

**Adoption of artificial intelligence in
Pharmacovigilance during Covid-19 Pandemic. Will
the case processors benefit from the novel
technologies of ChatGPT and NLP? A case study
among the Leading CROs in Ireland**

Dissertation submitted in partial fulfilment of the requirements for M.Sc. in Pharmaceutical
Business & Technology (QQI)

Griffith College Dublin

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Declaration

I hereby certify that this dissertation entitled “Adoption of artificial intelligence in Pharmacovigilance during Covid-19 Pandemic. Will the case processors benefit from the novel technologies of ChatGPT and NLP? A case study among the Leading CROs in Ireland” which I now submit for assessment on the program of study leading to the award of the M.Sc. in pharmaceutical Business and Technology is my own; based on my personal study and research, and have acknowledged all material and sources used in its preparation. I also certify that I have not copied in part or whole or otherwise plagiarised the work of anyone else, including other students.

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Date: 11/05/2023

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Acknowledgment

I am forever indebted to god for his blessings. Praise to god for bestowing me with good health, peace, and, the willpower for completing this work.

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List of Abbreviations

Artificial Intelligence- AI

Pharmacovigilance- PV

Individual Case Safety Reports- ICSR

Machine Learning- ML

Natural Language Processing- NLP

Clinical Research Organization- CRO

Subject Matter Experts – SME

Health Products Regulatory Authority- HPRA

National Adverse Reaction Reporting System- NAARS

European Medicines Agency- EMA

Pharmacovigilance Risk Assessment Committee

World Health Organization – WHO

General Data Protection Regulation - GDPR

Abstract

Adoption of artificial intelligence in Pharmacovigilance during Covid-19 Pandemic. Will the case processors benefit from the novel technologies of ChatGPT and NLP? A case study among the Leading CROs in Ireland

Swetha Somasekharan Nair

Pharmacovigilance (PV) is an area that was extensively impacted due to Covid-19. The organizations handling PV activities had to incorporate many new technologies to cope with the stress. The finding of this research highlights how the adoption of Artificial Intelligence (AI) has impacted the PV field during and after the COVID-19 pandemic. The participants were provided with surveys and interviews and their views on the topic were collected and recorded. The finding of the study was compared to the secondary research findings and conclusion were made. Several benefits of the adoption of AI tools were showcased by the case processors who participated in the survey and interviews. It was observed how AI tools can be utilized for enhancing the daily productivity of case processors and also, how new AI tools such as ChatGPT can be incorporated into different steps for providing efficient case processing techniques. However, there were some concerns raised by the individuals performing case processing activities. Handling patient data with AI tools does come with a certain amount of risks. So, it was proposed that the case processors should be provided with adequate and systematic training to overcome the risks associated with it. The participants have put forward many suggestions on how the case processors can prepare themselves to participate in case processing without posing any threat to the patient data which is handled. The suggestions from the participants would help in enhancing the case processing techniques and thereby play a vital role in improving patient safety.



Figure 1: Phases of Clinical Trial (MS Research, 2019)

The significance of monitoring the drug once it is marketed is very important. Unfortunately, due to a plethora of reasons the drug safety information reported is very limited. This is where the role of PV activities becomes inevitable. As defined by WHO, PV is the branch of science that deals with the detection, assessment, evaluation, and prevention of adverse drug reactions (ADR) (WHO, 2021). An ADR is any noxious or unprecedented reaction that occurs in humans and has a causal relation to the drug used usually in normal doses administered to humans. It is alarming that around 4% of hospitalizations are due to ADRs caused by the prescribed drugs. This shows the importance of ADR monitoring in the day-to-day scenario (Lee and Chen, 2019) (Surendra and Garlapati, 2020) (Lathifa and Aman-Ullah, 2022).

The market for AI on a global scale reached \$10.4 billion in 2021 and is projected to grow at a Compound annual growth rate of 38% by 2030 (Shirer, 2022) (Market Analysis Report, 2023). Both developed and developing nations have seen a considerable impact of automation on healthcare. AI can be described as the technology and science of developing machines with intelligence that perform tasks similar to the human brain. Machine Learning (ML) and Natural Language Processing (NLP) are the two main subsets of AI where AI algorithms were first implemented (Zayas-Cabán *et al.*, 2022) (Ball and Dal Pan, 2022).

ChatGPT is another cutting-edge technology that utilises NLP and ML to help the users to initiate useful interactions with virtual assistants. ChatGPT is a chatbot developed by OpenAI

that can comprehend and react to intricate data in a natural human-like way. It is created to be exceptionally intelligent and accessible to the normal people. ChatGPT is remodelling the ways by which humans interact with technologies so that a new era of AI can be made possible for the coming generation (King, 2023).

In a world that continues to grow progressively data-driven, the volume of PV data being generated is continually increasing (Mittu *et al.*, 2016). This leads to resource capacity restrictions as well as an unmeasured "human error" rate in PV. Larger pharmaceutical companies in particular are being prompted by this to explore PV technologies that are more effective. During the pandemic season, the utilization of AI became more obvious due to the need of developing the vaccine in a very short period. The pandemic made an obvious statement on AI is a slowly but steadily evolving tool that PV companies should utilize to manage PV activities in a safer way.

1.2 Study context

Pharmaceutical companies across the world have a handful of activities to be performed and monitored for the successful marketing of the drug. PV is the most complex section of this process due to a large amount of data, the PV activities is being redistributed by the companies to Clinical research organizations (CROs) to maintain the integrity of the data and also to meet the regulatory timelines. Many regulatory agencies across the world are in the process of developing guidelines for the integration of AI tools in the region of healthcare. From the literature review, it is clear that AI has started influencing the field of PV. But, the number of CROs who have adopted AI or making full use of this technology is still limited. In the future, the critical aspect to be addressed is the challenges faced during the utilization of these technologies. In the Field of PV, the challenges, as well as opportunities to the case processors, should be taken into concern. The aspect of productivity will be a critical factor when we analyze the impact of AI tools on the PV system. This study emphasizes learning the advantages and setbacks of the adoption of AI in PV case processing with a main focus on case quality and productivity.

1.3 Research Aim and Objectives

The main objective is to understand the adoption of AI in PV and evaluate how far AI helped in case processing during the tough times of Covid-19. Also, to evaluate how the case processors will benefit from the adoption of novel technologies of ChatGPT and NLP and how it can be used as a productivity-increasing tool in CROs in Ireland.

1.3.1 Research questions

There are several research questions that are to be addressed with the help of this study.

1. How AI has influenced the working pattern of CROs in Ireland during COVID-19 and how they have utilized the help of novel technologies such as ChatGPT in case processing?
2. Which phases of case processing can be modified with the adoption of AI and what are the challenges the case processors have faced during the adoption?
3. How did the adoption of AI tools affect the productivity and efficiency of PV case processors?

1.3.2 Objectives

1. To evaluate the impact of AI in the pharmacovigilance case processing during the pandemic and how technologies such as ChatGPT and NLP will be beneficial in case processing.
2. To analyze the challenges and setbacks they faced in incorporating the tools in case processing.
3. To make recommendations on how the AI tools can be incorporated into the different phases of Pharmacovigilance to improve productivity

1.3.3 Research gap

When an extensive literature review was done, it was observed that there are no recent studies that were done in terms of this topic in Ireland. This research is being conducted to fill this gap. This research aims to concentrate on the fact that how AI has helped in PV activities during the pandemic and to explore the extent to which AI has influenced improving the productivity of the case processors.

1.4. Significance of the study

The study mainly aims on understanding the utilization of AI tools in PV case processing. In which all areas AI was incorporated and how the case processors and CROs benefitted from the adoption. The main emphasis will be made on both advantages and challenges faced while adopting these tools to the case processing steps. Recommendations on the skills and competencies required for a case processor for adapting to this change will be put forward. The future of PV case processing with the adoption of novel technologies such as ChatGPT and NLP will be elaborated as well. 35 participants who have been handling case processing for 6 months and above will be selected for participating in the survey. And, 5 subject matter experts (SMEs) who have been performing case processing for two years and above will be selected for participating in the interview. The data collection window is 4 weeks.

1.5 Study Framework

This work “Adoption of artificial intelligence in Pharmacovigilance during Covid-19 Pandemic. Will the case processors benefit from the novel technologies of ChatGPT and NLP? A case study among the leading CROs in Ireland.” The dissertation is systematically arranged into 5 chapters which are listed below

Chapter 1: Introduction

This chapter includes an overview of the topic of choice. The aim, objectives, and purpose of the research were outlined in this section. The scope and significance of the study in the current scenario were also elaborated in this first section.

Chapter 2: Literature Review

This section details the review of articles published about the proposed research article and objectives arranged into different headings and subheadings. The literature review helps in gaining a better understanding of the research questions and objectives. It also helps in analyzing the gaps in the study in the proposed research area. This chapter illustrated the Conceptual framework of the study.

Chapter 3: Methodology and Research Design

Detailed data about how the study was navigated through the research process was discussed in this section. The research philosophy and approach adopted for this research will be explained in this section. The sample size, methods used for the data collection, and data analysis methods will be discussed as well.

Chapter 4: Discussion and Analysis

The data obtained through the primary research will be explained in detail with the help of graphs, charts, and tables. The analysis of the collected data will be depicted. The answers to each of the research questions will be well explained.

Chapter 5: Conclusion and Recommendations

This chapter will be mainly focus on explaining the conclusion of the results obtained from the research. The limitation of the study will be included in this section. Recommendations will be made which can be adopted when conducting a future research on this topic.

Chapter 2

Literature review

“Research is formalized curiosity. It is poking and prying with a purpose”-

American Anthropologist Zora Neale Hurston.

2.1 Introduction

Ireland is an Island in the Northern Atlantic with an average population of 7.2 million. Being a low-populated country compared to other European countries, the number of deaths from adverse reactions to medicines was reported to be highest in the year 2019. Over 250 patients died from the adverse reactions and, over 10,398 ADRs were reported (NMIC, 2019) (EMA, 2020). This highlights the importance of upgrading the PV activities in the country to make sure that the ADRs are being reported correctly to bring down the death rate related to AEs to medicines.

Regulatory agencies across the world have a strong policy that mandates the marketing authorisation holders to monitor the safety, not only during the clinical trial phase, but also throughout their use in the healthcare system. During the clinical trial phase the adverse reactions are being monitored and recorded in a smaller group of people but, once the drug is approved, the post marketing surveillance helps in monitoring the all the possible adverse reactions in larger group of people over a long period of time which is very important in assessing the safety profile of the medicine. (EMA, 2018)

The pharmaceutical companies are always striving to meet the demand of the population for newer medicines for different disease conditions. It is a vital step in the drug development process to make sure that the medicines reaching the market is effective and safe. The therapeutic benefit should always outweigh the adverse reactions or side effects caused to the people. (Liang *et al.*, 2022a)

2.2 Pharmacovigilance in Ireland

Health Products Regulatory Authority (HPRA) is the responsible authority who monitors the safety assessment of the drugs in Ireland. They are responsible for the National Adverse Reaction Reporting System (NARRS). The legal basis PV for medicines intended for human use in Ireland is written down in Directive 2001/83/EC and Regulation (EC) No 726/2004, as amended. The European Union (EU) regulation was revised and was added to Irish law on 25 July 2012. The Regulation (EU) No 520/2012 details all the operational regulation which is in action now (HPRA, 2023).

Europeans Medicines Agency (EMA) holds the responsibility to advise the EU and member states regarding any regulation which affects the evaluation of medicinal products. They have been the backbone in building the infrastructure for EU PV since 1995. Since 2012, a crucial role was played by the Pharmacovigilance Risk Assessment Committee (PRAC) to assess, monitor and manage PV activities in Ireland. Reports of possible adverse reactions are gathered and stored in the EudraVigilance database, which is accessible online. ADRs that occur in the EU must be officially recorded in the database by the Member States and those in possession of the marketing authorization (Kaeding *et al.*, 2017) (Hall, 2021)

2.3 Pharmacovigilance- An overview

Once the drug has been launched in the market after a detailed study of its clinical and therapeutic effects, every nation put forward a post marketing surveillance program to monitor the ADRs and other vital information about the marketed drug. These activities help the regulatory agencies to come to a conclusion quickly and also play a significant role in lowering the hospitalization, morbidity, and mortality rates related to ADR. By understanding the benefits and setbacks of a newly marketed drug, a safety profile of the drug can be created. There is a general thinking that the safety profile of the medicines that was launched to the market is good and there will not be any ADRs occurred due to them. However, it is proven that even older drugs can be a cause of serious ADRs and risks. A plethora of factors can lead to such situation which includes an inefficient manufacturing, storing and monitoring of the manufactured drugs. To tackle such situations and to continue to provide standardised

medicines to the society, it is essential to integrate the manufacturing and monitoring activities throughout the medicine's lifecycle (Sardella *et al.*, 2021).

The data collected during the process of adverse event monitoring is very elaborate and complicated. So to maintain the integrity of the data, most of the pharmaceutical companies outsource their PC activities to CRO's. The CRO's actively participate in the ADR monitoring of the drugs. In determining the risk-benefit ratio of a certain pharmaceutical product, Individual Case Safety Reports (ICSR) are crucial. If an ICSR has at least one identifying patient, one identifiable reporter, one or more suspect adverse drug reactions, and one or more suspect identifiable products, it is deemed legitimate for reporting to a regulatory body. The reported ADRs according to their severity, causality and seriousness will be prioritized and will be reported to the respective regulatory authority (Jalali, 2018).

2.3.1 PV Databases

Over the decades, the launch of extensive databases and statistical analyses that are computerized and automated has significantly changed how drug safety and risk assessments are made nowadays. After more than 100 deaths occurred in the United States as a result of the use of sulphanilamide elixir, which contained diethyl glycol as the solvent, the Federal Food, Drug, and Cosmetic Act was established in 1938, marking the establishment of the first governmental organization for pharmacovigilance (Bihan *et al.*, 2020). PV systems came into action to ensure the safety profile and efficacy profile of all new pharmaceuticals prior to their marketing authorization. In the 1950s, a specific drug called thalidomide was given to expectant mothers as an antiemetic. Thalidomide was eventually found to be responsible for the congenital abnormalities of new-borns. This catastrophe was one of main reasons which paved way to the adoption of pharmaceutical regulations in the Europe (Bihan *et al.*, 2020).

The Drug efficacy amendment was approved in 1962, which enabled the Federal Food Drug, and Cosmetic act to approve the drugs with "yellow card" (Pearce, 2004). Since 1980s, the main aim of PV activities have been monitoring and gathering data to create a safety profile the medications in use. Their main focus was to detect signals (the AEs reported) and also to great extent, they have focused on the establishing the causal relationship between the medicine and the reaction reported. The signal were detected from various sources such as

literatures, spontaneous reports, and from various publications. All the signals generated from different sources will be sent to various databases (Bihan *et al.*, 2020).

A number of PV databases were made accessible to the public to provide awareness to the public and thereby improving the public reporting of ADRs. The first and foremost database was Vigibase which was launched by World Health Organization (WHO) in 1967. The WHO launched a website application VigiAccess in the year 2015 to grant a limited access for public to the Vigibase database. Another important database is the EudraVigilance which was launched in 2001 by the EMA which contains approximately 7 million cases from spontaneous reports and case studies. Every country has their own database which was launched their by regulatory authorities (Fouretier *et al.*, 2016)

Table 1 Countries and their PV databases (Fouretier et al., 2016)

<u>COUNTRY</u>	<u>DATABASE NAME</u>
WHO	VigiAccess
USA	FDA
EU	ADRREPORTS
UK	MHRA
AUSTRALIA	TGA
CANADA	MedEffect
Germany	BfArM
JAPAN	PMDA

2.3.2 PV Case Processing Steps

The PV case processing primarily consist of three important steps. i) Case Intake ii) Case Processing iii) Case reporting. The process of case intake, processing and reporting might differ compared to the CROs and the client requirements. The database chosen by the client and the instruction put forward them will play a major role in these steps (See Appendix 1).

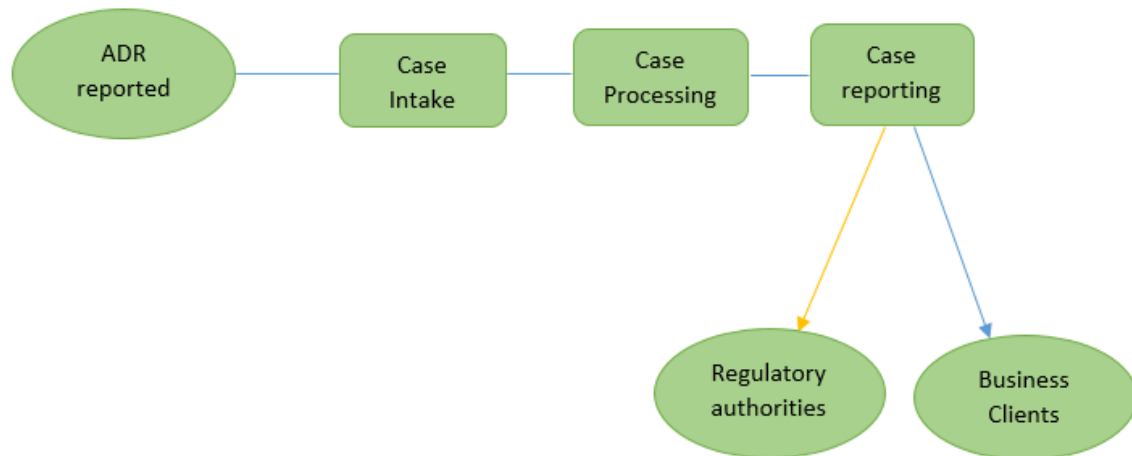


Figure 2 Review of steps in PV case processing (Idea adopted from (Ghosh et al., 2020))

2.4 Automation in the new era

The European Medical agency and HMA conducted a joint workshop in 2021 which provided evidence regarding the importance of adopting AI in the healthcare system (EMA, 2021). The important aspect in the adoption of AI is that the people involved in the activities should be provided with proper training and support catch up with these revolutionary techniques. The workshop mentioned above highlighted the need of skill training and the lack of participation by conducting a training survey in the EU region (EMA, 2018).

Trusting automation is a vital step taken forward by the healthcare industry. The industry is now enabled to take data driven decisions which gives a positive shift towards accuracy and productivity. Automated technologies do play an important role in the clinical decision making and also in the monitoring of ADRs. Deep learning-based artificial intelligence is also employed in the healthcare industry for speech recognition, also known as NLP. It is an important AI tool, primarily employed to collect or extract patient data from patient records. It can be applied to social media sentiment analysis or to determine a customer's worthiness (Alugubelli, 2016).

ML is described as the practice-based process of learning computer algorithms to support process automation. It is a part of AI where computer based applications are made by

enabling them to carry out tasks that often call for human intelligence. The use of ML in healthcare is expanding daily, and new ML algorithms are being created for various healthcare industries. There are many instances in daily life where we can see various AI tools are being applied. When we search a specific item or product in a search engine, we would see a number of advertisements or updates regarding the same on our social media profiles. This is an example where the machine recognises what we are looking for and provide us with different options for the same.

2.4.1 Automation in PV

Before being included into any activity, automation often requires extensive programming by the field's expertise; the same is true in the case of PV. The ML algorithms are capable of doing several forms of training. Learning that is supervised, unsupervised, and reinforced. In supervised learning, the machine will be given the training sets as input so that it can operate according to the rules given. The difficult process of unsupervised learning will let the computer discover the comparisons and differences on its own. Another technique is reinforcement learning, which works similarly to how humans learn in that the computer learns from mistakes and makes necessary adjustments. Thus, ML could be described as a system that uses the data that is provided to make predictions or decisions. The most widely used algorithms are those based on statistics and mimicking neuronal behaviour.

The scope of Artificial Intelligence in Pharmacovigilance (AIPV) will be more understandable when the objectives are well defined. Big data is defined as a part of AI where a large amount of data is available for utilizing for the patient safety management. This is being collected from various sources such as professionals in the healthcare field and also from contributors (Hauben and Hartford, 2021). FDA has also come forward with the utilization of this tool to generate safety alerts using the data sets which are already collected (Böhm *et al.*, 2016).

Pharmaceutical businesses who manufacture and market these medications pay a price for the race to get these products to market in order to improve patient quality of life. They risk income loss if their goods or services are unsuccessful because the conventional drug development method is unstable and pricey. Additionally, it is essential that patients receive care that is both safe and effective (Robinson, 2021).

An industry survey conducted was pointed out in the article which focused mainly how automation affects patient safety, they highlighted the risks as well. The result implicated that the use of automation was limited at that point of time. The important aspect of productivity and the setbacks experienced by the individuals were not included in the survey which would have added more depth to the study (Ohana *et al.*, 2021).

The PV activities were redistributed to different CROs, mainly during the pandemic. As it was observed that the pressure on the CROs increased tremendously during this period. They had to increase their employee resources to meet this demand. Covid-19 vaccines were marketed at a very high rate during the pandemic. Understanding the drug safety profile of the vaccines were a necessity in the given short span of time. This has led to the necessity of automation in the field of PV (Trifirò and Crisafulli, 2022).

2.4.2 Advantages of automation

There are many potential advantages for the automation in PV. The first and foremost is that it allows to verify an ADR and create safety profile of the medicine that was approved for marketing, reporting from many sources is necessary. In such a case, automation technologies will help compile AE information from numerous places depending on occurrence, frequency, and severity. Also, automation makes it possible to process many data sets at once and can be utilized as a method of processing information. The storage of certain files are possible because it ensures that scheduled backups are made without the data deteriorating and, automation guarantees the privacy and anonymity of patient information. (Schmider *et al.*, 2019). It will also pave to minimize the redistribution of activities to other companies and thereby can save revenue.

2.4.3 Artificial Intelligence during Covid-19

During COVID-19, it became urgently clear how important an agile and quick approach is. The pharmaceutical companies were required to discover a mechanism to advance quickly in order to keep up with the rapid regulatory process changes implemented by the FDA for new drugs. Before the pandemic happened, the reporting of an AE happened in a definite order. The AE reported was initially transferred to the Market Authorisation Holders and the drug manufacturers before getting reported to the Medical and Healthcare Products Regulatory

Agency (MHRA). The approach of the regulatory agencies changes as a result of the pandemic. They started incorporating AI to the PV processes. In 2020, Genpact, AI experts was paid 1.5 million pounds for the development of an AI tool which helps to get through the AEs reported during the pandemic. The MHRA proposed the “Yellow Card” programme which was aided by integrating AI for helping the people to report the ADRs directly to MHRA (Negi *et al.*, 2019).

The importance of PV in the Covid-19 era lies on the fact that the AEs associated with the post vaccine administration should monitored. It is of prime importance considering the fact of vaccine hesitancy with the public and also, novel vaccine technologies were utilized for the first time. Robust surveillance had to be deployed to monitor the adverse effects following immunization (Hussain *et al.*, 2022).

The pandemic era was a period where an increase in number of ICSRs was reported. There was an exponential growth to the ICRS reported due to the number of AE associated with the administration of vaccines and the new drugs administered to billions of people due to Covid-19. The technology had to step up to manage the huge amount of data generated globally due to the vaccine and the drugs during Covid-19. In Europe, a new system named “The Medication Shield” was put forward by the regional PV centres in collaboration with Synapse medicine which allowed real time AE reporting with the use of AI (Garret, 2021).

Ms. Annette Williams and Mr. Barry Mulchrone pointed out how IQVIA, one of the leading CRO handled the situations when Covid-19 hit the world. They understood that their basic signal detection method had to be modified the huge data generated. IQVIA adapted robotic process automation and generation of auto narratives as a part of implementing AI tools in case processing (Williams and Mulchrone, 2021).

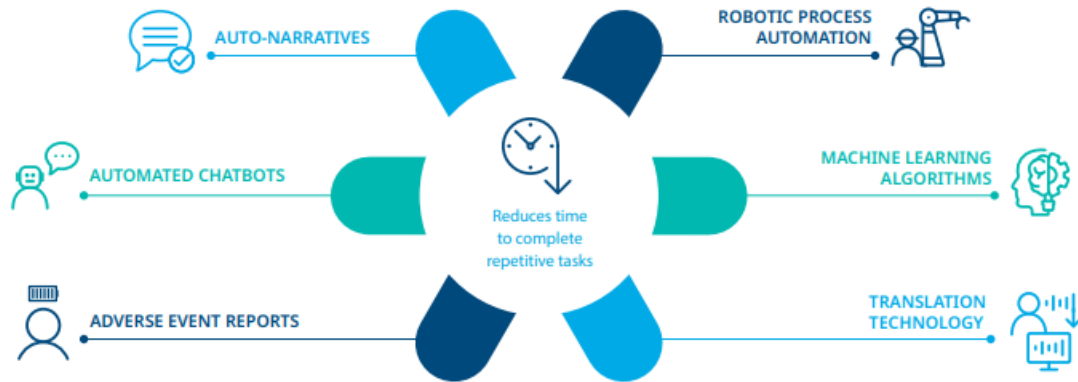


Figure 3: Adoption of AI tools by IQVIA during Covid-19 (Williams and Mulchrone, 2021)

2.4.4 Setbacks and challenges of AI adoption in PV

The adoption of AI in PV is being happening in a rapid [pace since the pandemic. It is necessary that it should happen in a furthermore faster rate. The primary cause of concern is the patient safety which can be compromised if the data is not handled properly. The concept HIPPA should be always be kept in mind (Rickert, 2020). When HIPPA law was passed, the rate of sharing of data with technologies and third parties was not even in the question. The adoption of AI in PV system should be subjected to further evaluation by law and regulatory aspects. The CROs are held up by the regulatory concerns as there are no proper regulatory guidelines issued yet for the approval of the processes carried out in PV using AI tools. (Bate and Stegmann, 2023). The automated systems will be only as good as the sets of data that has been used to train them. So the integrity of these datasets are always a question mark. It should be ensured that the datasets are properly formulated so that patient safety is not compromised (Pilipiec *et al.*, 2022).

2.4.5 Systematic review of literature

The systematic use of AI in the field of PV was critically analysed in the article by Bates *et al.* A detailed description on how AI can be utilized is outlined in the article. The study has tried to focus on a vital aspect of automation which is very relevant considering the current scenario. The study has been successful but it lacks the clarity on how it can be successfully incorporated into the current system and how to cope with the setbacks (Bates *et al.*, 2021).

The article by Liang et.al have discussed about the need of urgent development of databases that should cope with the rapid automation happening in PV. They have discussed the challenges and solutions, but lacks a clarity regarding a more systematic solution that should start in the organizational level by considering the perspectives of the employees who are struggling with the difficulties (Liang *et al.*, 2022b).

The challenges of incorporating AI in handling patient data was discussed in the article by James Rickert. The article discussed by various ways by which the patient data van be compromise when AI is used. It has also discussed the legal and authority level steps which can be taken to protect the safety data. The author believes that an effort to understand the root cause of these challenges would result in more meaningful ways by which the issues can be handled. The author argues that the solution of this issue should start from the individuals who are handling the data in the PV setting (Rickert, 2020).

The article by Negi et.al has focused on the importance of AI tools have played on the case processing activities during the pandemic. They have highlighted the importance of automation in the field of PV. The effort was commendable in this section. However, the lack of analysis of the suggestions and comments from the individuals participating in these activities directly has given a chance to do further research in this topic (Negi *et al.*, 2019).

There are many commendable researches which highlights automation and the importance of automation in PV during the pandemic period. There was a lack of studies conducted about automation in respect with concept of productivity. Also, the new novel technologies like ChatGPT has been employed in a very extensive manner in PV. Advantages, limitations and setbacks will give scope to do further research in this area.

2.5 Conceptual framework

The conceptual framework for this research showcases the relationship between a number of variables which can be used to determine the answers for the research questions. This framework has enabled to establish coherent conclusions regarding the study objectives. The researcher's main focus was to gain more insights on the study topic, the advantages and setbacks of the adoption of AI with main focus in productivity. During Covid-19 pandemic, the

rate of adoption of AI with PV case processing had taken a positive turn with the sudden surge in cases. There were many variables which had to be considered during this time.

The researcher has created a conceptual framework which is represented in the form of a sequential diagram. An extensive literature review was done keeping in mind the objectives and research questions of the research. The findings of the literature review and the concepts to be explored regarding the objective of the study helped the author in forming a well-structured research methodology.

Once the literature review was completed, the author was able to determine the Independent variables and the Dependent variable. The literature review helped in gaining a deep understanding of the topic and identifying the research gap. When this was completed, the author identified the mediator variables, moderator variables, and control variables which helped to understand what would be the contribution of this research to the current scenario and, also to understand the setbacks or challenges of the current study.

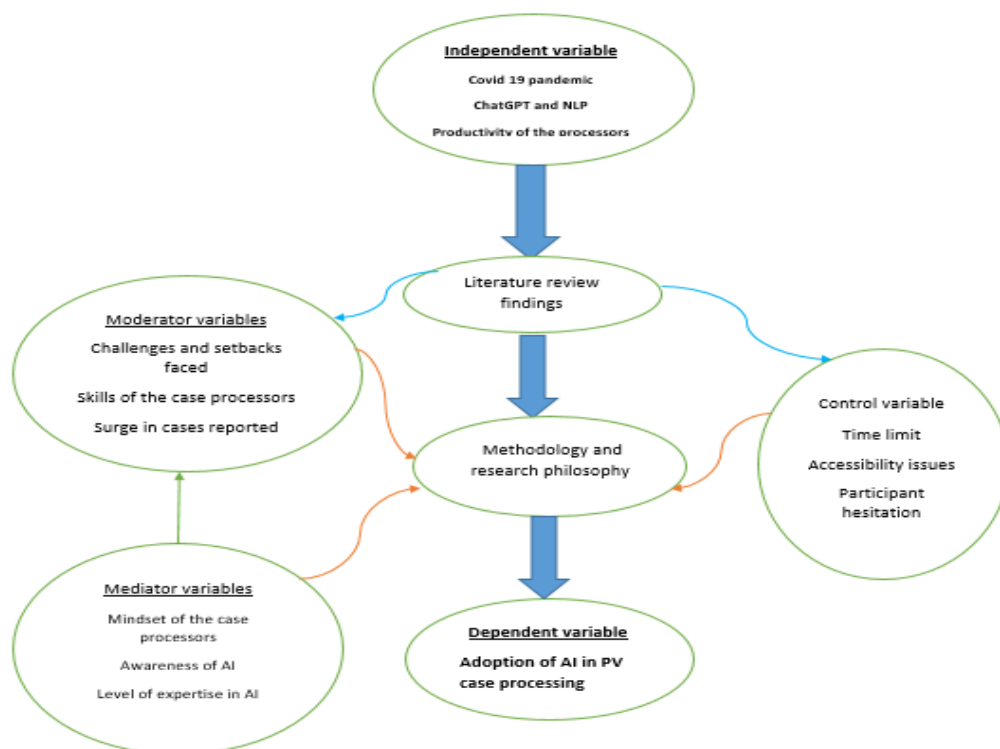


Figure 4 Conceptual Framework (by author).

Chapter 3

Research Methodology

3.1 Overview

“Every problem can be solved as long as they use common sense and apply the right research and techniques” – Daymond John.

Research methodology is the scientific study of how an investigation or a piece of research is carried out. It often entails applying a set of logical processes to methodically solve the study topic or problem. Adopting an appropriate research methodology aids in the analysis of the research findings as well as in the comprehension of the consequences and limitations. It involves putting together a plan for the collection and analysis of data according to the research topic. A study's methodology and research design are always the key determinants of its accuracy and legitimacy. (Patel and Patel, 2019) (Kothari, 2004) (Garg, 2016).

Crafting a research methodology for the research is a significant process. It involves many factors such as research philosophy, research approach, research strategy, and research choice and research time horizon. As per Saunder’s research onion model, the development of the research methodology is like peeling an onion layer by layer. To reach the final step in the research process, each of the above-mentioned factors has to be considered and applied carefully. For the successful execution of a research process, there should be a correlation between the three factors as shown below (Saunders *et al.*, 2019).

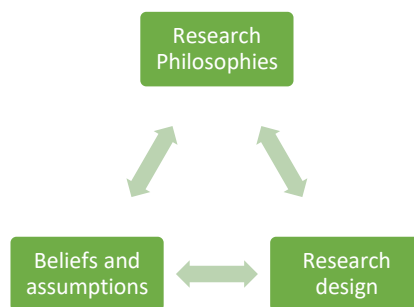


Figure 5: Correlation between Research philosophy, Beliefs, and Research design (Saunders *et al.*, 2019)

The following is a summary of the research philosophies, methodologies and the data collection methods used for the research. It gives an overview on how the research was done.

Serial No:	Primary data	Part A	Part B
1	Research Philosophy	Interpretivism and realism	Interpretivism
2	Research Methodology	Quantitative and Qualitative	Qualitative
3	Time Horizon	Cross-sectional	Cross-sectional
4	Data Collection Methods	Questionnaire A well-designed questionnaire with 2 sections.	Interview To collect expert recommendations and opinions
5	Participants	Pharmacovigilance case processors with more than 6 months of experience	Subject matter experts in PV case processing with more than 2 years of experience

Figure 6: Research Methodology Overview (author)

3.2 Research Philosophy

When conducting research, the philosophical approach throws light on the researcher's thoughts and thereby helps to comprehend the findings of the researcher. The attempt to gain more insight into a specific area or topic is the basis of the research and, using an appropriate philosophical approach will make the process of finding answers to the research questions a lot easier.

The research Philosophy adopted for this research is a combination of realism and interpretivism. Author has chosen realistic approach as it would be helping the author analyse and explain the cause of an identified phenomenon. Usually, realism is often associated with quantitative researches, however it can be also applied to qualitative studies as well as realism make sure that there are many causes and reasons to a process which has been identified widely. It is applicable to this research as it is a philosophy that mainly focuses on objectivity and accurate observation (Yong *et al.*, 2021) (Turyahikayo, 2021).

Interpretivism, also known as constructivism or naturalism is the philosophy followed in this study, by interacting with the Subject Matter Experts (SME), the researcher aims to put forward recommendations for the successful adoption and utilization of AI in PV. Interpretivism is the greatest philosophy to use in this kind of research since it holds that a good conclusion will be more likely to be developed as a result of the contributions of a variety of perspectives. According to interpretivism, the researcher cannot be viewed as a spectator; rather, he or she must be a passionate, engaged member of the group being studied (Yong *et al.*, 2021) (Turyahikayo, 2021).

Being a relatively new topic, the author will rely on the responses and feedbacks of the participants to reach a conclusion. The research outcomes are expected to be subjective, even if the author is taking a neutral position. Thus the author argues that Realism and Interpretivism are the appropriate philosophies for this research.

3.3 Research Strategy and Methodology

The research strategy was to understand more on the utilization of AI in PV during the COVID-19 pandemic. Also, to understand the challenges and advantages experienced by the case processors in Ireland in the adoption of AI with a main focus on the impact on productivity. The approach adopted by the researcher is the mixed method (quantitative and qualitative) with the use of online surveys and interviews. A quantitative research approach is where the data collected can be represented numerically which can be then analyzed statistically to get the results. It helps in understanding the current trend or

pattern in the study cohorts and, also provides a basic framework for the researcher to work up on in the future (Goertzen, 2017). Quantitative research often helps in identifying the behavior of a certain set of populations, but it fails to provide insight into the reasons for it (Goertzen, 2017). This is where qualitative methods play an important role. By using this method, the researchers usually try to address the research questions in an idealistic way. Even though the data is not represented in numbers, it gives a clear picture of the character, behavior, and attitude of the population. In recent times, qualitative research is best known for giving a new avenue for qualitative research is put forward which cannot be determined by variables (Prathak *et al.*, 2013).

For the quantitative analysis, an online survey was designed by the researcher which was distributed electronically to the participants. The participants who have agreed to be a part of the research study were asked to read, understand and fill out the online survey form. This made it possible for the author to obtain relevant information and data for the analysis. The online survey form has both type of questions. The questions were designed in such a way that the participants were not influenced to answer in a certain way. The questions gave the participants all the liberty to express their honest opinion about their experience.

For the quantitative analysis, a Zoom call was chosen for conducting the interviews. SMEs from the PV field were interviewed and their thoughts about the study topic were discussed in detail. Their opinions were recorded using open-ended questions which gave them enough space to express their opinion without restricting them with closed-ended questions. Each participant was given 20 minutes or more to share their insights on the interview questions. Any additional ideas put forward by the participants were also recorded.

3.4 Sample Size and Questionnaire

3.4.1 Sample size

According to the list published on the International Council for Harmonization Good Clinical Practice (ICHGCP) website, as of 2023, there are mainly 12 CROs in Ireland across different locations (ICHGCP CRO List, 2023). Out of which the number of people who

actively participate in PV case processing with at least a minimum of six months of experience would come up to 1200. To get a valid result, 34-45 participants were considered to be the sample size for the quantitative study. The study cohort was calculated with the aim of minimizing the risk of intervention by including more participants than needed. The data collection was planned to continue till a saturation point in the result generated is achieved.

3.4.2 Structure of the Questionnaire

3.4.2.1 Section 1: Consent and Purpose

Section 1 consist of two questions that make sure that the participant had consented to take part in the study and also, the participant has completely understood the purpose of the study.

3.4.2.2 Section 2: Introduction

In this section, two questions were included to make sure that the participant is qualified to take part in the study. It also helps us to establish the level of expertise of the participant in the field of PV and the extent to which they have used AI in PV case processing. The participants were reassured that the general data protection regulation (GDPR) would be followed in handling and storing the data collected.

3.4.2.3 Section 3: Adoption of AI

In this section, a total of 6 questions were included to understand the adoption of AI tools in PV case processing. Out of which, 2 questions were closed-ended and 4 were open-ended. Questions were structured in such a way that it gives a clear understanding of the advantages and setbacks in adopting AI in PV case processing.

3.4.2.4 Section 4: Impact of Covid-19

A total of five questions were included in this section to explore the impact of Covid-19 on the utilization of AI tools in PV case processing. Out of the five questions, three questions were closed-ended and two were open-ended.

3.4.2.5 Interview Questions

There will be 5 questions which will be shared with individuals who have been handling PV activities for more than two years. The interview will be conducted via Zoom with the participants.

3.5 Time-Horizon

As the study was conducted in a small timeframe, the data was collected through surveys and interviews at a designed time frame. The researcher was trying to evaluate and understand a specific idea or interest prevailing in a cohort at a certain point in time. Hence, the study was considered a cross-sectional study.

3.6 Data Collection

Certain criteria had to be considered for the primary data collection.

3.6.1 Selection of CROs

Out of the 12 CROs in Ireland, the CROs who are actively participating in the PV activities are selected for the study.

3.6.2 Selection of Participants

The author reached out to the participants mainly via social media platforms such as LinkedIn and Facebook. The aim and purpose of this study were explained to the individuals. Positive feedback was received from certain individuals and they were selected to participate in the study. The author also utilized help from her friends and former colleagues who are currently working in the PV field in Ireland. The method of sampling used for the quantitative study is convenient sampling where the participants were selected based on the ease of access of the researcher. The researcher also utilized the snowball sampling method where the participants who were already recruited suggested this study to their colleagues or friends. For the qualitative study, the purposive sampling method was utilized as it helps in identifying sources with relevant and vital information related to the research.

For the quantitative data collection, drug safety associates working in the CROs with a minimum of 6 months of experience was selected. The data was collected with the aid of a questionnaire structured into 4 sections with both open-ended and closed-ended questions. The survey was distributed electronically and was filled out by the participants

in the absence of the author to make sure that the responses are neither biased nor influenced by the author.

For the qualitative data collection, SMEs in the field of PV with more than 2 years of experience were selected. SMEs were selected as the participants for the survey as they will be having more experience and will be able to provide more ideas and insights regarding the research questions.

3.6.3 Inclusion and exclusion criteria

For survey, participants having more than 6 months of experience in case processing was included and for qualitative data collection SMEs who have been handling PV cases for more than two years was selected. The individuals who does not satisfy this criterion were excluded from the study.

3.6.4 Ethical issues

All the participants were briefed about the aim and purpose of this research. The participant's right to participate in the study and to withdraw from it was explained to them. The survey and interview questions were crafted with utmost caution which makes sure that the participant does not have to reveal their personal or organizational details. Any details about their client or project they are currently working with were not included. The questions were well within the scope of the study objectives. The participants were made aware that participation in this study is strictly by their own choice and they can withdraw from the study without any penalty.

3.7 Data analysis

3.7.1 Quantitative data analysis

All the responses received from the participants will be recorded in a spreadsheet. Further analysis of the data was done by representing the data received from the survey graphically using the Microsoft Excel. The data was analysed thoroughly and was represented using bar or pie charts.

3.7.2 Qualitative data analysis

The responses from the Zoom interviews were carefully transcribed into text. The text data obtained was then subjected to analysis and a thematic representation was created. This data was further analysed and the conclusions were made.

3.8 Conclusion

A mixed method (qualitative and quantitative) was utilized to conduct the study. The researcher collected data through surveys and interviews by which the ideas of participants were recorded for analysis. The data collected from the study were analyzed and conclusions were made. The findings from the data collection were diagrammatically represented. All the conclusions were compared to the key findings from the literature review performed earlier. The key findings and analyses are detailed in the subsequent chapters.

Chapter 4

Findings and Analysis

“What gets measured, gets managed”.

-Peter Drucker

(American Management Guru)

4.1 Overview

This chapter focuses on the responses gathered from the qualitative and quantitative data collection. Analysis and interpretation of the qualitative and quantitative data helped the author to gain insight into the research goal and research questions. The quantitative data collected was analyzed and presented using Microsoft Excel. The qualitative data was analyzed and presented using a software named QDE miner lite.

4.2 Introduction questions

Part 1

Before commencing participation in this survey, two introductory/ agreement questions were included in the questionnaire. A brief description of the purpose and goal of the study was included in the introduction part of the survey. The participants were instructed to contact the author in case of concerns or queries. They were advised that participation is strictly voluntary and they could decide not to participate in the study at any point in time.

Question 1: The first question was included to make sure that the participants have read and understood the purpose of the study. It was marked as a mandatory question.

Out of the 31 participants who filled out the survey form, all the participants answered “yes” as they have read and understood the purpose of this research.

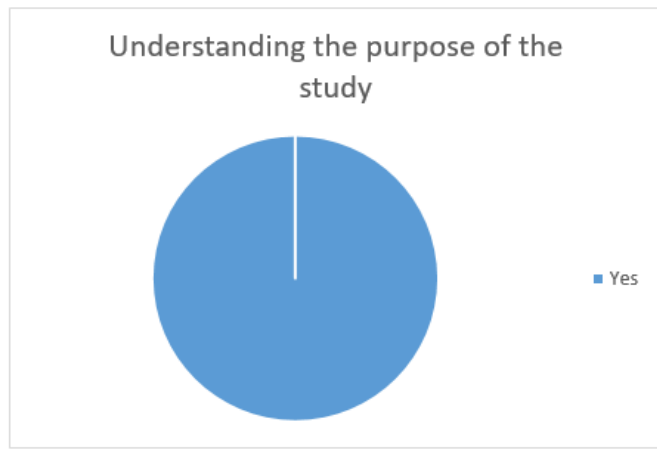


Figure 7: Understanding the purpose of the research

Question 2: The second question in the introductory section was included to make sure that the participant voluntarily agrees to participate in the study. The question was marked as a mandatory question. The questionnaire was circulated among more than 50 individuals working in the CROs in Ireland who actively participate in the PV case processing. The participants who did not want to proceed with the survey withdrew from the study at this point.

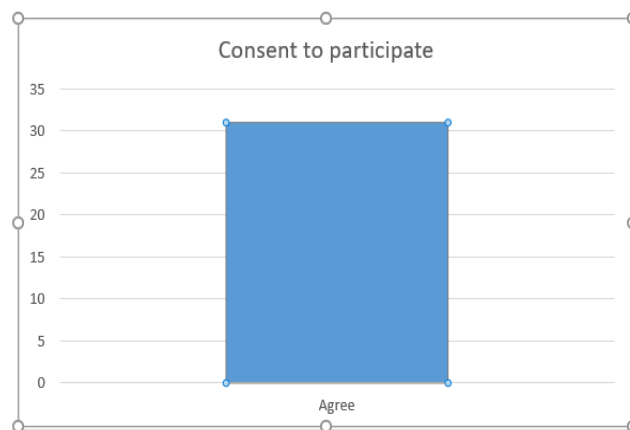


Figure 8 Consent to participate

Part 2

In this section, two questions were included to ascertain the eligibility of the participants.

Question 1: If the participants did not have more than 6 months of experience in the field of PV case processing, they were excluded from the study. Out of the 31 participants who

voluntarily participated in the survey, 2 participants had experience of 6 months-1 year, 13 participants has experience of 1-2 years and 16 of them had more than 2 years of experience in PV case processing.

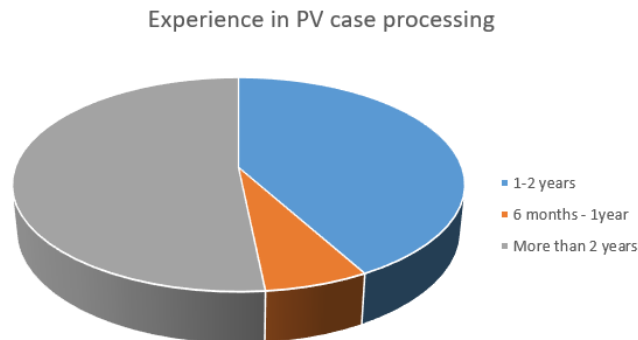


Figure 9 Experience in PV case processing

Question 2: The second question in this section was intended to understand the steps in which the participants have utilized AI tools in PV case processing. The response from the participants indicated that out of the 31 participants, 16 of them utilized AI tools for Data entry, and Narrative writing, 4 of them utilized AI tools for data entry, and narrative writing, and for other steps in PV, 4 of them utilized it for Case Intake alone, 2 of them used it for narrative writing alone, and 1 participant each utilized it for Case intake, narrative writing, data entry and other. This data indicates that the majority of them used it for data entry and narrative writing.

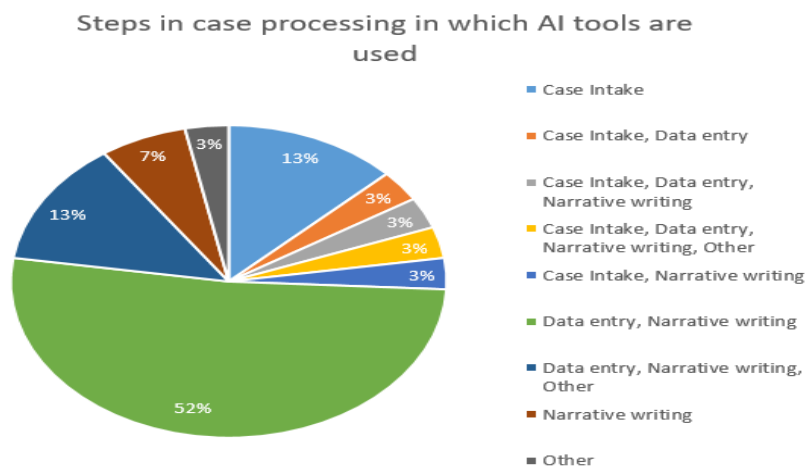


Figure 10 AI tool utilization PV case processing steps

4.3 Analysis of Survey Questions

The quantitative data collected with the help of a questionnaire were analyzed and represented with the help of Microsoft Excel. The qualitative data obtained from the questionnaire were thematically analyzed with the use of Microsoft Excel. The Questionnaire was set up into 2 major sections or categories. The first category was the Adoption of artificial intelligence. It consists of three closed-ended and three open-ended questions to understand different aspects of the adoption of AI in PV case processing steps. The second category was AI's Influence on the Pandemic. It consists of three closed-ended and two open-ended questions.

4.3.1 Category 1: Adoption of AI

Question 1: How will you rate the process of adoption of artificial intelligence (AI) in case of processing steps in terms of its contribution towards different steps in case of processing with a main focus on overall productivity?

The participants were asked to rate the overall process of adoption of AI in case of processing steps in keeping productivity as the main aspect. The intention was to understand whether the participants agreed or disagreed with the fact that the adoption of AI in case processing had a positive impact on the daily productivity of the processors.

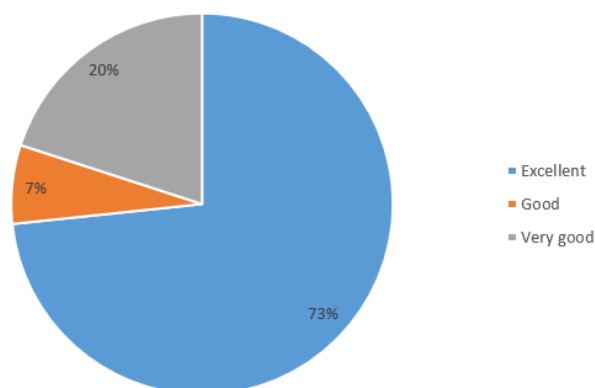


Figure 11 Response to question 1 to rate the impact of AI in case processing steps

Findings- The above chart represents the response of the case processors for survey question number one. 73% of the participants rated the adoption of AI in case processing with a main focus on productivity as excellent and 20 % of the total participants rated it as very good and 7 % rated it as good. None of the participants rated it as poor or very bad.

Discussion- From the above data, the researcher reached an understanding that the case processors are in favour of the utilization of AI tools in case processing steps, also AI tools can positively impact the productivity of the case processors when processing cases. This comes in agreement with the fact stated in the article (Aly, 2020) that AI has a positive relation with labour productivity.

Question 2: Which of the advantages of employing artificial intelligence for PV case processing is, in your opinion, the most beneficial? Please choose one.

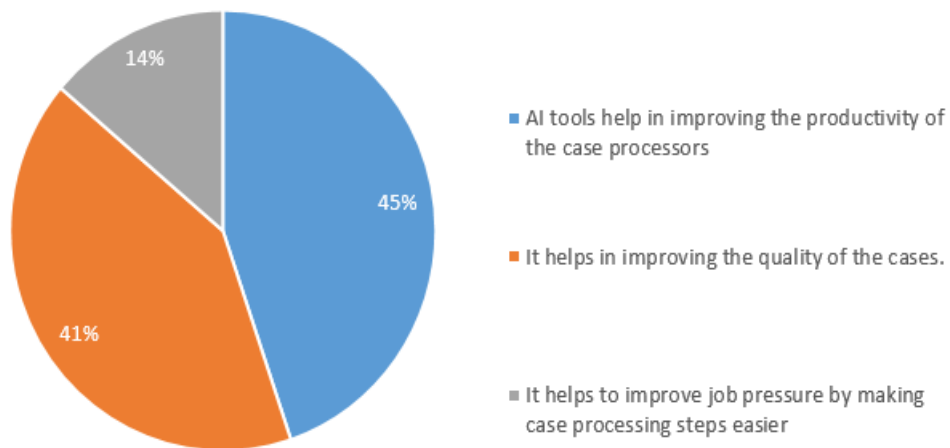


Figure 12 Response to survey question 2- The most beneficial advantage

Findings- With the use of a 5-point Likert scale, the participants were asked to indicate the most beneficial advantage of employing AI in PV case processing. They were asked to choose

one out of the five options listed. The response is illustrated below using a pie diagram. 45% of the respondents agreed with the statement that AI tools help in increasing the productivity of case processors. 41 % of the respondents agreed with the statement that AI tools helped in improving the quality of the cases and, 14% were in agreement with the fact that AI tools help to improve the job pressure by making case processing steps easier.

Discussion- From the above findings that it is evident that the majority of the participants are in agreement with the fact that AI tools can be beneficial for the productivity of case processors. It supports the fact stated in the previous question. A good majority of the participants stated that AI tools can be used to improve the overall quality of the cases. The fact that participants have also stated that AI tools also play a significant role in reducing job pressure is not surprising. All these factors are interconnected.

Question 3: Integrating AI tools into case processing can significantly improve case quality by reducing the number of errors. Do you agree or disagree? Please elaborate.

The participants were asked to express their opinion on integrating AI tools in case processing to reduce the number of errors in different steps of processing, thereby improving the quality of the cases.

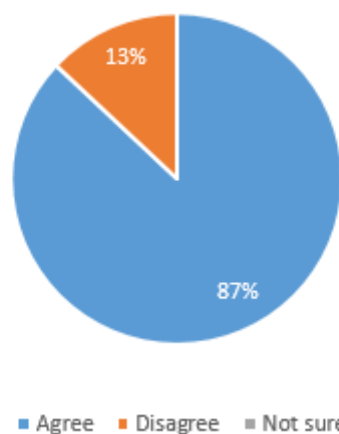


Figure 13 Response to the question: Integration of AI tools

Findings: 87% of the participants agreed with the statement that AI tools can be utilized for the reduction of errors in case processing and 13% of the participants disagreed with the fact. None of the participants voted not sure.

Discussion: The participants who disagreed with the statement elaborated on their opinion for several reasons. They stated that even though automation saves time, there are chances that the automated systems themselves may cause errors. One participant had the opinion that AI tools don't have any direct impact on errors. The researcher is certain that this might be the reluctance in accepting the use of AI tools by these populations, not limited to one participant.

The participants who agreed stated several reasons.

- Oversight errors- The participants suggested that when AI tools are being utilized, the extent of oversight errors can be reduced to a great extent. When we use AI search engines, the data collected will be auto-populated in the fields in the database which in turn will reduce the oversight errors. The participants also highlighted the use of multilingual guided forms which reduces the errors in the intake step.
- Time-saving- The participants suggested that the use of AI tools in case processing steps mainly Intake and narrative step will save time in case processing and thereby reduce the pressure on case processors.
- Humane and judgemental errors- The participants suggested that humane and judgemental errors will be minimized to a great level when using AI tools. This aspect comes into light in the case of Causality assessment, expectedness assessment, and auto narrative generation.
- Data quality- The participants also suggested that the use of AI tools will improve the overall data quality of the cases as the narratives and other fields are auto-populated. Grammatical or unnecessary errors can be avoided when AI tools are being used.

Question 4: Did you face any setbacks or challenges in adopting AI techniques in PV case processing? If yes, could you please specify the step and explain the challenges you faced?

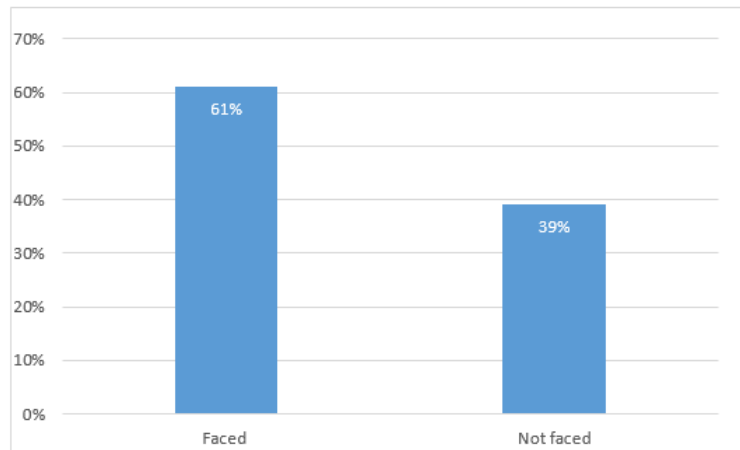


Figure 14: Response to the survey question "Did you face any setbacks or challenges in adopting AI techniques in PV case processing? If yes, could you please specify the step and explain the challenges you faced? "

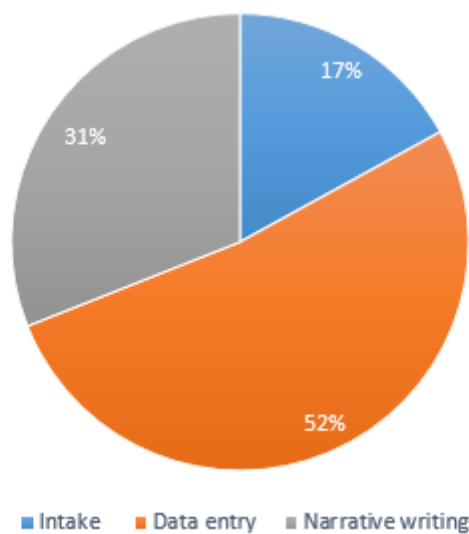


Figure 15 Specific step in which case processors faced difficulty

Findings: Out of the 31 respondents, 61% responded that they have faced challenges during the adoption of AI, while 39% responded that they have not faced any challenges. Out of the respondents who stated that they have faced difficulties, 52% stated that they have faced difficulty in the data entry step, 31% stated that they had difficulty in the narrative writing step and 17 % pointed out that they have faced difficulty in the intake step.

Discussion: The people who have not faced any significant difficulties might have been trained on or have been receiving training on this. Even though 61% of the respondents stated they have faced difficulties, the author finds that the challenges they have faced are not very hard, but critical in the case of PV case processing.

- Handling of data- Many of the respondents stated that the handling of the unstructured data which is usually part of the literature cases, spontaneous cases, or medical reports, is the most difficult step. Proper data entry of the critical data is difficult when handling these unstructured data.
- Lack of basic knowledge- A good number of respondents stated that they have faced difficulty in utilizing the tools as they did not have strong basic computer knowledge. So, they faced some challenges when the database they have been working on was integrated with AI tools.
- Integrity of the data- A couple of the respondents stated that they did not trust AI tools in case processing steps. Even when the data was automatically coded to the data entry fields and the narrative was automatically generated, they had the habit of checking the data entered manually in each step. So it was even more time-consuming. Many of them still believe that AI tools that work with the help of trained data sets cannot be trusted fully and some level of human intervention will be essential.
- Transition-related challenges- The respondents stated that they did not get any specific training on the changes in the database interfaces that happened and also in the adoption of AI tools in specific case processing steps.

From the responses received, the author concludes that AI tools can be used to create a positive impact on the case processing steps, but not for all cases. There are difficulties faced in cases of unstructured data, as the AI algorithms might not be able to detect them. The lack of proper knowledge and the sense of compromise in data integrity also pose challenges in the adoption of AI.

Question 5: Do you think that AI tools such as ChatGPT and NLP will play a vital role in the pharmacovigilance case processing steps? If yes, what in your opinion is the biggest concern in incorporating them with the manual case processing system?

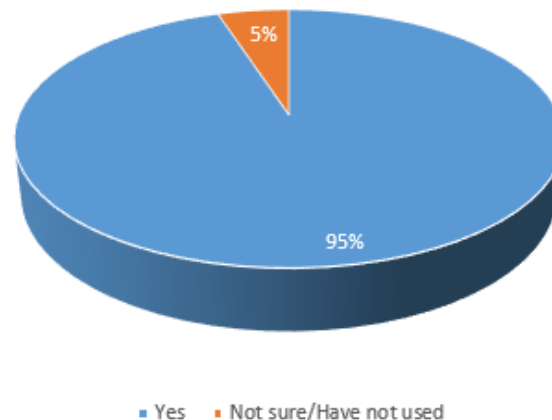


Figure 16 Response to the survey question- Do you think that AI tools such as ChatGPT and NLP will play a vital role in the pharmacovigilance case processing steps? If yes, what in your opinion is the biggest concern in incorporating them with the manual case process?

Findings- 95% of the respondents stated that novel technologies such as ChatGPT will play a major role in the PV case processing steps. Whereas 5 % of the participants responded that they are not sure of its use or they have not used it yet.

Discussion: The author poses a conclusion that the population that voted not sure or not used might not be aware or might not have got the chance to use novel technologies such as ChatGPT in case processing. The majority of the population is in agreement with the fact that the utilization of these technologies will be of great importance in the field of PV case

processing. The participants had different opinions with which they supported these statements.

- i) **Use of ChatGPT models-** The participants suggested that the use of different ChatGPT models in each of the case processing steps is of great importance in the future of PV. It will help in streamlining the PV activities more efficiently. The main example quoted by a few participants is the use of AI search engines powered by ChatGPT for gathering AEs. The participants have also taken the example of Chatbots which are used for automated review of the processed case reports.
- ii) **Review of Unstructured Data-** The use of ChatGPT for handling unstructured data was mentioned as a benefit by several respondents. This will solve the biggest concern put forward by the respondents in survey question 4. The use of Chat GPT will be a revolutionary step in case processing because it will be beneficial for handling spontaneous reports where AE is being captured from different platforms such as Blogs, social media platforms, etc.
- iii) **Time-saving-** With the adoption and integration of these technologies, case processors can perform case processing in a time-efficient manner. When the steps are getting automated, the time spent on each of the steps can be reduced to a greater extent. The participants have stated examples of automated narratives, identification of potential AEs in a report and extraction of AEs from different reports with the use of NLP, and data mining with the aid of ChatGPT are the revolutionizing steps with the use of these new technologies. With the use of the above-mentioned tools, more AEs can be detected and reported which will in turn help towards maintaining drug safety.

The biggest concern with the use of these novel technologies was pointed out by the respondents

- i) **Data privacy and safety-** The majority of the respondents expressed their concern regarding data privacy when handling patient data with AI tools. After all the data is handled by machines that are being trained with a definite set of algorithms. So these trained models will be as good as the training they have received. However, if there are any errors or biases in the datasets on which the machines are being trained, it might compromise data safety. Even in the case of handling unstructured documents,

the extraction of data and storing it keeping in mind the data safety is proposed as a concern.

- ii) **Underreporting or Over reporting of the AEs-** AI search engines and technologies were introduced to extract AEs from different sources such as social media platforms and even from certain blog posts. However, when the system handles these data, there high chance that the system cannot cope with or understand a symptom or a condition that has been reported that is outside the scope of the trained datasets. There are chances that a minor symptom can be detected as an AE. This will eventually lead to a burden on the case processors' work in the data entry step. So there are concerns about underreporting or over-reporting of AEs when utilizing AI tools in case processing.
- iii) **Risk of full automation-** It was interesting to note that a couple of respondents expressed their concern regarding which will result in the complete elimination of human intervention. The concern of Job loss was also proposed as a concern. Automation to some extent can be regarded as a revolutionizing initiative in case processing, but full automation in handling patient data and drug safety data will pose threats to the integrity of the data handled.

Question 6: Do you believe that handling patient data with the help of AI tools without proper training will pose a threat to patient safety and privacy?

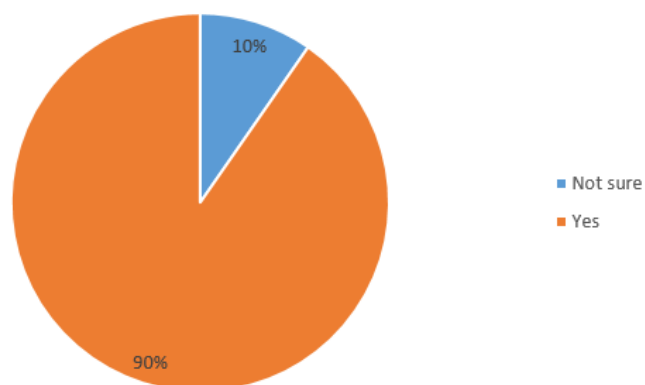


Figure 17 Response to survey question 6: Does Improper handling of data using AI tools cause patient safety

Findings- Out of the 31 respondents of the survey, 90% of the participants believed that if the patient data is not handled vigilantly, it will pose a threat to patient safety. 10 % of the participants expressed their opinion as they were not sure about the patient safety concern. None of the participants thought that it will not pose a risk to patient safety.

Discussion- The above findings throw light on the fact that in PV case processing if the data is not handled by the case processors using AI tools, it will pose a threat to patient safety. The above findings from this study support the fact highlighted in the article (Rickert, 2020) about jeopardizing patient safety with the use introduction of artificial intelligence in healthcare. From analyzing the findings, the researcher has concluded that the same applies to PV case processing. And, it is also surprising that even a few members involved in case processing are not sure about how the Improper use of AI tools affects the data they are handling.

4.3.2 Category 2: Pandemic Influence

Question 1: The field of pharmacovigilance was exposed to a period of drastic change and development. Do you agree or disagree? Please elaborate.

Findings- Out of the 31 respondents, all were in agreement with the statement that PV activities were subjected to a period of drastic changes during the pandemic.

Discussion- According to the responses received from the participants it was clear that the PV activities were influenced largely by the Covid-19 pandemic. The survey responses also highlighted different opinions of the respondents which led to this conclusion.

- i) **Increase in the number of AEs reported-** A majority of the responses stated that there was an exponential increase in the number of AEs reported and processed during the pandemic period. The response was in agreement with the findings from the literature review. It was majorly due to the AEs reported due to new vaccines and drugs launched in light of the pandemic. Also, COVID-19 has added a serious event to the list

of events in almost all of the ongoing studies. Hence, the number of case reports received increased in a great number.

- ii) **Increase in job opportunities-** The responses highlighted the fact that to cope with the exponential increase in the AEs reported and the increase in case reports, the CROs had to hire several professionals. This helped in enhancing the PV Case processor's pool and also new talents were introduced into the field.
- iii) **Awareness of ADR reporting among public-** The Covid-19 pandemic had greatly influenced the public by enhancing their knowledge regarding ADR reporting. The common people became more aware of this which was earlier only discussed among a very limited population. The author believes that this will help in enhancing the working conditions of PV.

Question 2: The adoption and utilization of AI tools in case processing steps were fast-moving during the pandemic period.

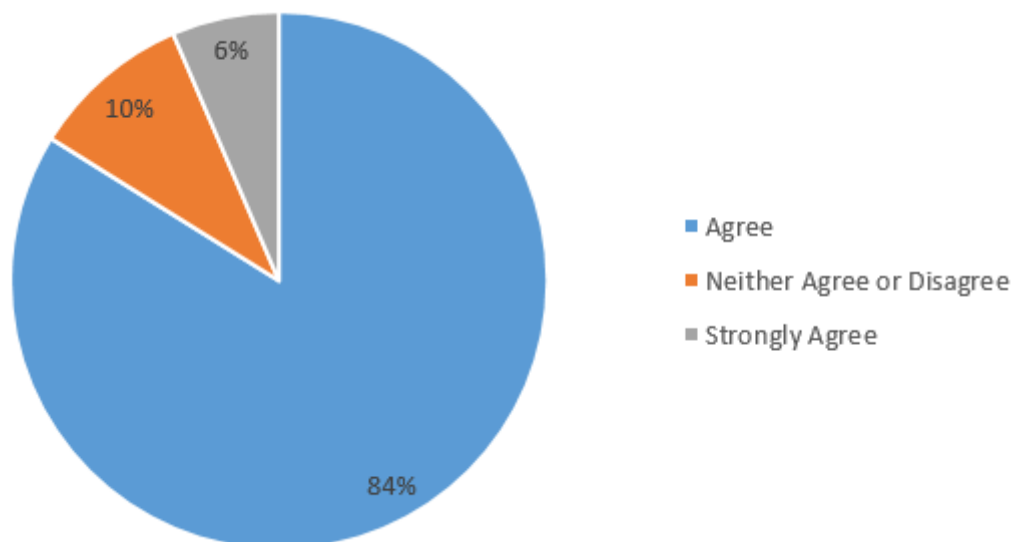


Figure 18 Response to the survey question- Adoption of AI is fast-moving during the pandemic

Findings- Out of the 31 respondents, 81% of them stated that they agree with the fact that the adoption of AI tools in case processing was fast-moving during Covid-19. 10 % of the

participants did not agree or disagree with this statement and 6 % of the participants strongly believed that the adoption of AI tools was rapid during the Covid-19 pandemic.

Discussion: From the above findings that it is evident that most of the participants agreed with the fact that the adoption of AI during the Covid-19 pandemic was at a higher rate than before. The researcher puts up an argument that the participants who have stayed neutral with the statement might have been using AI tools even before the pandemic. None of the participants disagreed with the statement. The researcher believes that this is in agreement with the literature review which stated that artificial intelligence played an important role during a pandemic.

Question 3: The adoption of artificial intelligence had made case processing more convenient in terms of accuracy and productivity than it had been before the outbreak.

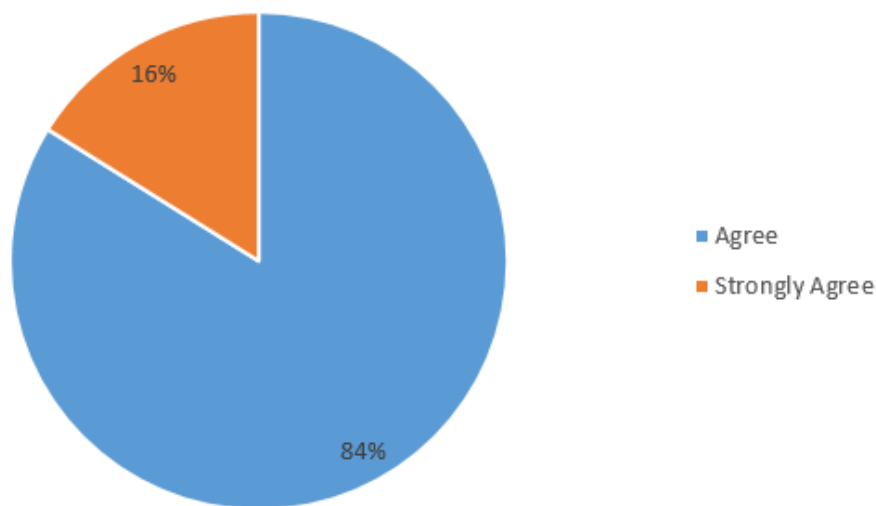


Figure 19 Response to the survey question to determine if Ai is more convenient for accuracy and productivity than it had been during the pandemic

Findings- 84 % of the total respondents agreed to the fact that AI has made the case processing steps more convenient in terms of accuracy and productivity during the pandemic.

16 % of the population is in strong agreement with the statement. None of the participants disagreed with this statement.

Discussion- The author states that this statement is in agreement with the previous findings. Even during the pandemic, the integration of AI tools in PV case processing has resulted in maintaining the productivity and accuracy of case reports. The pandemic was a crucial time for the case processors. Various AI tools employed in different steps played a vital role in managing the huge influx of cases during that time.

Question 4: Do you believe that the incorporation of AI tools helped the case processors in maintaining a work-life balance by improving their productivity even when there was a huge influx of cases during the Covid-19 pandemic?

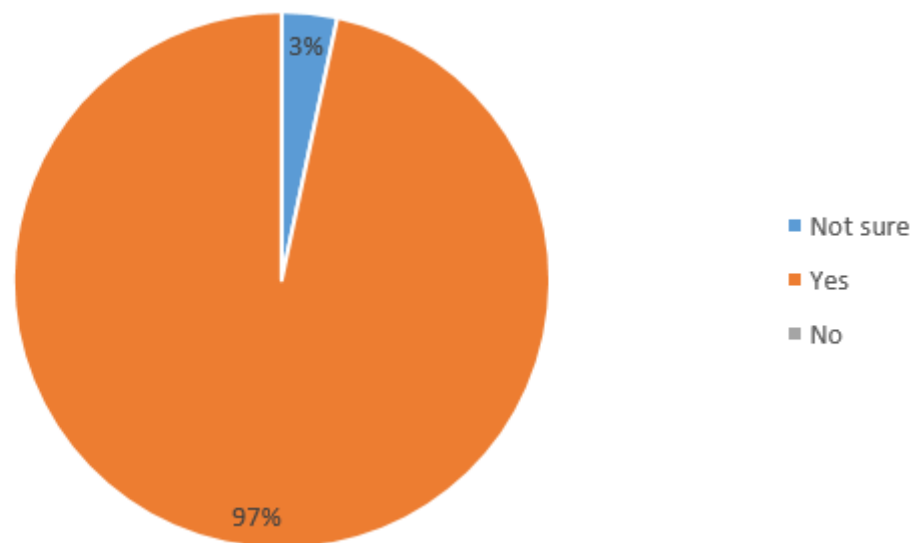


Figure 20 Response to the survey question- The use of AI in maintaining work-life balance during the pandemic

Findings- 97% of the participants answered yes to the question stating that they agree that adopting AI tools in PV case processing has helped them maintain a work-life balance during the pandemic. 3% of the total respondents expressed their uncertainty regarding this matter.

Discussion- The author believed that the agreement of the participants to this question highlights the previous finding that AI tools have played a major role in maintaining the productivity of the participants. During the pandemic, the number of case reports received and processed by the individual handling cases increased tremendously as compared to before the pandemic. Most of the CROs advised working from home as a measure of containment of Covid-19. However, this has affected the work-life balance negatively. This finding highlights that AI was a lifesaver during that period. The author argues that 3% who were uncertain regarding this topic might not have been working remotely.

Question 5: Based on your experience, which stage of the case processing process do you think can be greatly enhanced by the use of AI tools? Please elaborate.

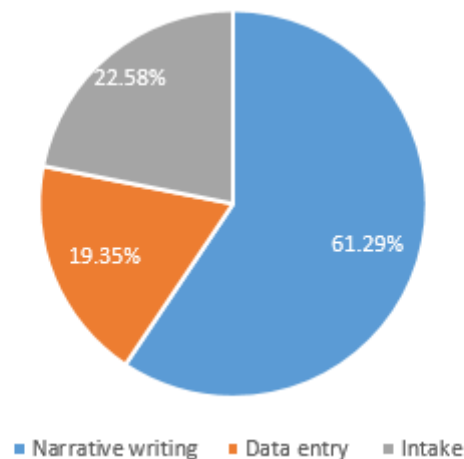


Figure 21 Case processing stage greatly impacted by AI tools

Findings: Out of 31 responses, 61.29% stated that narrative writing is the most impacted step, 19.35% stated that data entry is the most impacted and 22.58% suggested that intake is the most impacted step.

Discussion: It was observed that all the participants had opinions and supporting arguments that led to the conclusion. In the case of automated narratives, it was observed that the use of narrative automation was helpful in the case of literature cases and legal cases during the pandemic period. Automated narratives helps in generating narratives with minimum errors. The participants commented that AI tools help in improving the efficacy of handling narratives when the document is in native language. Complex case with a huge amount of data can be easily processed with the help of automated narratives.

In the case of Intake, the participants suggested that with the use of AI search engines, AE detection and AE extraction can be greatly enhanced in with the use of AI tools. AE detection can be effectively done. ChatGPT can be used to extract data when a lot of unstructured data has to be handled. In the case of data entry, the field will be auto populated from the intake step. A case report with a lot of data can be effectively handled in data entry step with use of AI tools. The vital point is that the case level seriousness and causality assessment can also be enhanced with the help of this, which will result in a positive impact on case compliance with regulatory timelines.

4.4 Analysis of the interview questions:

The interview questions were analysed thematically based on the responses from the participants. All the interviews were recorded and converted to Interview transcripts. Once the transcripts of every participant is created, then the responses were subjected to thematic analysis. A theme was selected and the responses from the participants were marked as specific codes. If one or more codes carry the same purpose or meaning, they are merged. This analysis will help the reader to thematically visualize the responses.

The participants of the interview are individuals who are actively participating in case processing and who also happened to play the role of Subject Matter Expert (SME) in the PV case processing field.

1. Participant 1- SME with 2.5 years of experience.
2. Participant 2- SME with 3.5 years of experience.
3. Participant 3- SME with 2.5+ years of experience.
4. Participant 4- SME with 2.5 years of experience.
5. Participant 5- SME with 3 years of experience.

Interview question 1:

Question 1: What are the suggestions you would propose to the case processors in the adoption of artificial intelligence to different steps of the case processing?

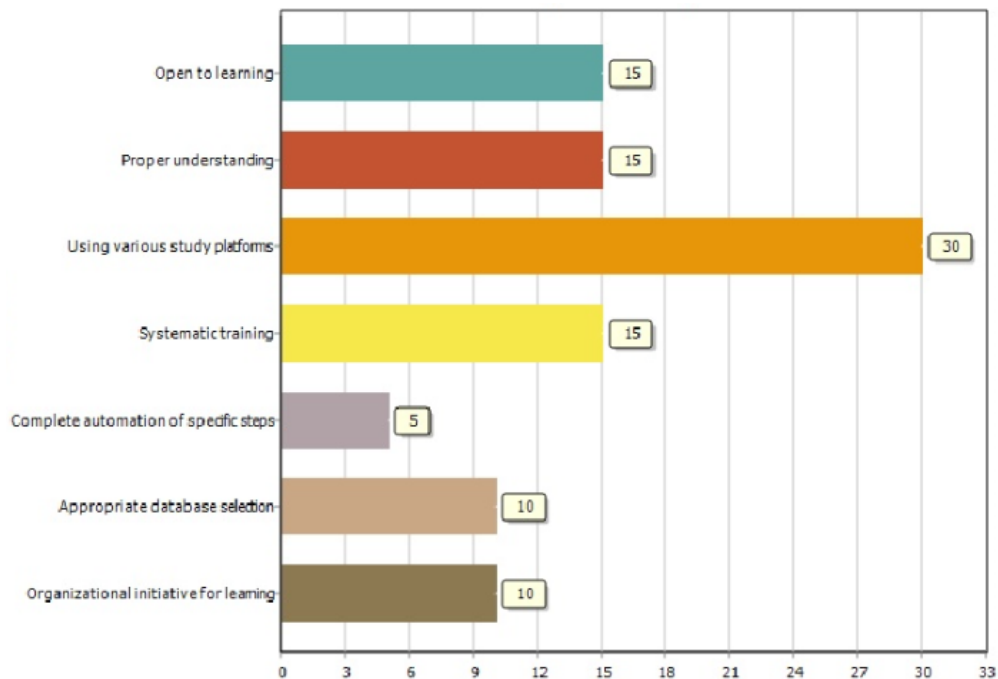


Figure 22 Response to the interview question: 1. What are the suggestions you would propose to the case processors in the adoption of artificial intelligence to different steps of the case processing?

The respondents' opinions were recorded and analysed thematically. The author was able to group similar responses to a similar code and then expressed the codes under the same theme.

Using various study platforms- The respondents were had a strong opinion about utilizing different study platforms available to learn the basics of AI and to understand their benefits and limitations. The case processors should make use of the online platforms to make sure that they are being updated on the current topics and scenarios. It is important to learn about

the two sides of a system when it is being newly adopted to an ongoing process. One of the respondents stated that

“The second thing is that there are many ways to improve their knowledge about AI and other novel technologies by using various study platforms. There are many online certificate courses that offer insights into these technologies. It would be a great opportunity for the case processors”.

Open to learning- The respondents had a strong view of the attitude and perception of the case processors on the adoption of AI. It was proposed that the case processors should bear an open mind to the adoption of AI and they should be proactive enough to learn the basics of these novel technologies. As technologies are changing rapidly and automation is being adopted for almost all the steps, case processors must be willing to learn to understand and upgrade their knowledge to the next level.

Organizational initiative for learning- It was fascinating to know that many organizations are coming forward and offering training to their employees regarding the adoption of new tools to the ongoing system.

A respondent stated that “The second thing we have been following is that weekly SME sessions and flyers which are circulated among the case processors with tips and new information regarding the many topics which also includes utilization of AI tools. It helps in getting a better understanding of AI tools”

Appropriate database selection and proper training- The participants suggested that an appropriate database selection would aid in the smooth adoption of AI tools. Also, systematic training should be given to the case processors regarding the adoption of these AI tools and the proper handling of the database as well.

Question 2: What effect do you think the pandemic had on case processing, particularly case processors? How have AI tools helped to cope with the situation?

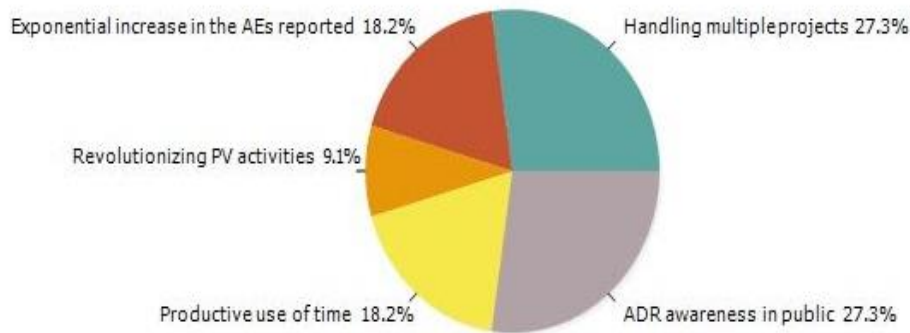


Figure 23 Response to the question Do you think that the case processors benefitted from the adoption of artificial intelligence during the pandemic period? If yes, which step in the case processing process had the most positive impact due to the adoption?

The respondents had mixed opinions in the case of this question. The same aspect was put forward by the respondents negatively and positively.

Handling multiple projects- The respondents suggested that many of the case processors were asked to handle multiple projects during the pandemic period because the number of projects launched suddenly increased in number. However, they think that they were able to cope with the situation with the help of AI tools mainly with the help of automated narratives and intake management tools.

SME with 3 years of experience suggested that “There were instances when experienced case processors like me were asked to handle more than one project due to a huge influx of cases. So AI tools like automated narratives and Intake management tools have helped during that period”.

ADR awareness in public- It was promising to notice that the response that the pandemic has led to increased awareness among the public regarding the concept of ADRs. It was not a well-discussed concept regarding the public and the knowledge of the public was also limited. But when the pandemic hit and new medicines and vaccines were launched within a limited time, the public, media, and social groups started discussing about the concept of ADR. This has also increased spontaneous reports as well.

A statement from an SME with 2.5 years of experience states that “And also, I believe Covid-19 has brought the concept of ADRs to the general public. The general public has become more aware and there was an increase of spontaneous ADR reports during and after the pandemic”.

The author argues that this statement is in strong agreement with the literature review findings as it suggests that the public became more vigilant towards ADRs after the pandemic.

The exponential increase in the AEs – In agreement with the above statement, it was stated by the reporters that there was an exponential increase in the number of AEs. It was mainly due to the introduction of vaccines to the market within a limited timeframe and also because Covid-19 was included in the list of serious events in many ongoing studies and trials.

Revolutionizing PV activities- In the case of PV activities, due to the pandemic, several steps in PV have undergone revolutionary changes which are beneficial to the case processors. Increased automation in the case processing steps is one of the important benefits, which helps in providing and protecting patient safety in an upgraded environment.

Question 3: During the pandemic period, there was a huge influx of cases that had to be handled daily by the case processors. Do you think the case processors were able to utilize AI tools to achieve their daily productivity? Please explain.

It was fascinating to note that almost all the respondents commented that the case processors were able to utilize AI tools to maintain their daily productivity. It was noted that a respondent commented that productivity does not mean completing the daily target alone.

An SME with 3.5 years of experience commented that “In PV case processing, productivity does not necessarily mean completing the task, it also means to complete the task efficiently

without any errors. Because in many CROs' they follow the system of correcting the cases by the same case processor if there are many errors in the case".

The responses stated that AI tools help them in saving time and they will be able to able to allocate more time to complex cases like literature or CT cases. Thereby indirectly improving the productivity of the case processors.

The researcher argues that this statement is in agreement with the literature review finding that AI helps in reducing workload with the help of automation. With this study, it can be stated is applicable in the case of PV case processing as well.

Question 4: Do you believe that if the AI tools are not handled vigilantly in pharmacovigilance case processing, it will compromise the confidentiality of patient data which will eventually pose a threat to patient safety? If yes, what are your suggestions to avoid the same?

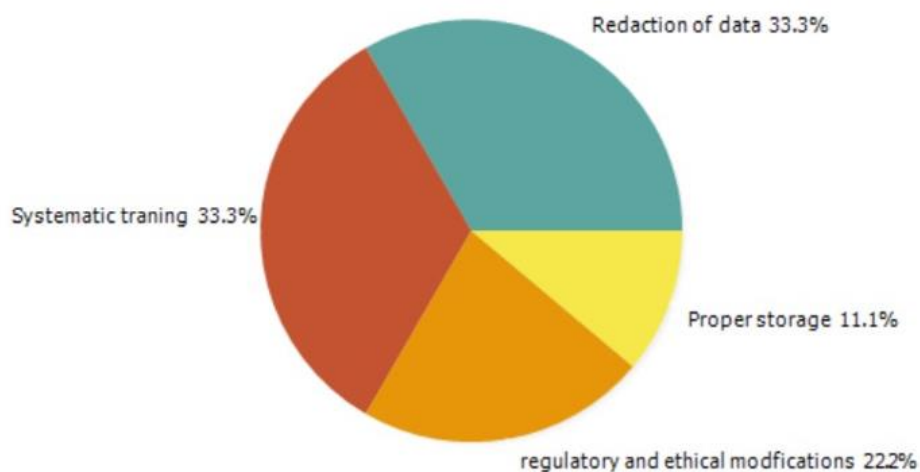


Figure 24- Do you believe that if the AI tools are not handled vigilantly in pharmacovigilance case processing, it will compromise the confidentiality of patient data which will eventually pose a threat to patient safety? If yes, what are your suggestions to avoid?

The responses received to this question were quite promising. It shows that the case processors handling the safety data are aware that if they improperly handle the safety data

with the help of AI tools, it will pose a threat to the data and then eventually to patient safety. All the participants agreed to the fact that if not vigilantly handled it will pose a threat to patient safety.

The participants put forward several suggestions to overcome this issue.

Systematic training- All the participants had the same opinion that the case processors and all the individuals handling the data should be given systematic training regarding the proper use, handling, and storage of data. Many workshops and other courses are available on different platforms so that the case processors can utilize them to gain systematic knowledge.

SME with 3.5 years of experience suggested that “As we have discussed earlier, the main step to take is to provide systematic training in handling private data. Once the case processors have understood the basics in AI handling, we can ensure that patient safety is protected”.

Redaction of documents: The participants suggested an important step in protecting private and confidential information received in the intake document. Whatever the case, special care should be taken to read and redact any personal information received in the intake document. All the source documents should be carefully read and all the data compromising the patient’s privacy and safety should be redacted.

An SME responded “Nowadays, we are using AI-based tools and systems to detect AEs from social media platforms such as Facebook and Twitter. So care should be taken when these AE are reported. All the personal data should be redacted from the source document”

Regulatory and Ethical Modifications: The participants suggested that with the incorporation of AI into the case processing steps, it is high time that the regulatory guidelines and ethical guidelines are modified. With the introduction of these new technologies, several factors are at stake. So the regulatory agencies and the ethical boards should come forward and analyze the current situation. Proper guidance is required to overcome this challenge.

Proper storage- It was stated by the participants that proper storage of the safety data in our databases and the organizational cloud also plays a very important role in ensuring patient

safety. All the case processors should be trained in proper data handling techniques. Improper storage of the data can result in data breaches and thereby will result in compromised patient safety.

Question 5: What are the skills and competencies that you would propose to a team of case processors to aid in their future automation transition and for the incorporation of novel technologies such as ChatGPT and NLP into the field of pharmacovigilance?

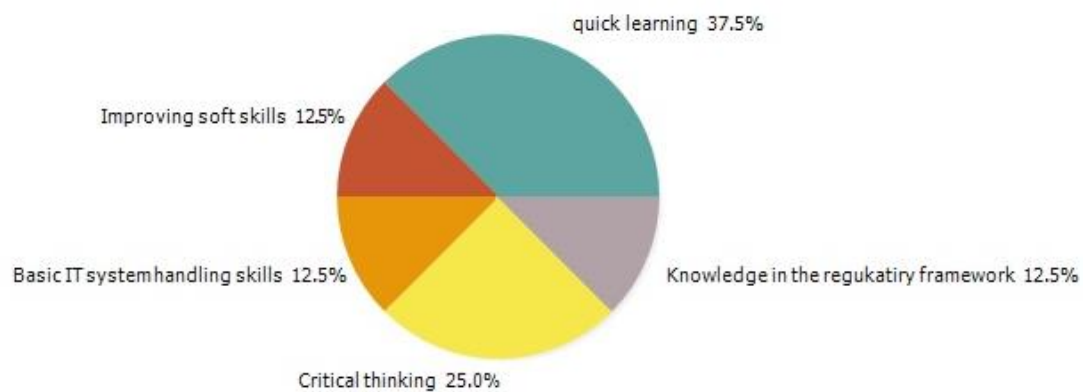


Figure 25 Response to the question: Skills and competencies

The participants have put forward several suggestions to improve the automation process in the future.

Critical thinking- The participants suggested that the case processors should enhance their critical thinking skills to perform better with the help of tools. The novel technologies such as ChatGPT are powered by robotics. To cope with these mechanisms, the case processors should be able to critically think and behave. Handling patient safety data with AI tools requires someone who is always open to thinking out of the box and coming up with exciting solutions.

Basic IT handling techniques: It is alarming to know that many case processors don't even know the basics and still struggle with basics such as Microsoft Excel. However, it was

suggested that the case processors who are handling patient data should possess the basic skills so that they do not pose any threat to the safety profile of the drug.

Quick learning: The author concludes from the responses that people should be able to quickly grasp the information conveyed. Quick learning skills always help the case processor to quickly interpret the problems accordingly. For quick learning, proper knowledge checks must be done at correct intervals.

It was stated by an SME with 2.5 years of experience that “In our company, being an SME, I have taken the initiative to conduct interactive sessions or quiz programs where innovative ideas are taken up for discussion to make sure that knowledge is shared among peers”.

Improving soft skills- The participants suggested that the case processors should work on improving their soft skills. They stated that it is essential to ensure a smooth transition to automation. Many of the respondents suggested that there should be weekly SME sessions that make sure that all needs are being taken care of.

Knowledge of the regulatory framework: In the automation step, it was suggested that it is important to know and understand the regulatory guidelines which outline the PV activities. In agreement with the previous point, it was again suggested that the regulatory framework should be monitored and amended as necessary to make sure that patient safety is guaranteed.

Chapter 5

Conclusion and recommendations

5.1 Answer to the main research questions

What changes do the CROs had to undergo to cope with the changes brought in by the pandemic and what are the struggles faced by the individuals in the adoption of AI in PV activities

How AI has influenced the working pattern of CROs in Ireland during COVID-19 and how they have utilized the help of novel technologies such as ChatGPT in case processing?

The working pattern of CROs after the adoption of AI tools was critically analyzed using the survey questionnaire and the interview session. The response of the participants to the interview and survey has shown us how CROs work towards providing patient safety. The author was able to conclude that there was an enormous increase in the utilization of AI tools in different stages of case processing from the responses. The case processors and the SMEs suggested that they have been using different AI tools right from the beginning of the case processing step till the case was reported to the respective regulatory authority.

The author believes that this transformation of the working pattern of the CROs greatly depends on the factor that they have understood the benefits of adopting AI tools in case processing outweigh the risk factors of automation. The time taken for case processing activities is critical in the field of case processing as each of the cases comes with a definite timeline that has to have adhered to meet the regulatory requirements. The finding that AI tools help save time and also help to complete tasks more efficiently underlines why CROs have come forward for the integration of AI tools.

The utilization of Novel technologies such as ChatGPT is highly promising for a country like Ireland. The responses have highlighted that the CROs have adopted these technologies for very crucial steps in the processing of cases. Despite the uncertainties regarding data privacy, it is promising that ChatGPT-powered tools are revolutionizing PV case processing activities.

The case processors who participated in the survey and interview showcased how ChatGPT has helped the CROs in enhancing the different steps such as automated narratives, ChatGPT-powered search engines, and also, most importantly handling unstructured documents.

Even though the responses revealed that most of the CROs have been utilizing novel tools in case processing, there were concerns about the proper utilization of these tools and the concerns about adopting these to handle patient data. It was surprising and even more fascinating to see that there were organization-level and employee-level programs carried out to help the employees to nourish and enhance the processors' knowledge of these new technologies and how the CROs' have been shaping themselves for the future automation transitions.

Which phases of case processing can be modified with the adoption of AI and what are the challenges the case processors have faced during the adoption?

The phases which can be impacted by the adoption of AI were well explained by the responses received from the participants of this study. The literature review suggested that there was an enormous increase in the number of cases reported during the pandemic. The study response was in agreement with this fact. It was intriguing to know how the CROs were able to handle these cases all of a sudden. It was interesting to note that from this study, the researcher was able to conclude that the adoption of AI tools played an important role in handling cases, particularly during the pandemic period.

The steps in case processing are positively impacted by the integration of AI tools to them. Right from AE detection to the regulatory submission, each step was modified using AI tools. Using NLP for data mining and ChatGPT-powered search engines for AE detection are the most important changes in the intake steps. In agreement with the findings of the literature review, the most vital step which was modified was the narrative writings step. Automated narratives were considered a blessing in the case of complex cases like literature reviews and legal cases. Intake, data entry, and narrative writing were all modified using AI tools. However, the understanding that AI can be further utilized will change the perception of case processors toward adoption.

To some extent, the case processors were able to cope with the surge in cases with the adoption of AI. However, some challenges had to be faced by the case processors during this

transition. The most important one is the poor knowledge about the basics of automation and how it works. In agreement with the literature review, it was observed that the concern of interpreting ambiguities, the case should ensure that they are skilled enough to handle the tools trained with a set of pre-programmed data sets. The CROs when integrating AI tools into their current working pattern have preferred a change of database where AI tools can be utilized better. So, lacking proper training and knowledge of the database was also a difficulty they faced. Despite all the difficulties, the case processors and CROs should work hand in hand to overcome all the difficulties and ensure smooth working in the field of PV with the use of AI tools.

How did the adoption of AI tools affect the productivity and efficiency of PV case processors?

Different AI tools employed in aiding the case processing techniques can play a vital role in managing the productivity of the case processors. In a fast-paced era, the productivity of an employee is an important factor in determining the growth of an organization. During the pandemic season, the case processors had to put in a lot of effort to cope with the high pressure they had to face. So it is important that they had to make use of the time they had more productively.

The automated narratives and auto-filling of the data entry fields from the intake data were vital in case of determining how AI has affected the productivity of the case processors. When the productivity of the case processors was positively impacted, it also led to better management of their work-life balance. As most of the employees were working in a 'work from home' system, they needed to make space and distinguish their professional work from their personal life. It was also noted that when the employees are working in a stress-free environment, the room for judgmental and oversight errors is also less.

5.2 Limitations of the Research

The main limitation of the study was the time constraints and also, the relatively small number of people interviewed regarding the topic. The adoption of AI tools, particularly ChatGPT is a new development in the area of pharmacovigilance and the author believes that to get more insights and data on the topic, more extensive research over a greater period has to be done.

The author argues that being a very new area of research in the field of PV, it might take another 5 years to get the automation to become a full-fledged development in the field of PV. So research with wider research objectives will play a vital role in the future.

5.3 Contributions of the research

Despite all the limitations, the researcher was able to conclude the study efficiently. When the secondary research was completed, the author concluded that there was a gap in the literature that focused on the adoption of AI in PV with more focus on the productivity of the case processors. Also, there were no studies found on how AI tools such as ChatGPT can be efficiently used in each of the case processing steps. Thus, this study has tried to showcase these points through this work.

5.4 Recommendations from the Study.

- Systematic and timely training should be provided so that they understand the basic and updated information about all the technologies.
- AI tools can be beneficial, but at the same time, they can pose many threats if not handled properly. Special care should be taken on that.
- All the individuals participating in case processing should be open to learning to cope with the advancements in the field.
- Organizational-level initiatives are to be taken to ensure that a basic understanding of the tools is complete.
- A wider study with more population will help in understanding the effects of AI tools such as ChatGPT and NLP in a more informative manner.

References

- Alugubelli, R. (2016) 'Exploratory Study of Artificial Intelligence in Healthcare'. *INTERNATIONAL JOURNAL OF INNOVATIONS IN ENGINEERING RESEARCH AND TECHNOLOGY*, 3(1), pp. 2394–2399. DOI: 10.1177/20420986211038436.
- Aly, H. (2020) 'Digital Transformation, Development and Productivity in Developing Countries: Is Artificial Intelligence a Curse or a Blessing?' *Review of Economics and Political Science*, 7(4), pp. 238–256. DOI: 10.1108/REPS-11-2019-0145.
- Ball, R. and Dal Pan, G. (2022) "'Artificial Intelligence" for Pharmacovigilance: Ready for Prime Time?' *Drug Safety*, 45(5), pp. 429–438. DOI: 10.1007/s40264-022-01157-4.
- Bate, A. and Stegmann, J.-U. (2023) 'Artificial Intelligence and Pharmacovigilance: What Is Happening, What Could Happen and What Should Happen?' *Health Policy and Technology*, p. 100743. DOI: 10.1016/j.hlpt.2023.100743.
- Bates, D.W. *et al.* (2021) (1) 'The Potential of Artificial Intelligence to Improve Patient Safety: A Scoping Review'. *Npj Digital Medicine*, 4(1), pp. 1–8. DOI: 10.1038/s41746-021-00423-6.
- Bihan, K. *et al.* (2020) 'Uses of Pharmacovigilance Databases: An Overview'. *Therapies*, 75(6), pp. 591–598. DOI: 10.1016/j.therap.2020.02.022.
- Böhm, R. *et al.* (2016) 'OpenVigil FDA – Inspection of U.S. American Adverse Drug Events Pharmacovigilance Data and Novel Clinical Applications'. *PLOS ONE*, 11(6), p. e0157753. DOI: 10.1371/journal.pone.0157753.
- EMA. (2020) *2019 Annual Report on EudraVigilance for the European Parliament the Council and the Commission*. Available at: https://www.ema.europa.eu/en/documents/report/2019-annual-report-eudravigilance-european-parliament-council-commission-reporting-period-1-january_en.pdf (Accessed: 24 April 2023).
- EMA. (2018) *Pharmacovigilance: Overview*. European Medicines Agency. Available at: <https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance-overview> (Accessed: 27 January 2023).
- Fouretier, A., Malriq, A. and Bertram, D. (2016) 'Open Access Pharmacovigilance Databases: Analysis of 11 Databases'. *Pharmaceutical Medicine*, 30(4), pp. 221–231. DOI: 10.1007/s40290-016-0146-6.
- Garg, R. (2016) 'Methodology for Research I'. *Indian Journal of Anaesthesia*, 60(9), p. 640. DOI: 10.4103/0019-5049.190619.
- Garret, A. (2021) *Pharmafocus March 2021*. *calameo.com*. Available at: <https://www.calameo.com/read/0061133858eb13eaef04?page=18> (Accessed: 4 May 2023).
- Ghosh, R. *et al.* (2020) 'Automation Opportunities in Pharmacovigilance: An Industry Survey'. *Pharmaceutical Medicine*, 34(1), pp. 7–18. DOI: 10.1007/s40290-019-00320-0.

- Goertzen, M. (2017) 'Applying Quantitative Methods to E-Book Collections'. *Library Technology Reports*, 53(4), pp. 12–18. DOI: 10.4103/0019-5049.1906123.
- Hall, S. (2021) 'Changes in Pharmacovigilance Following the End of the Brexit Transition'. *Therapeutic Advances in Drug Safety*, 12, p. 204209862110422. DOI: 10.1177/20420986211042208.
- Hauben, M. and Hartford, C.G. (2021) 'Artificial Intelligence in Pharmacovigilance: Scoping Points to Consider'. *Clinical Therapeutics*, 43(2), pp. 372–379. DOI: 10.1016/j.clinthera.2020.12.014.
- HPRA. (2023) *EU Pharmacovigilance Legislation*. Available at: <http://www.hpra.ie/homepage/medicines/regulatory-information/pharmacovigilance-and-post-authorisation-safety/eu-pharmacovigilance-legislation> (Accessed: 15 April 2023).
- Hussain, Z. *et al.* (2022) 'Artificial Intelligence–Enabled Social Media Analysis for Pharmacovigilance of COVID-19 Vaccinations in the United Kingdom: Observational Study'. *JMIR Public Health and Surveillance*, 8(5), p. e32543. DOI: 10.2196/32543.
- ICHGCP CRO List. (2023) *List of Contract Research Organizations (CRO) in Ireland - CRO Database - ICH GCP*. Available at: <https://ichgcp.net/cro-list/country/ireland> (Accessed: 22 April 2023).
- Jalali, R.K. (2018) 'Chapter 28 - Individual Case Safety Reports' Vohora, D. and Singh, G. (eds.). *Pharmaceutical Medicine and Translational Clinical Research*, pp. 413–418. DOI: <https://doi.org/10.1016/B978-0-12-802103-3.00029-8>.
- Kaeding, M., Schmälder, J. and Klika, C. (2017) *Pharmacovigilance in the European Union*. 1st Edition. Wiesbaden: Springer Fachmedien Wiesbaden DOI: 10.1007/978-3-658-17276-3.
- King, M.R. (2023) 'A Conversation on Artificial Intelligence, Chatbots, and Plagiarism in Higher Education'. *Cellular and Molecular Bioengineering*, 16(1), pp. 1–2. DOI: 10.1007/s12195-022-00754-8.
- Kothari, C. (2004) *Research Methodology Methods and Techniques (PDFDrive).Pdf*. 2nd Edition. New Age International Publisher Available at: [http://lms.aambc.edu.et:8080/xmlui/bitstream/handle/123456789/212/Research%20Methodology%20Methods%20and%20Techniques%20\(%20PDFDrive%20\).pdf?sequence=1](http://lms.aambc.edu.et:8080/xmlui/bitstream/handle/123456789/212/Research%20Methodology%20Methods%20and%20Techniques%20(%20PDFDrive%20).pdf?sequence=1) (Accessed: 18 April 2023).
- Lathifa, Z. and Aman-Ullah, A. (2022) 'The Impact of Pharmacovigilance Training Programs on Healthcare Professionals' Knowledge, Attitudes, and Practices in Developing Countries: A Study on MENA Countries'. *Sage Science Review of Educational Technology*, 2(1), pp. 60–65.
- Lee, C.Y. and Chen, Y.-P.P. (2019) 'Machine Learning on Adverse Drug Reactions for Pharmacovigilance'. *Drug Discovery Today*, 24(7), pp. 1332–1343. DOI: 10.1016/j.drudis.2019.03.003.
- Liang, L. *et al.* (2022a) 'Artificial Intelligence-Based Pharmacovigilance in the Setting of Limited Resources'. *Drug Safety*, 45(5), pp. 511–519. DOI: 10.1007/s40264-022-01170-7.
- Liang, L. *et al.* (2022b) 'Artificial Intelligence-Based Pharmacovigilance in the Setting of Limited Resources'. *Drug Safety*, 45(5), pp. 511–519. DOI: 10.1007/s40264-022-01170-7.
- Mahan, V.L. (2014) 'Clinical Trial Phases'. *International Journal of Clinical Medicine*, 05(21), pp. 1374–1383. DOI: 10.4236/ijcm.2014.521175.

Market Analysis Report. (2023) *Artificial Intelligence Market Size & Share Analysis Report 2030*. Available at: <https://www.grandviewresearch.com/industry-analysis/artificial-intelligence-ai-market> (Accessed: 24 April 2023).

Mittu, R. *et al.* (2016) 'Introduction to the Symposium on AI and the Mitigation of Human Error'. *AAAI Spring Symposium Series*, 4(1), pp. 2–6. DOI: 10.34013.13004/13004-56102.

MS Research. (2019) *What Are Clinical Trials?*. *MS Trials*. Available at: <https://mstrials.org.au/what-are-clinical-trials/> (Accessed: 9 April 2023).

Negi, K. *et al.* (2019) 'A Novel Method for Drug-Adverse Event Extraction Using Machine Learning | Elsevier Enhanced Reader'. *Informatics In Medicine Unlocked*, 17(1), pp. 1–6. DOI: 10.1016/j.imu.2019.100190.

NMIC. (2019) 'NMIC BULLETIN ADVERSE REACTIONS TO MEDICINES'. *National Medicine Information Centre*, 25(4), pp. 1–6. DOI: 10.1016/j.trip.2020.100240.

Ohana, B., Ltd, B. and Sullivan, J. (2021) 'Validation and Transparency in AI Systems for Pharmacovigilance: A Case Study Applied to the Medical Literature Monitoring of Adverse Events'.

Patel, M. and Patel, N. (2019) 'Exploring Research Methodology: Review Article'. *International Journal Of Research & Review*, 6(3), pp. 48–55.

Pearce, S.H.S. (2004) 'Spontaneous Reporting of Adverse Reactions to Carbimazole and Propylthiouracil in the UK'. *Clinical Endocrinology*, 61(5), pp. 589–594. DOI: 10.1111/j.1365-2265.2004.02135.x.

Pilipiec, P., Liwicki, M. and Bota, A. (2022) (2) 'Using Machine Learning for Pharmacovigilance: A Systematic Review'. *Pharmaceutics*, 14(2), p. 266. DOI: 10.3390/pharmaceutics14020266.

Prathak, V., Jena, B. and Kalra, S. (2013) 'Qualitative Research'. *Perspectives in Clinical Research*, 4(3), pp. 192–193. DOI: DOI:10.4103/2229-3485.115389.

Rickert, J. (2020) 'On Patient Safety: The Lure of Artificial Intelligence—Are We Jeopardizing Our Patients' Privacy?' *Clinical Orthopaedics and Related Research*, 478(4), pp. 712–714. DOI: 10.1097/CORR.0000000000001189.

Robinson, J.C. (2021) 'Funding of Pharmaceutical Innovation During and After the COVID-19 Pandemic'. *JAMA*, 325(9), p. 825. DOI: 10.1001/jama.2020.25384.

Sardella, M. *et al.* (2021) 'Monitoring the Manufacturing and Quality of Medicines: A Fundamental Task of Pharmacovigilance'. *Therapeutic Advances in Drug Safety*, 12, p. 20420986211038436. DOI: 10.1177/20420986211038436.

Saunders, M.N.K., Lewis, P. and Thornhill, A. (2019) *Research Methods for Business Students*. eighth edition. New York: Pearson Education.

Schmider, J. *et al.* (2019) 'Innovation in Pharmacovigilance: Use of Artificial Intelligence in Adverse Event Case Processing'. *Clinical Pharmacology & Therapeutics*, 105(4), pp. 954–961. DOI: 10.1002/cpt.1255.

Shirer, M. (2022) *Worldwide Spending on AI-Centric Systems Will Pass \$300 Billion by 2026, According to IDC*. IDC: The premier global market intelligence company. Available at: <https://www.idc.com/getdoc.jsp?containerId=prUS49670322> (Accessed: 24 April 2023).

Surendra, E. and Garlapati, R. (2020) 'Development of Pharmacovigilance Culture'. *International Journal of Pharmacy Research & Technology*, 10(1). DOI: 10.31838/ijprt/10.01.01.

Trifirò, G. and Crisafulli, S. (2022) 'A New Era of Pharmacovigilance: Future Challenges and Opportunities'. *Frontiers in Drug Safety and Regulation*, 2, p. 866898. DOI: 10.3389/fdsfr.2022.866898.

Turyahikayo, E. (2021) 'Philosophical Paradigms as the Bases for Knowledge Management Research and Practice'. *Knowledge Management & E-Learning: An International Journal*, pp. 209–224. DOI: 10.34105/j.kmel.2021.13.012.

WHO. (2021) *Pharmacovigilance*. Available at: <https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance> (Accessed: 9 April 2023).

Williams, A. and Mulchrone, B. (2021) 'The Future of Pharmacovigilance. How COVID-19 Has Inspired Innovation'. *IQVIA*, 1(1), pp. 1–10.

Yong, W.K., Husin, M. and Kamarudin, S. (2021) 'Understanding Research Paradigms: A Scientific Guide'. 27(2), pp. 5857–5865. DOI: 10.47750/cibg.2021.27.02.588.

Zayas-Cabán, T., Okubo, T.H. and Posnack, S. (2022) 'Priorities to Accelerate Workflow Automation in Health Care'. *Journal of the American Medical Informatics Association*, 30(1), pp. 195–201. DOI: 10.1093/jamia/ocac197.

APPENDICES

Steps in case processing:

Intake of cases:

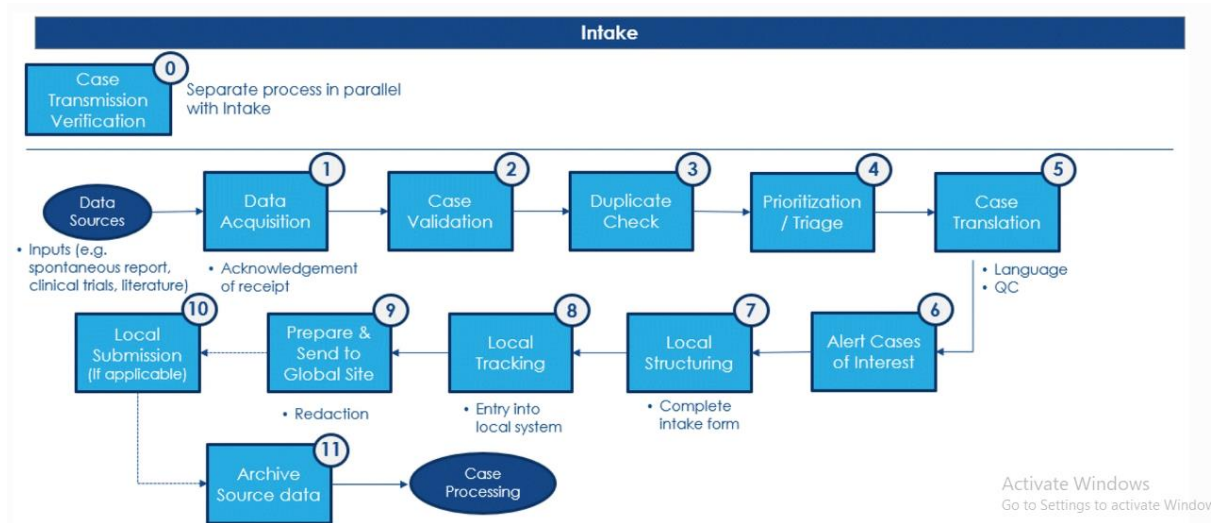


Figure 26 Intake of cases(Ghosh et al., 2020)

Case processing:

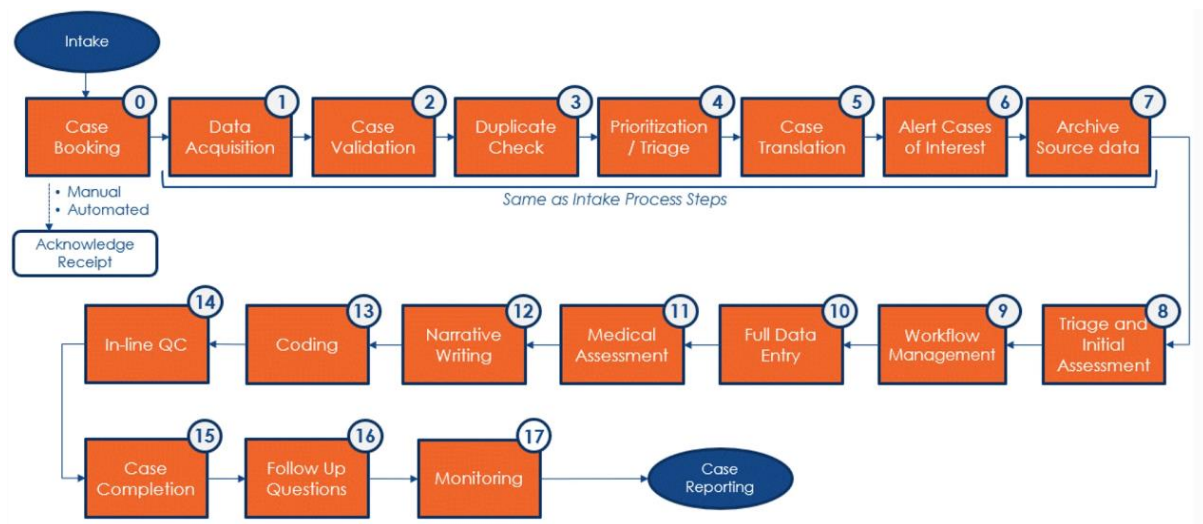


Figure 27 Processing of cases(Ghosh et al., 2020)

Reporting of cases:

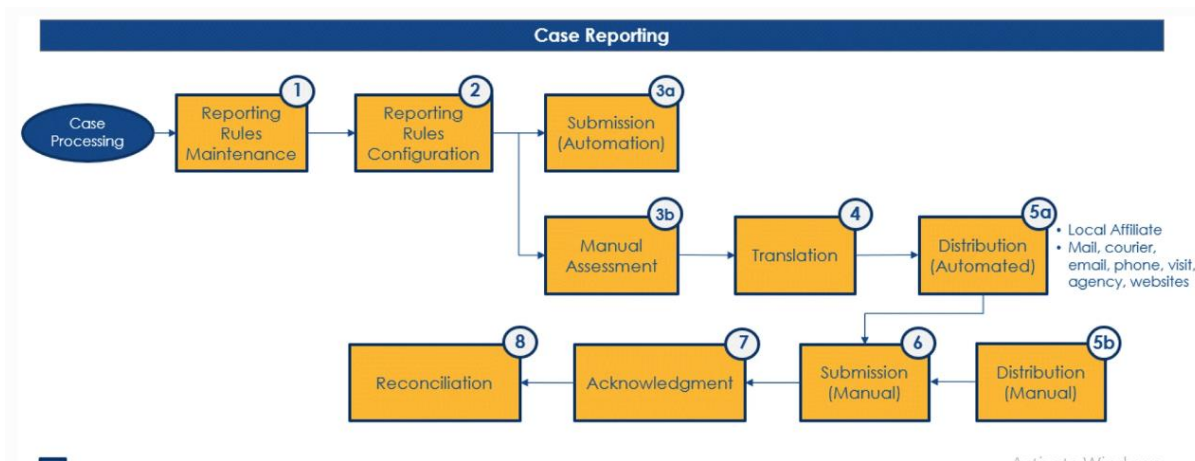


Figure 28 Reporting of cases (Ghosh et al., 2020)