# Enhancing the Patient Safety by using the Explainable Artificial Intelligence in Pharmacovigilance

**Ganesh S A[1], Megha Rani Raigond[2]**

[1]Department of CSE Visvesvaraya Technological University Kalaburagi, Karnataka India

[2]Department of CSE Visvesvaraya Technological University Kalaburagi, Karnataka India

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**Abstract -** The Artificial intelligence is a technology in pharmacovigilance (PV) and in explainable artificial intelligence used a tree-based approach (Random Forest Classifier) that enhances the artificial intelligence. Though there have been many previous attempts to select papers, with a total of 781 papers being confirmed, only 25 of them manually met the selection criteria. Side-effects of drugs and interaction studies. Adverse drug reaction (ADR) is widely concerned for public health issue. ADRs are one of most common causes to withdraw some drugs from market. Prescription event monitoring (PEM) is an important approach to detect the adverse drug reactions. The main problem to deal with this method is how to extract the side-effects from medical events (drug reactions), which are collected from day-to-day clinical practice which is extracted from big medical data from the Health Improvement Network database, is created to characterize the medical events for the patients who take drugs. The detected adverse drug reactions are based on computerized methods further investigation is needed. In this project it provides the side-effects of medicines(drugs) to be aware of tablets they were using in their daily life based on the real data it performs and the data is collected from recent medical healthcare. This project's goal is to determine uses and providing the adverse drug reaction or side-effects of medicines and studies in employing XAI in the pharmacovigilance (PV) domain. While artificial intelligence (AI) is being utilized extensively in drugs safety for the patient by XAI. AI model goals align with the patient safety goals to reduce harmfulness of drug to the data addressing security and privacy concerns for patient, the accuracy of this XAI project is 82 %.

***Key Words***: predict the drugs for patients safety, by using the tree-based algorithm (random forest classifier).

## 1. INTRODUCTION

The world health organization defines the pharmacovigilance (PV) as the science and activities related to the detection, assessment, understanding and prevention of adverse effects or other drug-related problems Artificial intelligence (AI) can improve PV, but its use in PV is still in the early stages of research. Various machine learning (ML) techniques, together with natural language processing and data mining, can be applied to electronic health records, claims databases and the social media data to improve the characterization of known drug side effects and reactions, and to detect new signals AI-based technologies have been criticized for their inexplicable algorithms, despite their high predictive power. In critical decision areas such as healthcare, the reasoning behind a decision is as important as the decision itself, which is why there is growing interest in and research and development around Explainable Artificial Intelligence (XAI) XAI was developed to improve the transparency of AI systems and generate explanations for them, and seeks to increase trust and understanding by assessing the strengths and limitations of existing models Recent artificial intelligence-based technologies can be an efficient complement to traditional PV methods, which can be costly and time-consuming and can result in adverse drug reactions (ADRs) that go unreported to healthcare professionals. Approaches that extract information from a model's decision-making process, such as post-hoc explanations, can provide useful information for practitioners and users interested in case-by-case explanations rather than the internal workings of a model XAI increases the explainability and transparency of AI algorithms by making it possible to interpret the variables that influence decisions, complex internal features, and learned decision paths within a decision process I.R. Ward et al. successfully quantified the importance of features using an XAI algorithm, further demonstrating the potential contribution of XAI to PV monitoring importance of PV in medicine is relevant to all species affected by medical interventions, and ensuring medical safety requires attention and research into approaches such as drug safety reporting and the exchange of reliable and timely information on PV activities. The global pharmacovigilance and drug safety software market size was valued at USD 6.9 billion in 2021 and is estimated to expand at a compound annual growth rate (CAGR) of 10.5% between 2022 and 2030 The aim of this study was to review the literature on the use of XAI in PV by identifying publications related to ML/AI and drugs and the rationaled for the reported findings. From the perspective of

AI and XAI usage, these studies were analyzed, and the findings were summarized, in which the use of XAI in the field of PV is referred to as “PV XAI”. The main contributions are highlighted and discussed This study is clearly an early attempt to review XAI research in PV. Unlike other fields, we found that XAI research in PV is at an early stage of development, limited to a few articles and some methodologies [1]. The primary type of data used in PV are individual case safety reports (ICSRs), which are records of suspected adverse events collected via multiple channels, aggregated and organized into large databases, and constantly monitored to detect safety signals [2]. ICSRs come from a multitude of sources, including chatbot interactions, electronic health records (EHRs), published literature, patient registries, patient support programs, or even directly from patients via social media [3]. Reports are collected worldwide and characterized by heterogeneity in format, language, and unique characteristics of the underlying healthcare systems. Adverse events must be identified and analyzed in order to find the potential emerging safety issues in medicines and vaccine. The central challenge of PV is how to make sense of these large and heterogeneous data to quickly and reliably find the ‘needles in the haystack’, which are safety signals that require escalation and triage [4]. Care must be taken when attempting to extrapolate the success of ML in other areas compared with PV since there are specific factors that may account for the recent success of ML that may or may not be present for PV applications [5].

## 2. BODY OF PAPER

Divya, P et al. [6] has proposed the Pharmacovigilance: The Etymological roots for the word “Pharmacovigilance” are Pharmaco (Greek) = medicinal substance, and Vigilance (Latin) = to keep. watch.Rifat et al. [7] has proposed the pharmacovigilance (PV) is the science and actions relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. Adverse drug reactions are reported world in a variety of languages and formats, as well as in organised, unorganized, and handwritten documents; on average, several businesses get more than 3 lakh ADRs annually. With manual processes, human mistake is possible, and the whole project cost eventually increases. It is possible to apply AI-based technology to enable case validity assessment and extraction from AE source documents. Automation is the process of carrying out tasks or eliminating tasks with the aid of technology, hence minimising human dependency. Many government health authorities participate in pharmacovigilance activities on a daily or irregular basis. Machine learning (ML) and artificial intelligence (AI), as described by Lewis and McCallum, have begun to alter how safety and pharmacovigilance (PV) experts handle and interpret data to support decision making. Devlin et al. [8] has proposed the AI is the advent of transformer-based language models, that can achieve state-of-the-art (SOTA) performance in a wide range of natural language processing (NLP) tasks. Brown et al. [9] has proposed the Data set size and the number of parameters tend to increase exponentially with language model development in pursuit of improved model performance. For example, the GPT3 model consisted of 175 billion parameters and was trained with 499 billion tokens. A. D. Torres et al. [10] has proposed the Artificial Intelligence (AI) based algorithms, especially using deep neural networks, are transforming the way we approach real-world tasks done by humans. Recent years have seen a surge in the use of Machine Learning (ML) algorithms in automating various facets of science, business, and social workflow. The surge is partly due to the uptick of research in a field of ML, called Deep Learning (DL), where thousands (even billions) of neuronal parameters are trained to generalize on carrying out a particular task. Successful use of DL algorithms in healthcare. Douglas J. et al. [11] has proposed the other algorithms, on the other hand, are much more transparent and let the developers know what their “thought processes” were. Decision trees are a good example of transparent algorithms. This distinction became important when banks started granting or denying credit based using the machine algorithms. When some clients, who had been as judged at high risk of insolvency sued them, the organizations that were using for example neural network algorithms, were unable to explain in court why the decision was taken and found themselves in a difficult situation. E. Bunde et al. [12] has proposed AI-based technologies have been criticized for their inexplicable algorithms, despite their high predictive power. In critical decision areas such as healthcare, the reasoning behind a decision is as important as the decision itself, which is why there is growing interest in and research and development around Explainable Artificial Intelligence (XAI). XAI was developed to improve the transparency of AI systems and the generate explanations for them, and seeks to increase trust and understanding by assessing the strengths and limitations of existing models. Approaches that extract information from a model’s decision-making process, such as post-hoc explanations, can provide useful information for practitioners and users interested in case by-case explanations rather than the internal workings of a model. J. K. Aronson et al. [13] has proposed Artificial intelligence (AI) can improve PV, but its use in PV is still in the early stages of research. Various machine learning (ML) techniques and together with natural language processing and data mining, can be applied to electronic health records, claims databases and social media data to improve the characterization of known drug side effects and reactions, and to detect new signals. Marcum et al. [14] has proposed an Rising attention has been paid to the early warning of adverse drug events (ADEs) in hospitalized children. ADEs are defined as medication-related patient injury caused during any stage of the medication process, some of which are preventable due to errors, whereas some are adverse drug reactions (ADRs) and non-preventable. Sakuma et al. [15].

AI models: includes the tree based, neural network, graph-based models.

• Tree-based-model: ML model with the XAI techniques can act as an early warning system for per patient disease related adverse outcomes and harmful drugs in a pharmacovigilance system.

• Neural-network-model: It is based on idea that the computations of the neuron involves the waited some of input values where the waited some core response for the combination of these neuronal values and the value scaling performed by the synapses rather then the simply outputting a waited some a neuron perform a functional operation on a combine inputs with in neuron.

• Graph-based-algorithm: the graph neural networks GNNS a pioneering study of deep learning methods in non-euclidean spaces GNNS generate the random state embedding vectors and the state of nodes.

A. Data selection

The dataset used for this project is a part of the Open Source collection and is publicly available. Data is collected from the Kaggle, and it saved in Microsoft excel in table form. It is used to predict the drugs for patients safety, it is used to predict the drug name in this project.

B. Preprocessing

The preprocessing method means executing the other drugs also. The feature set was augmented with new drug names in order to prepare the dataset hence, improving its representation before feeding into a Random Forest Classifier. Scaling is performed on the features to standardize them. The target variable is scaled such that values below 0 are worse outcomes and values above 0 are better ones. This helps to transform both positive and negative results that the model should capture. On the whole, this step of preprocessing affects not only better performance but also convergence when training the model.

C. Tree based Model Development

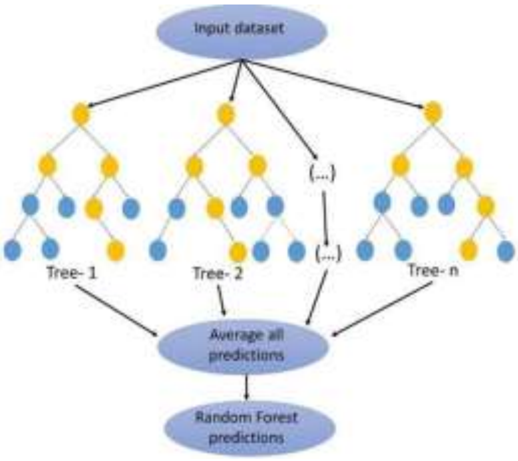


**Figure 1: Architecture of drug prediction system**

It consists of more then one tree i.e., sub-trees and in this the result will be majority of voting is the final output and it is also an known as the bagging technique, and the RFC is the classification of the supervised learning.

D. Random Forest Classifier

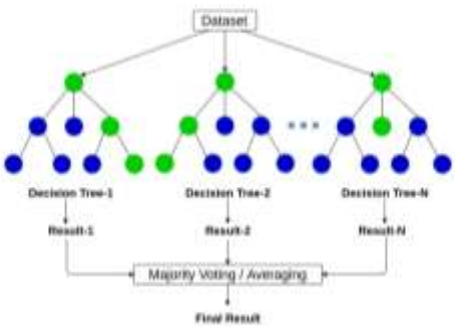


**Figure 2: Architecture of Random forest classifier**

Random Forest, combined with SHAP/LIME, not only predicts adverse drug reactions with high accuracy but also provides transparent explanations, which enhances patient

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safety and the supports are provide the trust worthy pharmacovigilance decisions.

## 3. CONCLUSIONS


**Figure 3: Invalid data**

The above figure shows that entered drug name is invalid because it is not exists.

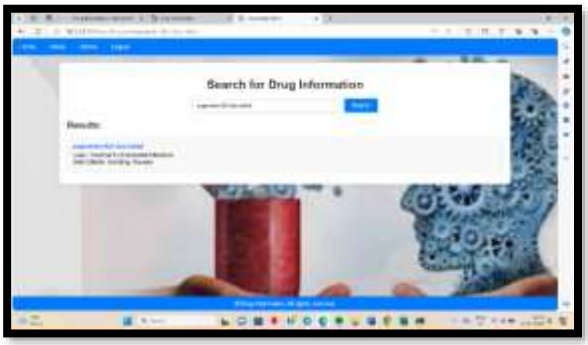


**Figure 4: valid data**

In the above figure should be entered drug name for prediction is valid.

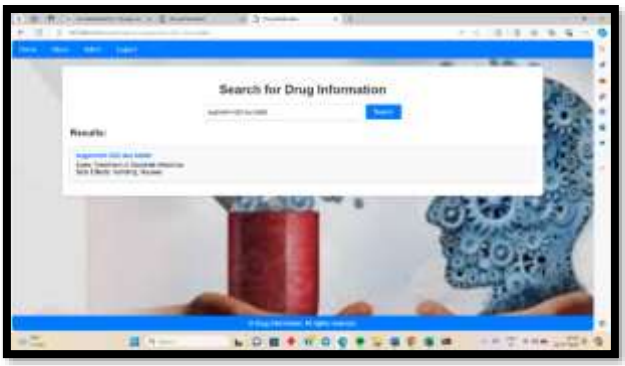


**Figure 5: Result page**

The above figure shows where we get the predicted result as the uses and side effects of drugs.

Considering the outcomes of the entire process that was conducted completed in a building an application for classifying drug safety using the tree-algorithm, this study shows that the neural network algorithm can classify drugs safety for the patients well. And the accuracy of this project is 82 %. Because it gives the information of the medicines on recent data to prevent the harmfull side-effects of drugs for the diseased patient, from the results of the tests that have been carried out, this study can implement the algorithm in pharmacovigilance, the aim was to access the extent to which the PV has been improved by the current learning based on the AI-techniques. The traditional AI-model despite their high accuracy often operate has like artificial intelligence making it challenging for the health care professional to understand the problems behind the predictions. The models used in the paper is developed employing python libraries such as NumPy, Pandas, joblib, sklearn, train_test_split, etc. The dataset contains an many drug names to predict the drug for patients safety.The drug is predicted by using this project and to enhancing drug safety monitoring in pharmacovigilance. These model can effectively identify the potential safety signals and classify detected alerts into the different categories. There is discussion of how to predict the drugs for the patient safety about the awareness of the drugs they were taking in their daily life and predicting the drugs for patient safety is critical for the enhancing patient safety pharmacovigilance and the various methodologies particularly tree-based models and the machine learning techniques, have been effectively employed to identify the potential adverse drug events. In the previous result there is no uses of the drug to prevent the related disease of them, and also there is no information of side effects

of the disease they were facing in their life. But in this project they can able to know the uses of the drugs to prevent the disease and they can also able to know side effects of the medicines. It gives the information of the medicines on recent data to prevent the harmfull side-effects of drugs for the diseased patient, from the results of the tests that have been carried out, this study can implement the algorithm in pharmacovigilance, the aim was to access the extent to which the PV has been improved by the current learning based on the AI-techniques. The traditional AI-model despite their high accuracy often operate has like artificial intelligence making it challenging for the health care professional to understand the problems behind the predictions, the accuracy of this project is 82%.

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**REFERENCES**

[1]. Suenghee Lee Suehyun Lee received the Ph.D. degree in medical science from Seoul National University College of Medicine, Seoul, South Korea, in 2017.

[2]. Office of the Commissioner. Individual Case Safety,Reports.2019.Availableat: https://www.fda.gov/industry/fda-resources-data-standards/individual-case-safety-reports.

[3]. Stergiopoulos S, Fehrle M, Caubel P, Tan L, Jebson L. Adverse drug reaction case safety practices large biopharmaceutical organizations from 2007 to 2017: an industry survey. Pharmaceutical Med. 2019.

[4]. Edwards RI. Adverse drug reactions: finding the needle in the haystack. BMJ.

[5]. Bate A, Hobbiger SF. Artificial intelligence, real-world automa- tion and the safety of medicines. Drug Saf. 2021;44:125–32.

[6]. Divya, P., Susmita, A., Sushmitha, P., Ch, R.

and Chandini, K., 2022. Automation in pharmacovigilance: artificial intelligence and machine learning for patient safety. Journal of Innovations in Applied Pharmaceutical Science (JIAPS), pp.118-122.

[7]. Rifat, M.J.R., Noori, S.R.H. and Hasan, M.R., 2019, July. Pharmacovigilance study of opioid drugs on Twitter and PubMed using artificial intelligence. In 2019 10th International Conference on Computing, Communication Networking Technologies (ICCCNT) (pp. 1-7). IEEE.

[8]. Devlin, J., Chang, M.-W., Lee, K., and Toutanova, K. (2018). Bert: Pre-training of Deep Bidirectional Transformers for Language Understanding preprint.

[9]. Brown, T. B., Mann, B., Ryder, N., Subbiah, M., Kaplan, J., Dhariwal, P., et al. (2020).

[10]. A. D. Torres, H. Yan, A. H. Aboutalebi, A. Das, L. Duan, and P. Rad, “Patient Facial Emotion Recognition and Sentiment Analysis Using Secure Cloud With Hardware Acceleration,” Comput. Intell. Multimed. Big Data Cloud with Eng.

[11]. Douglas J. The Apple Card algo issue: What you need to know about A.I. in everyday life. 2019.

[12]. C. Meske and E. Bunde, “Transparency and trust in human-AI-interaction: The role of model- agnostic explanations in computer vision-based decision support,” in Proc. Int. Conf. Hum.- Comput. Interact. Berlin, Germany: Springer, Jul. 2020, pp. 54–69.

[13]. J. K. Aronson, “Artificial intelligence in pharmacovigilance: An introduction to terms, concepts, applications, and limitations,” Drug Saf., vol. 45, no. 5, pp. 407–418, May 2022, doi: 10.1007/s40264- 022-01156-5. And R. Ball and P. G. Dal, “‘Ai-pharmacovigilance: Ready for prime time?” Drug Saf., vol. 45, no. 5, pp. 429–438, 2022.

[14]. Marcum, Z. A., Arbogast, K. L., Behrens, M. C., Logsdon, M. W., Francis, S. D., Jeffery, S. M., et al. (2013). Utility of an adverse drug event trigger tool in veterans affairs nursing facilities. The Consultant Pharmacist 28, 99–109. doi:10. 4140/tcp.n.2013.99.

[15]. Sakuma, M., Ida, H., Nakamura, T., Ohta, Y., Yamamoto, K., Seki, S., et al. (2014).