSR information, is becoming a more prevalent usage of AIPV. Artificial intelligence (AI) can recognize complicated pathways that lead to a certain outcome.

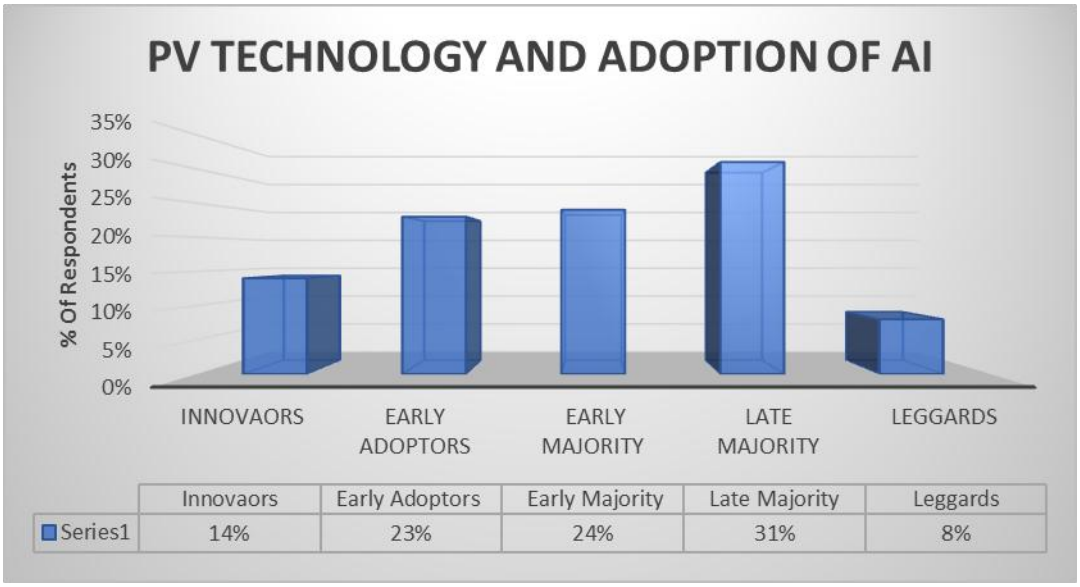


Fig. No. 3: Pharmacovigilance and Adoption of AI.

Identifying toxicity during medication development, for example, might lead to worse patient outcomes. Even though smaller, typical preclinical animal toxicological data sets are less favorable to AI, it is appropriate not to limit searches to human research to avoid missing papers regarding AIPV for transspecies toxicity prediction. AI can detect complicated processes that contribute to negative patient outcomes, such as toxicity during medication development.[15]

CONCLUSION

In the realm of pharmacovigilance, generating accurate and timely safety profiles across the course of a drug's market life is a continuing struggle, yet it is crucial for patient safety. AI-assisted medication safety measures might grow more advanced in the future. In the realm of AI, more study in the area of PV is required. AI, databases, and software are still in the early stages of development, and their progress in the field of PV might be significant in the future. Through the presence of Artificial Intelligence in PV, it's been easy to analyze the drug toxicity level and prevent the cause of drug toxicity during the formulation of dosage forms. In the future, may have the chance to get drugs without causing any adverse drug reaction through the involvement of AI in Pharmacovigilance.

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