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PHARMACOVIGILANCE
AUTOMATION IS THE FUTURE

Whitepaper

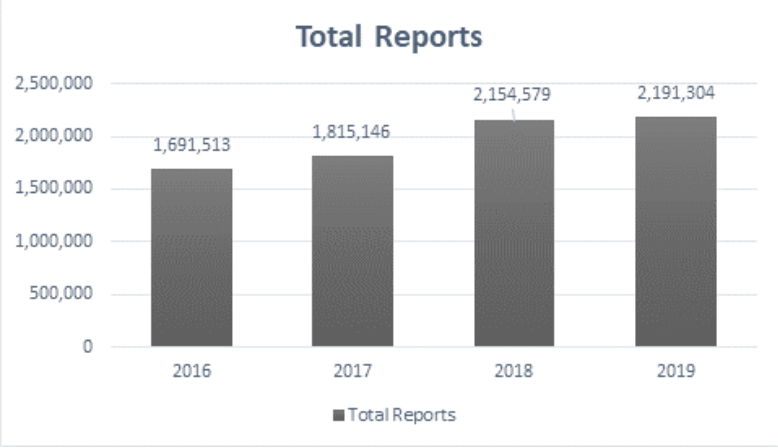
INTRODUCTION

Safety is a critical factor for any drug to sustain in the market. Pharmaceutical companies need to closely monitor the drug in clinical and post-marketing set up to ensure that the drug is safe and effective. The pharma companies are responsible for the collection of the safety data from multiple sources (such as patients, healthcare professionals, lawyers, hospitals, health authorities, patient support programs, patient registry, social media, etc.), evaluation, and periodic sharing of reports to the regulators.

THERE ARE MULTIPLE CHALLENGES IN PHARMACOVIGILANCE, WHICH PRIMARILY INCLUDES:

- The collection of adverse event data from various sources like spontaneous, literature, social media, etc., may lead to noisy data. Such data may not be useful to determine the safety signal during the signal detection process.
- Variations in the format of reports from different sources makes the process of preparing ICSR reports complex.
- With the increase in the amount of data collected year on year, ensuring the right insights on the safety of a drug is a challenging process.
- Pharmacovigilance processes are complex, labor-intensive, and costly.

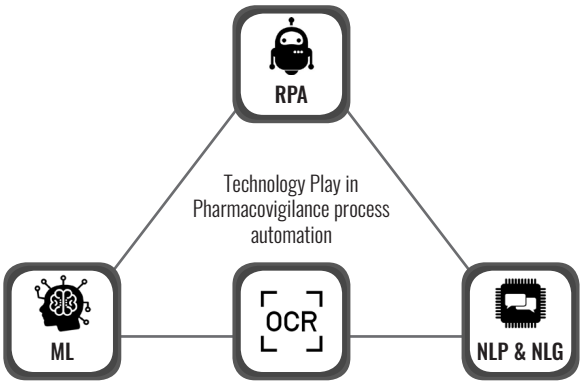
As per FDA FAERS public dashboard report, in the year **2016, 1,691,513** reports were received by report type that is increased by **29.54%** to **2,191,304** reports in the year **2019.**



These challenges have forced the pharma organizations to think alternatively and address them with the help of modern-day technologies.

LEVERAGING NXTGEN TECHNOLOGIES IN PHARMACOVIGILANCE

Robotic Process Automation (RPA) coupled with NXTGen technologies like Machine Learning (ML), Optical Character Recognition (OCR), Natural Language Processing (NLP), Natural Language Generation (NLG) will help to build a robust platform to serve pharmacovigilance needs.



ROBOTIC PROCESS AUTOMATION (RPA)

Robotic Process Automation (RPA) helps to automate repetitive tasks, reduce manual labor, time and increase efficiency and quality of the task. Some of the open-source programming languages that can be utilized to build RPA are python and selenium.

In most of the pharmacovigilance processes, the business logic and conventions are clearly defined. Implementing RPA in data entry processes will help to overcome common issues like oversight errors and generate quality reports within a short time.

The trained bots are also capable of coding the medical history, laboratory information, and adverse events with MedDRA. The company product, concomitant medication, and past drug history can be effectively coded with the WHO drug dictionary by training the bot. RPA effortlessly carries out auto-scheduling of reports in the safety database and makes the case ready for the medical review.

OPTICAL CHARACTER RECOGNITION (OCR)

Optical Character Recognition (OCR) helps to convert images, PDF files, and scanned documents into editable and searchable data.

The availability of a wide range of OCR tools has made it possible to have a 100% extraction of data from adverse event report forms. Available OCR tools can be used based on their cost and quality of data extraction. Some of the open-source tools include Calamari, OCRopus, and Tesseract. OCR tools with cloud services include Abbyy Cloud, Google Cloud Vision, and Microsoft Azure Computer Vision. OCR tools will essentially help in the data entry process, which needs accurate data extraction from report forms. In Pharmacovigilance, source data is received in various formats such as PDF, images and scanned paper documents, etc. Choosing the right OCR engine will help to get better quality data.

NATURAL LANGUAGE PROCESSING (NLP)

Natural Language Processing (NLP) employs a computational method for learning, understanding, and producing human language content. NLP plays an important role in handling unstructured data by converting it into structured data. NLP techniques can be applied to extract information from various fields of source documents, including reporter information, narrative, autopsy data, etc. NLP has potential in digital media screening, extracting, classifying data from source documents, and checking for duplicates.

MACHINE LEARNING (ML)

Machine Learning (ML) is a powerful tool that helps the system to automatically learn and improve from experiences that helps in recognizing patterns and perform prediction. ML helps in automating pharmacovigilance in multiple tasks, primarily those which include supervised and unsupervised learning. To add, it helps in handling the mailbox of the safety team by identifying adverse event reports and categorizing adverse event mails as expedited, and non-expedited. These mails are prioritized on the basis of seriousness, initial receipt date, and reporting country.

Instead of direct annotation of source documents, algorithms are trained using the data fields of the safety database to reduce the time and cost of annotation. Open-source tools such as python and selenium can be effectively utilized to build the ML model to perform assigned pharmacovigilance tasks.

According to a study, the ML ensemble model of Causal Sentence Classification was able to classify 84% of the actual causal relationships between a drug and a medical condition in the test dataset. ML also helps in determining the Adverse Drug Reaction (ADR) signals in signal detection.

NATURAL LANGUAGE GENERATION (NLG)

Natural Language Generation (NLG) is a process that automatically transforms data into Plain-English content. NLG finds potential use in writing safety narratives with the help of structured data inputs.

The combination of technologies like RPA, OCR, ML, NLP, and NLG can add a lot of value and efficiency to Case Intake, Case Prioritization, Data Entry, Reporting, and Evaluation, Signal Detection, etc.

Key challenges in adopting automation and new technologies in Pharmacovigilance

The regulators are continuously trying to build a drug safety provision to build good quality, safe and effective medicines. These changing regulations need to be kept in mind while grouping technologies to ensure compliance with data privacy regulations.

CONCLUSION

The ultimate goal of automation is to transform pharmacovigilance into a quality-driven process, which will help to evaluate the benefit/risk profile of the medication. Maximizing accuracy in evaluating the benefit/risk profile of medication will benefit the patients by ensuring the safe use of the medication.

However, the success of Pharmacovigilance automation depends upon choosing the right combination of technologies. Also, we cannot rule out the dependency of automation based on the regulatory challenges along with regular up-gradation of the safety database. We cannot deny the fact that there is a possible solution for every complex issue that we encounter while automating the processes which require human intelligence. Automating the Pharmacovigilance processes will help pharmaceutical companies to generate quality reports with lesser investment and also help to utilize the human resources effectively in value-added tasks.

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