ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

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Pharmacovigilance

To track and monitor the adverse reactions experienced due to any drug/vaccines is the objective of Pharmacovigilance.

Anyone who is taking drug/ vaccine and has experienced any adverse reaction, or any unexpected benefit can report this to the Regulatory agencies or the Drug Manufacturers.

Why artificial intelligence in pharmacovigilance

Now that we know where to report the adverse reactions lets understand what pharmacovigilance process is and why AI is needed in this practice.

Pharmacovigilance (PV) is a complex process of identifying, tracking, and reporting of adverse events. This process is time consuming, repetitive, and manual. Over few decades awareness on reporting the adverse events to the Government bodies/ Drug Manufacturers has increased which has led to the rise in reporting of adverse events to the Drug Manufacturers. This reporting is done by the patients and HCPs through various means which in turn increases the Case volume. This sometimes leads to being non-compliant to Regulatory Authorities with the cases being unreported.
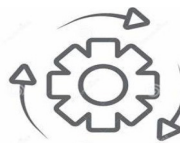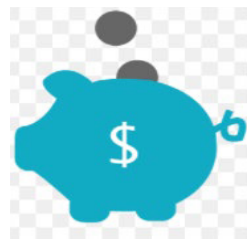
Artificial Intelligence is used to automate the end-to-end PV process fully/partially. Moreover, Artificial Intelligence and Machine learning are used to augment human efforts in making better decisions and ensuring regulatory compliance.

Challenges

- Manual extraction of Data from various sources is time intensive and could lead to loss of important data.

- Database the extracted information within the regulatory timelines.

- Increased Volume in the number of cases being reported.

- Bandwidth issue (Skilled Human resource) and lack of PV process knowledge.

- Increased volume in the number of cases leading to non-compliance in reporting.

Benefits using AI

- Data extraction using AI optimizes accuracy and saves time.

- Using AI reduces the Turnaround time, allowing the MAH to submit the information to the Regulatory authorities within SLA.

- The machine can understand linguistics better and reduces the manual effort to save time.

- Artificial intelligence can be used to read the text by imitating the human ability to understand the language.

- It can help in language translations, duplicate case search, multiple patients having adverse reaction, it can guide the reporter raising the complaint through phone calls and can help in narrative writing.

Data Annotation

What is Data Annotation: It is data categorization and labelling for AI applications.

The Major obstacle in the ICSR Case Processing is 'Event Coding' because data is received in a variety of formats such as text, voice, audio, and video. Data Annotation may be the best solution to go with if you want to save time while also focusing on lowering the risk associated with the coding. Because event coding is a critical field, developing AI and ML models that can mimic human behavior will necessitate a massive amount of data. For models to decide what needs to be coded, they must be trained to understand and analyze data.

Data Annotation can be used to label data, allowing the AI tool to identify information

used in case processing such as events, patients, reporters, products, concomitant drugs, and case seriousness.

The machine can simultaneously learn new scenarios that arise during day-to-

day Case Processing activities. Annotating multiple verbatim will allow the machine to learn and understand the sequence of events, the extraction of reporter/patient information, and product identification.
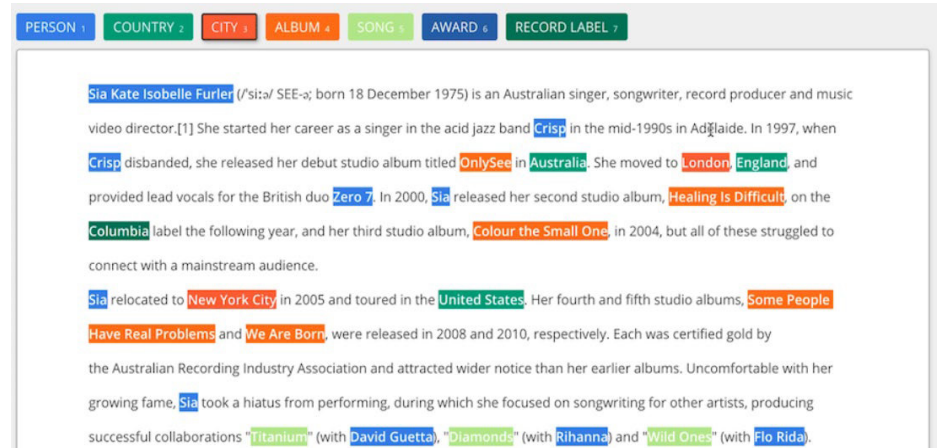

Fig: Data Annotation[1]

AI in Literature Search

Literature Review in Pharmacovigilance involves manual review of set of journals to identify the reportable adverse events for a particular drug. Manual review requires longer hours in reading the abstracts and articles in search of adverse event signals. This can still lead to oversight and under reporting of reportable events.

Introducing language heuristics as part of AI and ML capabilities can improve the accuracy of the signal search along with saving the time taken to do the search. AI can be trained to extract complex and precise data highlighting the key event signals and other

information which otherwise takes a lot of human effort.

Typical Industry Challenges and solutions[3]

Approximately 86% of the enterprises are unable to move from AI experimentation to production and **68%** of the Enterprises struggle to derive insights from their documents

Document extraction best-of-breed Artificial Intelligence (AI) and Machine Learning technologies can be used as a Solution for Literature Search extractions. These tools use pre-trained objects across

various document segments such as paragraphs, sentences, headings, and tables etc.

Chatbots Enabled PV Call Centre

PV organizations are constantly enhancing their Call Centers to address the critical challenges faced by the Patients/ reporters. Incoming volumes of calls lead to Productivity issues by the Call Center Associate. AI automation of information collection, data classification and validation ensure to improve and simplify the process, resulting increased productivity and decreased turnaround time.

Issues at Call Centers

- Information is dumped in case notes section instead of structured fields due to higher volume and story of information.

- Increase in To-and-fro communication due to unstructured data

- Turnaround Time is to be met to have timely submission by Case Processing team

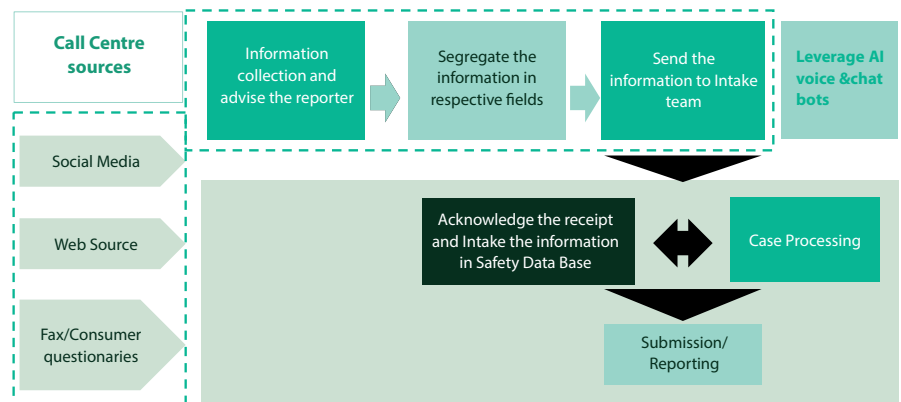- Handling large volume of data manually leads to loss in productivity

Fig: PV Call center process

Implementing AI-Powered Voice and Chat bots can have following benefits.

- Collecting the data received from the call center and place it in respective fields

- Efficient Data Cleaning and Data Validation

- Manual efforts can be reduced

- Average handling Time can be reduced

- Predictive analysis and deeper insights can be achieved

- Reduction in clarifications between Intake Team and Call Centre

Conclusion

According to Gartner, artificial intelligence is a multibillion-dollar market. According to the report, the business value created by AI will reach $3.9 trillion by 2022. This prediction is supported by a number of factors on the ground. Some of these include widespread awareness of the importance of pharmacovigilance among patients and the health care industry, stringent and dynamic regulations, and an enormous amount of data for processing and reporting. A collaboration of IT firms and life sciences firms can undoubtedly automate the entire case receipt to report process. Understanding the significance of AI's impact on the health industry, WHO also provides important guidelines for AI use

Companies will be able to analyze data more quickly as AI becomes more ingrained in Pharmacovigilance. They will be able to quickly uncover deeper and more accurate insights from massive amounts of data. This will eventually improve patient safety and reduce risk for pharmaceutical companies.

1. Humans should remain in control of health care systems and medical decisions.

2. AI products should be required to meet standards for safety, accuracy, and efficacy within well-defined use cases.

3. AI developers should be transparent about how products are designed and function before they are used.

4. AI must be designed to encourage inclusiveness and equality.

5. The performance of AI applications should be continuously and transparently assessed during actual use.

WHO Guidance for use of AI in health industry[3]

References

1. text-ann.png (897×455) (articleshubspot.com)

2. Infosys Nia - The Next-Generation Enterprise AI Platform (edgeverve.com)

3. https://ubc.com/the-future-of-ai-in-pv/

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