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Griffith College

Quantitative Analysis of IBM Watson's Impact on Operational Efficiency and Accuracy in Pharmacovigilance for UK Pharmaceutical Companies

By

SHARY RAMESH

Dissertation Supervisor: KATHY CLARKE

A thesis submitted in partial fulfilment of the requirements for MSc in Pharmaceutical business and technology

Innopharma Faculty of Pharmaceutical Sciences

Griffith College Dublin

SEPTEMBER 2024

DECLARATION

I, Shary Ramesh, hereby certify that the dissertation titled "Quantitative Analysis of IBM Watson's Impact on Operational Efficiency and Accuracy in Pharmacovigilance for UK Pharmaceutical Companies," submitted for the degree of MSc in Pharmaceutical Business and Technology, is the result of my own work. I have rigorously followed academic integrity standards, ensuring that all references to the work of others are properly acknowledged.

In conducting this research, I have undertaken comprehensive research and analysis, employing various scholarly sources and methodologies. Contributions from external sources have been appropriately cited, with full recognition given to the intellectual property of others. I affirm that this dissertation reflects my original insights, interpretations, and conclusions, derived from my personal academic efforts.

I declare that the work presented in this dissertation is entirely my own. All sources and references utilized in this study have been accurately acknowledged, and any assistance received has been clearly stated. I confirm that this research has not been previously submitted for any degree or professional qualification. Additionally, I have adhered to the ethical guidelines set by my institution throughout the course of this research.

Signed: SHARY RAMESH

Date: 24/08/2024

Supervisor Signature:

Date: 24/08/2024

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ABSTRACT

Pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It plays a critical role in ensuring drug safety and efficacy, particularly within the pharmaceutical industry. This study investigates the impact of IBM Watson on pharmacovigilance practices in the UK pharmaceutical sector, with a focus on quantifying reductions in manual workloads, improvements in data processing speeds, and enhancements in the accuracy of detecting adverse drug reactions (ADRs).

The justification for this research lies in the increasing reliance on artificial intelligence (AI) technologies like IBM Watson to optimize PV processes. As the pharmaceutical industry faces growing demands for more efficient and accurate drug safety monitoring, there is a pressing need to evaluate the effectiveness of these AI tools. By assessing both the benefits and challenges associated with IBM Watson's implementation, this study provides a comprehensive understanding of its role in advancing PV practices.

A thorough literature review is conducted to explore existing research on AI in pharmacovigilance, highlighting current trends, technological advancements, and the potential of AI to transform drug safety monitoring. This review also identifies gaps in the literature, particularly regarding the real-world application of IBM Watson in the UK pharmaceutical industry, thereby establishing the necessity of this study.

The research employs a quantitative methodology, utilizing surveys distributed to professionals within the UK pharmaceutical sector to gather relevant data. Statistical analyses are performed to evaluate the impact of IBM Watson on operational efficiency and ADR detection accuracy. The findings reveal that a significant majority of respondents reported improvements in literature monitoring efficiency, reductions in manual workloads, and faster data processing with IBM Watson, confirming the hypotheses related to these outcomes. Additionally, the study addresses challenges such as data integration issues, the need for user training, and regulatory compliance, all of which are critical factors for the successful implementation of AI in PV.

Upon analyzing the findings, the study will provide practical recommendations and identify critical success factors for optimizing pharmacovigilance practices through AI integration. These recommendations will be aimed at enhancing data integration, improving user training programs, and ensuring compliance with regulatory standards. Ultimately, this research contributes valuable insights into the role of AI in healthcare, offering guidance for future implementations of AI technologies in pharmacovigilance and potentially influencing industry-wide best practices.

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ADR: Adverse Drug Reaction

AI: Artificial Intelligence

DDIs: Drug-Drug Interactions

EHRs: Electronic Health Records

EMA: European Medicines Agency

FDA: Food and Drug Administration

GDPR: General Data Protection Regulation

H1: Hypothesis 1

H2: Hypothesis 2

IBM: International Business Machines

LSM: Literature Surveillance Monitoring

MLC: Machine Learning Code

NFC: Near Field Communication

NLP: Natural Language Processing

PV: Pharmacovigilance

ROI: Return on Investment

SPSS: Statistical Package for the Social Sciences

SR: Safety Reporting

TAM: Technology Acceptance Model

1. INTRODUCTION

Pharmacovigilance, as defined by the World Health Organization (WHO), involves the science and activities dedicated to detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) and other drug-related issues to ensure medicinal product safety and efficacy. Pharmacovigilance is essential for ensuring the safety and efficacy of medicinal products through the monitoring and detection of adverse drug reactions (ADRs) (Kengar et al., 2019). A critical aspect of this process is literature monitoring, which involves screening scientific publications for ADR reports. However, the exponential growth of published articles has rendered manual monitoring ineffective. To address this challenge, IBM Watson, an AI solution leveraging natural language processing and machine learning, has been proposed as a potential remedy (Chang, 2023).

IBM Watson can streamline literature review and data acquisition, making these processes faster and more accurate. Despite this, IBM has faced declining revenues since 2011, with only a slight increase in 2021 followed by declines in 2022 and 2023, even after investing $1.23 billion in advertising (Statista, 2024). Barriers to AI adoption in healthcare include low technological uptake, stringent regulatory requirements, and resistance from practitioners (Wuni and Shen, 2020).

The UK pharmaceutical industry, known for its rigorous standards and innovative practices, provides a valuable context for evaluating the impact of IBM Watson on pharmacovigilance. Successfully overcoming implementation barriers could lead to significant advancements in drug safety and encourage broader AI applications in healthcare (Abraham, 2023).

AI has revolutionized the pharmaceutical sector by enhancing drug discovery and safety surveillance through its high data processing capabilities (Chang, 2023). IBM Watson, in particular, has proven highly effective for pharmacovigilance, particularly in monitoring Adverse Drug Reactions (ADRs), a crucial task for the £7 billion UK pharmaceutical industry (Lewis and McCallum, 2020; Korean, 2022). The integration of AI into pharmacovigilance allows for the rapid analysis of vast amounts of data, identifying potential safety issues more efficiently than traditional methods. However, challenges such as data integration and management remain significant barriers (Dong et al., 2022).

A 2023 study highlighted that 67% of pharmaceutical organizations have adopted AI technology for drug safety, leading to a 30% increase in productivity (Global Reports, 2021). To enhance the effectiveness of AI in pharmacovigilance, it is essential to address these challenges and ensure effective integration with existing systems. Critical success factors (CSFs) include robust data management practices, seamless integration with current systems, and continuous training for staff (Kengar Manohar, 2019). Recommendations for improving AI implementation in pharmacovigilance include investing in comprehensive data integration solutions, fostering collaboration between AI developers and pharmaceutical professionals, and developing standardized protocols for AI use in monitoring ADRs (Dong et al., 2022).

This research uses a quantitative approach to assess how IBM Watson has improved pharmacovigilance effectiveness within the UK pharmaceutical industry. The study aims to identify both the benefits and challenges associated with AI in literature monitoring, thereby contributing to a deeper understanding of AI's role in healthcare and its impact on pharmacovigilance.

1.1 Purpose

The purpose of the research is to thoroughly evaluate the impact of integrating IBM Watson into pharmacovigilance (PV) practices within the UK pharmaceutical industry. The study focuses on quantifying the reduction in manual workload, the enhancement of data processing speed, and the accuracy of adverse drug reaction (ADR) detection provided by IBM Watson compared to traditional manual literature review methods. By addressing these objectives, the research seeks to highlight the potential advantages of AI integration in PV, particularly in enhancing operational efficiency, improving ADR detection, and ensuring regulatory compliance.

Beyond assessing performance metrics, the study will also document and analyze the key challenges faced by UK pharmaceutical companies during the implementation of IBM Watson. These challenges may include issues related to data integration, user training, and adherence to regulatory standards. By identifying these obstacles, the research aims to offer actionable recommendations and develop a critical success framework for the effective integration of AI into PV practices.

The focus on the UK is driven by its advanced regulatory framework and strong pharmaceutical industry infrastructure, making it an ideal context for evaluating IBM

Watson’s integration in pharmacovigilance. The UK’s stringent regulatory standards, overseen by agencies such as the Medicines and Healthcare Products Regulatory Agency (MHRA), provide a rigorous environment to assess both compliance and effectiveness. Additionally, the country’s well-established pharmacovigilance system and high adoption rate of advanced technologies offer valuable insights into the practical challenges and benefits of implementing AI-driven solutions like IBM Watson. This focus allows for an in-depth analysis of how such innovations can be adapted and optimized within a leading pharmaceutical market.

The findings from this research will be crucial in guiding UK pharmaceutical companies on how to best leverage IBM Watson to enhance their PV processes, improve drug safety, and maintain regulatory compliance. The insights gained will be valuable for the future of pharmacovigilance practices, demonstrating the tangible benefits of AI implementation while addressing the associated challenges. The study will pave the way for more widespread adoption of advanced technologies in the pharmaceutical industry, leading to improved drug safety monitoring, faster identification of ADRs, and overall enhancement of public health outcomes. Moreover, the critical success framework developed through this research can serve as a guideline for future innovations and integrations of AI technologies in pharmacovigilance, ensuring that the industry continues to lead in technological advancements.

1.2 Background

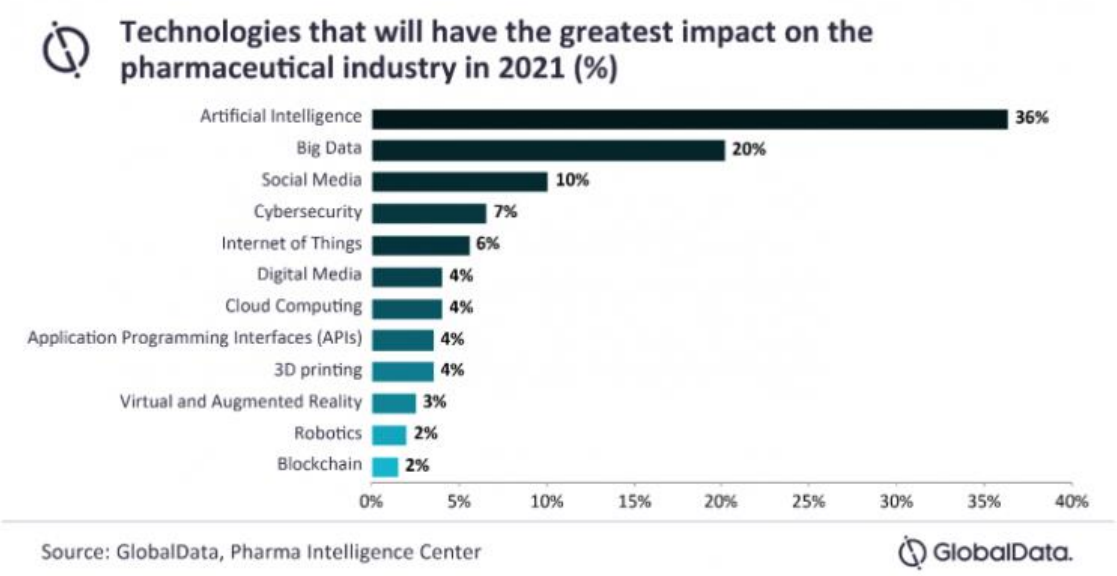
The UK pharmaceutical industry has increasingly adopted advanced technologies to enhance drug safety and efficacy. Artificial Intelligence (AI), as defined by Lake et al. (2017), involves programming computers to learn and think like humans, enabling them to process data and make decisions. IBM Watson, a prominent AI system, exemplifies this capability by analyzing large datasets to identify trends and make informed decisions. Kengar Manohar (2019) notes that IBM Watson's natural language processing (NLP) and machine learning features are particularly useful for pharmacovigilance, which involves monitoring and evaluating drug safety.

According to Globalreposts (2021), a significant portion of industry professionals (63 out of 198 surveyed) believe AI will have a transformative impact on the pharmaceutical sector. AI systems like IBM Watson enhance pharmacovigilance by rapidly analyzing data from scientific literature, clinical trials, and real-world evidence, thus improving the

detection of adverse drug reactions (ADRs) and ensuring accurate drug safety assessments (Chen, Argentinis, and Weber, 2016).

Pharmacovigilance, as described by Fam (2022), focuses on identifying, evaluating, and preventing drug-related problems to ensure medication safety. AI-driven literature monitoring systems keep track of various sources, such as journals and online publications, to provide timely safety information and ensure compliance with regulations (Lewis and McCallum, 2020). This proactive approach enables more accurate results, reduces manual workload, and improves patient outcomes (Kalaiselvan, Sharma, and Gupta, 2021).

AI systems like IBM Watson offer significant advantages over traditional methods by efficiently processing vast amounts of textual data and enhancing safety signal detection (Dong et al., 2022). This study aims to evaluate the benefits and challenges of using IBM Watson in pharmacovigilance within the UK pharmaceutical industry, providing insights and recommendations for improving drug safety and regulatory compliance. Despite its potential, challenges such as data integration, model development, and user acceptance require further investigation (Dwivedi et al., 2021).



Global data (2021) AI to be a most transformative technology for pharma, finds survey: Source (Hannah Balfour, 2021)

1.3 Significance of the Research

This research is significant as it addresses the transformative potential of AI, specifically IBM Watson, in enhancing pharmacovigilance (PV) practices within the UK pharmaceutical sector. By evaluating the impact on operational efficiency, accuracy in detecting adverse drug reactions (ADRs), and regulatory compliance, the study provides critical insights into the practical benefits and challenges of AI integration. The findings will offer actionable recommendations tailored to the unique needs of UK pharmaceutical companies, facilitating more effective AI adoption. Ultimately, this research aims to advance drug safety monitoring, improve public health outcomes, and set a precedent for future AI innovations in the healthcare industry.

1.4 Rationale

The rationale for this research stems from the growing need for improved literature tracking methods in pharmacovigilance (PV) due to the exponential increase in scientific literature and the critical importance of early and accurate adverse drug reaction (ADR) detection (Kengar Manohar, 2019; Dwivedi et al., 2021). With scientific literature doubling every nine years manual tracking becomes increasingly impractical (Mabe & Amin, 2012). Early ADR detection not only enhances patient safety but also significantly reduces healthcare costs (Arlett et al., 2014). AI technologies like IBM Watson present promising solutions for efficient and accurate literature monitoring. However, there is a notable lack of statistical evidence demonstrating their effectiveness and potential issues (Lewis & McCallum, 2020). This research aims to fill this gap by providing quantitative data on IBM Watson's impact on PV practices within the UK pharmaceutical sector, thus supporting the adoption of AI in healthcare.

1.5 Scope

The scope of implementing IBM Watson in literature surveillance within pharmacovigilance focuses on boosting the efficiency and precision of monitoring scientific literature for adverse drug reactions (ADRs). This study will assess IBM Watson’s ability to automate and expedite literature reviews, enhance ADR detection accuracy, and integrate with existing pharmacovigilance systems. By evaluating its handling of growing scientific literature volumes, the research aims to highlight improvements in ADR reporting and identify deployment challenges. Recommendations for future implementation include investing in robust data integration solutions to ensure seamless compatibility with current systems, providing comprehensive training for users

to maximize AI benefits, and developing standardized protocols for AI usage in literature surveillance. Additionally, fostering collaboration between AI developers and pharmacovigilance professionals will be crucial to addressing challenges and optimizing AI's role in advancing drug safety practices.

1.6 Aim

The aim of this research is to evaluate the effectiveness and impact of IBM Watson as a tool for enhancing pharmacovigilance (PV) practices within the UK pharmaceutical industry. The study seeks to systematically assess how the integration of IBM Watson can reduce manual workload, increase data processing speed, and improve the accuracy of detecting adverse drug reactions (ADRs) compared to traditional manual literature review methods. Additionally, the research aims to identify and analyze the key challenges faced by UK pharmaceutical companies during the implementation of IBM Watson, including issues related to data integration, user training, and regulatory compliance.

Through this evaluation, the research intends to develop a comprehensive understanding of the potential benefits and limitations of using AI in PV. By synthesizing these findings, the study aims to create a set of actionable recommendations or a critical success framework that can guide the successful integration of IBM Watson into PV practices, thereby enhancing drug safety, optimizing regulatory compliance, and contributing to the broader advancement of AI applications in healthcare. The ultimate goal is to provide evidence-based insights that can help shape future PV strategies and support the UK pharmaceutical industry in its efforts to leverage AI for improving public health outcomes.

1.7 Research Objectives

- To measure the manual workload reduction and data processing speed in UK pharmaceutical companies using IBM Watson.
- To compare the accuracy of IBM Watson in detecting adverse drug reactions (ADRs) and other critical pharmacovigilance information against manual literature review results.

- To document and analyse the key challenges encountered by UK pharmaceutical companies, including issues related to data integration, user training, and compliance with regulatory standards.
- To synthesise findings into actionable recommendations or a critical success framework for integrating IBM Watson into pharmacovigilance practices within the UK pharmaceutical sector.

1.8 Research Questions

- How has the incorporation of IBM Watson influenced the degree of manual involvement and the speed of data processing of the UK's pharmaceutical industries in pharmacovigilance?
- How effective is the case of IBM Watson in identifying ADRs and other pharmacovigilance information as compared to manual searching of literature?
- What are the key challenges that UK-based pharmaceutical firms face when applying IBM Watson in pharmacovigilance, particularly in the areas of data handling, user training and compliance?
- How does the result of the study contribute to the set and actionable recommendations or the best practices that can be applied to improve the implementation of IBM Watson in pharmacovigilance within the UK pharmaceutical industry?

1.9 Hypotheses

H1: The implementation of IBM Watson significantly reduces the manual workload involved in literature monitoring. This hypothesis posits that the adoption of IBM Watson will lead to a measurable reduction in the time and effort required for manual literature review, as the AI system automates and streamlines data processing tasks.

H2: IBM Watson accelerates the speed of data processing compared to manual literature review. This hypothesis suggests that IBM Watson will enhance the speed at which data is processed, providing quicker insights and facilitating more efficient monitoring of literature compared to traditional manual methods.

1.10 Dissertation structure

This dissertation is structured into five comprehensive chapters, each addressing different facets of the study on IBM Watson's impact on pharmacovigilance in UK pharmaceutical companies.

Chapter 1: Introduction

The introductory chapter provides the study's background, justification, and importance. It outlines the research purpose and questions, defines key concepts, and operationalizes them based on a literature review and theoretical frameworks. This chapter sets the stage for understanding the impact of IBM Watson on pharmacovigilance processes.

Chapter 2: Literature Review

This chapter reviews existing research on AI applications in pharmacovigilance, specifically IBM Watson's role in literature review and ADR identification. It identifies gaps in current studies and anchors this research in well-established theoretical frameworks. The conceptual framework is presented at the end of this chapter, guiding the study's approach and objectives.

Chapter 3: Methodology

Chapter 3 defines the research philosophy, design, and approach, including methods for data collection, participant sampling, and ethical considerations. It details the survey design, pilot testing procedures, and sample selection criteria to ensure the robustness of the research methodology.

Chapter 4: Findings and Analysis

This chapter presents a quantitative analysis of the data using SPSS, covering numerical data through descriptive and inferential statistics, regression analyses, and data visualization. It includes findings on manual workload reduction, data processing speed, and accuracy of IBM Watson compared to traditional methods. The analysis supports the acceptance of both hypotheses: H1 (IBM Watson reduces manual workload) and H2 (IBM Watson accelerates data processing). Here, the study's findings are reviewed in relation to existing theories and prior research. This chapter answers the research questions, highlights patterns, and identifies strengths, weaknesses, and implications for

similar studies. It provides insights into how IBM Watson's integration impacts pharmacovigilance and discusses the challenges faced.

Chapter 5: Recommendations and Conclusion

The final chapter synthesizes actionable recommendations for implementing IBM Watson in pharmacovigilance, addressing challenges such as data integration, user training, and regulatory compliance. It discusses the limitations of the study, and its implications for future research, and offers a framework for optimizing AI integration in the UK pharmaceutical sector. The conclusions affirm that IBM Watson enhances efficiency and accuracy in pharmacovigilance, with practical recommendations for future advancements.

2 LITERATURE REVIEW

2.1 Introduction

Pharmacovigilance, as defined by the World Health Organization (WHO), involves the science and activities dedicated to detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) and other drug-related issues to ensure medicinal product safety and efficacy. It involves the continuous surveillance and evaluation of drug safety to minimize risks and ensure that therapeutic benefits outweigh potential harm (Kengar et al., 2019). This process is crucial for maintaining drug safety and regulatory compliance, as it requires extensive literature reviews and data analysis to identify potential safety signals and ADRs.

The rapid advancement of artificial intelligence (AI) technologies has significantly impacted various industries, including pharmaceuticals. AI tools like IBM Watson, developed by IBM to perform complex data analysis using natural language processing (NLP) and machine learning, are transforming pharmacovigilance practices. IBM Watson can process and interpret vast amounts of data, enabling more efficient and accurate identification of ADRs compared to traditional methods (Choi, 2024). This integration of AI into pharmacovigilance enhances the efficiency of literature monitoring, improves the accuracy of ADR detection, and addresses challenges associated with data processing and regulatory compliance (Kengar et al., 2019; Dong et al., 2022).

AI and Pharmacovigilance: Linking Objectives

The objectives of this research are closely linked to the impact of AI, specifically IBM Watson, on pharmacovigilance within the UK pharmaceutical industry. The following sections detail how these objectives align with the advancements and challenges associated with AI integration in pharmacovigilance:

Objective: To measure the reduction in manual workload and increased data processing speed in UK pharmaceutical companies using IBM Watson.

IBM Watson's ability to automate routine tasks and analyze large datasets efficiently is expected to significantly reduce the manual effort required for literature reviews. The AI system’s advanced processing capabilities allow for faster data analysis, which can lead to more timely detection of ADRs and streamlined pharmacovigilance processes (Kengar et al., 2019; Choi, 2024).

Objective: To compare the accuracy of IBM Watson in detecting ADRs against traditional manual literature review methods.

IBM Watson's NLP and machine learning algorithms enable it to identify ADRs with high precision by analyzing and interpreting vast volumes of scientific literature. This contrasts with manual methods, which are more prone to human error and less efficient in processing large datasets (Dong et al., 2022). The research evaluates how IBM Watson's accuracy in ADR detection compares to that of traditional methods.

Objective: To document and analyze key challenges faced by UK pharmaceutical companies, including data integration, user training, and regulatory compliance.

Implementing AI technologies like IBM Watson presents several challenges, including integrating AI with existing systems, ensuring data quality, training users effectively, and adhering to regulatory standards. The research explores these challenges and provide recommendations for overcoming them to facilitate successful AI adoption in pharmacovigilance (Choi, 2024; Dong et al., 2022).

Objective: To synthesize findings into actionable recommendations or a critical success framework for integrating IBM Watson into pharmacovigilance practices.

The study develops a framework based on the research findings to guide the effective integration of IBM Watson into pharmacovigilance practices. This include recommendations for improving data integration, user training, and addressing regulatory compliance issues (Lewis and McCallum, 2020; Kengar et al., 2019).

2.2 Manual Workload Reduction and Data Processing Speed Improvement

The adoption of AI systems increases the possibility of reducing the amount of manual work searching for relevant pharmacovigilance information within huge amounts of scientific publications applying AI (Aronson, 2022). Lewis and McCallum (2020) stated that it is especially advantageous because, using tools for text analysis, the AI system can quickly filter the mentions of ADRs and drug-drug interactions (DDIs). This can lead to a significant reduction in time spent on the process and make it possible for them to process significantly more data by the end of the process for the pharmacovigilance teams. Additionally, Kalaiselvan et al. (2021) discussed that the rapid and uniform data extraction effectiveness of IBM Watson makes pharmacovigilance processes more efficient. Implementing the manual abstraction of information from unstructured text is

inefficient as the system can efficiently identify suitable pieces of information and convert these factors into a structured format for analysis and reporting. The identified objectives of the primary data collection include illustrating the exact types of improvements in efficient operation caused by the implementation of IBM Watson (Chen et al., 2016).

Ball and Dal (2022) highlighted that the number of person-hours that would have been spent on literature monitoring, the number of articles that can be processed in a given time, and the reporting efficiency of AEs could offer metrics of the bettering of pharmacovigilance processes that the use of the AI system delivers (Gal and Rubinfeld, 2019). Since the time-consuming and elaborate task of sorting through thousands of journal articles and other scientific documents would be significantly reduced by applying these AI systems, one can strongly infer that similar benefits in terms of temporal efficiency would translate to data extraction and compilation efforts (Rodgers, 2022). This can bring about significant increases in operational effectiveness by enabling enhancements to be made to drug safety surveillance processes concurrently while ensuring that valuable human resources are being used in the most efficient manner possible (Choi, 2024)). Asif et al. (2020) discussed that identifying efficiency gains using concepts like fewer working hours will bring improvements that can be measured analytically during primary research. Finally, the positive outcome of implementing AI for literature monitoring can reframe and transform the pharmacovigilance practices within the pharmaceutical business, enhancing post-market drug safety (Pesqueira, Bolog and Machado, 2024).

It is apparent that when AI systems such as IBM Watson introduce different fields, the work done by hand decreases, and the time required for data analysis is shortened. Expressing the degree of the increment of the operational efficiency these technologies are set to provide, these advantages are pretty compelling, while the disadvantages, on the other hand, are as follows (Aronson, 2022). It is advantageous because it enhances efficiency and productivity (Rodgers, 2022). During the discussion, one of the first pros mentioned about the application of artificial intelligence systems is the decrease of the load that is relieved by the system and, thus, the improvement of productivity (Ahmad et al., 2022). As Javaid et al. (2022) noted, a certain amount of information would take quite a while to sort through and evaluate for relevance if done by humans. For example, in the pharmaceutical domain, one of my specialisations is that AI can read more than a human can read scientific publications, clinical trials, and adverse event reports. This saves time

in completing tasks and gives researchers and other healthcare professionals time to manage complex things such as analysis of results. However, AI can cut down data processing time to a few hours, even days at best, which may be from weeks or even months in other circumstances (Pesqueira, Bolog and Machado, 2024). According to the study by Castro and New (2016), the use of AI in processing data was found to take only hours or days to process, while in other cases, it could have taken weeks or even months to do the same through automation and better algorithms at its disposal. Today, using Big Data technologies such as machine learning and natural language processing, AI systems, including IBM Watson, can effectively search for, read, and comprehend large and complex data sets in seconds (Gal and Rubinfeld, 2019). Research by Castaneda et al. (2015) highlights that IBM Watson significantly reduces manual effort and enhances data processing speed in pharmacovigilance literature monitoring within the pharmaceutical sector. The system's cognitive capabilities facilitate quicker analysis of extensive medical literature, improving operational efficiency and reducing workload burdens. These systems can operate and complete processes such as data mining, identification of patterns, and discovering anomalies beyond human computational capacity (Castaneda et al., 2015).

Moreover, AI can handle data of varying types simultaneously and take action without getting tired or bored, making it possible to work as fast and continually process data (Anagnostopoulos, Zeadally and Exposito, 2016). This efficiency significantly reduces the time for data analysis and making informed decisions within a given period. Nevertheless, it has some disadvantages, such as high implementation costs.

Long-term advantages of AI systems include acquiring software, updating machinery, implementing new technologies with other systems, and educating people to enforce innovation optimally (Rodgers, 2022). These high upfront costs can be a disadvantage, without question, particularly when it comes to relatively small organisations. According to Burgess (2017), investment costs of establishing AI systems mean thousands to millions of dollars, depending on the project's size and complexity. There are also fixed costs in overlaying and developing the structures of Artificial intelligence to ensure it functions even while maintaining security (Christian et al. 2018). One of the greatest challenges of implementing AI is the significant expenditures that may run from thousands to millions of dollars, which may be challenging for an organisation with a limited Financial Year (Aronson, 2022). These costs may include the physical equipment

such as laptops, servers, and application software. Moreover, constant costs like application upgrade fees and bug fixes, system and network security updates, and system improvements all play a part in the continuous effectiveness of AI systems (Bughin et al., 2017b). These elements affect the company's working balance and demand constant reinforcement of inputs. Cost is another factor; usually, it has high fixed and variable costs but has appealing qualities of high accuracy and precise effectivity that generate high benefits even if such benefits are saved and used in other platforms (Kengar et al., 2019). In addition, there is also a higher possibility for a correct diagnosis, which is even truer when contemporary images are applied. Therefore, this is particularly useful when doing certain activities like pharmacovigilance, which require identifying and analysing the impacts that can be adversarial to a particular drug (Chan, Ang and Li 2017). The research conducted by Lewis and McCallum (2020) suggested that AI systems helped reduce errors and increase efficiency in cases that include repetitive work, usage of predictive analysis, and analysis of large amounts of data, especially in matters of pharmacovigilance. Such systems guarantee omission-free analysis when using big data to view adverse drug reactions and global exposure, and this makes safety signs be identified with high levels of precision (Lake et al., 2017). Hence, this enables a better understanding of the safety of the drugs manufactured, identifying potential risks early enough and improving compliance with the laws governing the manufacture of narcotics (Kalaiselvan, Sharma and Gupta, 2021).

The lower incidence contributed to patient satisfaction and trust in the kinds of products, and the adherence to AI processing ensures that close attention and frequent updates are given to safety-related parameters to step up a preventive approach towards drug safety (Chen Argentinis and Weber, 2016). The bulk of it has the disadvantage of dependency and impact on the workforce. The disadvantage is, in particular, the over-reliance on automated processes, which poses the risk of adverse effects on the workforce. Koski and Husson (2018) posit that by outsourcing the work that requires the use of particular tools, AI can affect the ways employees negatively approach the performance of tasks by diminishing skills that involve thinking and problem-solving. The problem concerning potential over-reliance on the company's AI systems will be valuable here as it will define the possible changes in the workforce. Since automation is gradually shifting responsibility from people to algorithms, people may become over-dependent on such systems. As a result, their creativity, critical thinking and even problem-solving abilities

are predicted to deteriorate (Panda et al., 2023). Such dependence might make any employee less equipped to deal with unforeseen problems or develop some initiatives without relying on AI aid. In addition, there might be a threat of job loss as the process undergoes automation, which might impact workers who take on monotonous tasks in their line of work more or less. This displacement can lead to socioeconomic problems, such as employment opportunities for the affected workers, which requires intense retraining (Chen Argentinis and Weber, 2016). AI helps improve productivity, but management should consider the high impact of technology on the over-documentation of human skills, innovation, and professionals' ability to achieve complex results when required (Castaneda et al., 2015). Thus, this balance could be considered critical in addressing the adverse effects on the workforce while integrating AI technology. Therefore, using AI technologies like IBM Watson in industry operations brings many benefits because of efficiency, high productivity, high accuracy rates and much more (Gal and Rubinfeld, 2019). It is also significant to note that most of these improvements can be measured in terms of much time gained, lesser costs incurred, and minimising possible errors (Kengar et al., 2019). However, the internal implementation cost is high in the initiation stage, and there can be a negative impact on employees, a drawback organisation will have to overcome (Panda et al., 2023).

2.3 Accuracy Comparison: IBM Watson vs. Manual Literature Review in ADR Detection

According to Wong et al. (2018), the advantage of using systems such as IBM Watson is that via the algorithms of natural language processing, pharmacovigilance data can be extracted from scientific production with greater accuracy and in a more comprehensive manner. While the data-mining tool does allow a program to scan for specific terms, the natural language processing and machine learning of IBM Watson can be trained to systematically look for a more significant number of data points relevant to pharmacovigilance with a good level of specificity (Gal and Rubinfeld, 2019). The AI system can be designed to look not only for direct signs that point at ADRs but also for any subtle hints that there are risks for safety signals latent in case reports, clinical trials and post-market surveillance studies (Pesqueira, Bolog and Machado, 2024). With intelligent text analytics, IBM Watson can understand the context of unstructured text, making it possible to garner a wider set of pharmacovigilance data compared to the fraction of data obtained through manual analysis (Aronson, 2022). This encompasses

ADR reports and any information on additional drug effects and interactions, medication errors, or other safety concerns that might require further review (Adler et al., 2022). Raising concerns on the practical applicability of pharmacovigilance data extraction through IBM Watson, the literature review emphasizes empirical verification of the proposed method's performance compared to conventional manual analysis. Some of the performance indices like sensitivity, specificity, and positive predictive values of the AI system case detection of ADRs can be of value to the pharmacovigilance efforts (Dravida et al. 2021).

Scholl (2022) discussed IBM Watson's performance; the comparison should not be confined to simply comparing the detection rates of adverse drug reactions and other critical data on pharmacovigilance. Pharmacovigilance data accumulates very fast, and thus, there is a need to gather comprehensive data more quickly as it allows for safety signal detection and risk mitigation measures to be taken within the shortest time possible in the pharmaceutical industry. Studies comparing IBM Watson's performance with manual literature review methods, such as those by Chan, Ang, and Li (2017), demonstrate its effectiveness in accurately identifying adverse drug reactions (ADRs). The AI system consistently shows higher accuracy rates, minimising the risk of overlooking critical pharmacovigilance information crucial for patient safety (Choi, 2024). Pappa (2018) argues that the most vital step is to prove the superiority of IBM Watson in terms of the accuracy of data extraction in pharmacovigilance compared to the manual analysis of the data, which will be the key to unlocking the potential of AI integration. Concrete proof of the effectiveness of the AI system in various categories can provide more confidence in the system's performance to overcome doubts regarding data credibility, which are the necessary steps toward the widespread application of this beneficial technology within the pharmaceutical industry. It will, therefore, be essential to control the validation of the AI tightly to increase confidence in it and, consequently, the uptake and utilisation in critical activities such as pharmacovigilance (Ahmed et al., 2020).

Considering the match between IBM Watson results and activity of ADRs and critical pharmacovigilance information versus comparing the outcomes of its analysis to the outcomes of manual literature review implies the evaluation of the pros and cons of employing the given approach. As cited by Dravida et al., Dabral, and Sharma (2021), some of the strengths of the IBM Watson system are handling computerised biomedical

literature, clinical trial information, and real-world evidence with much speed. Indeed, unlike human reviewers, its broad-based NLP allows it to analyse and interpret textual data in an order of magnitude faster. The utilisation of` Watson increases the pace at which pharmacovigilance activities are conducted since Watson has a high work rate compared to human beings (Alomar et al., 2020). It can search through many sources of information within a relatively short amount of time to recognise different kinds of ADRs or safety signals, which can take a long time if done manually (Alomar et al., 2020). The rapid detection of issues by the pharmacovigilance department allows for prompt resolution of new safety concerns, enabling expedited decision-making while aligning with the requirements of the government. Nonetheless, IBM Watson encounters specific challenges, notably its reliance on high-quality data and susceptibility to bias. Faizullov and Yablonsky (2020) noted that the quality, quantity, and range of the data fed into IBM Watson greatly impact how reliable it is. Because of this, biases in the training data or the methods being used can affect how good and reliable the results are. This might cause ADRs to be missed or false-positive reports to be sent, which could affect patient safety and the decisions made about their care. Therefore, getting rid of data quality problems and ensuring that training is fair are important steps that can be taken to lessen this problem. Ball, R. and Dal Pan, G., (2022).

2.4 Challenges in Implementing IBM Watson: Data Integration, User Training, and Regulatory Compliance

Major industries, such as pharmaceutical companies, acquire structured and unstructured data from diverse sources, including clinical trials, post-marketing surveillance, and standardized and non-standardized regulatory submissions (Choi, 2024). However, Guidi et al. (2016) have highlighted challenges associated with integrating this array of fragmented data sources with IBM Watson's natural language processing capability, emphasising potential technical and operational complexities. Resistance from traditional users, accustomed to manual data review processes, may hinder the adoption of AI systems; therefore, proactive training initiatives may facilitate their transition. According to Cecil and Soares (2019), pharmaceutical companies are advised to make substantial investments in developing appropriate training programs to ensure that end-users can fully utilise IBM Watson's capabilities, interpret its outputs, and integrate the AI-derived insights into their operations. Various sources, such as Aronson (2013), have identified significant implementation challenges for IBM Watson in pharmacovigilance, including

complexities related to data integration, necessitating robust systems for effectively managing diverse data sources.

Moreover, issues related to user training and adaptation to new technologies pose additional hurdles that pharmaceutical companies must address for successful AI adoption. Specifically, regarding literature monitoring, reporting of adverse events, and risk management, the EMA and the FDA have set some rules that pharmaceutical companies need to follow (Aronson, 2022). In light of these key regulatory requirements, the review stresses that IBM Watson's implementation has to address these requirements to properly maintain the quality and integrity of pharmacovigilance data and reporting (Pesqueira, Bolog and Machado, 2024). Despite the promising results that the use of IBM Watson has demonstrated, it is essential to identify how challenges such as data integration, user acceptance, and compliance will influence the sustainable success of its applications in the pharmaceutical industry. Marshall and Lambert (2018) highlight that it is imperative that pharmaceutical companies actively strategize and employ strong management to counter these issues. This might be done by involving other departments, discussing with the relevant authorities, and creating special training to make users accept and understand the usage of the AI involved. In achieving the adoption of IBM Watson, the key consideration will be to balance, on the one hand, the application of new technologies as a tool to advance pharmacovigilance and, on the other, compliance with the regulatory provisions (Asif et al., 2020).

2.5 Actionable Recommendations for Integrating IBM Watson into UK Pharmacovigilance Practices

Alomar et al. (2020) pointed out that drug manufacturing businesses based in highly controlled countries must follow the rules and regulations of the EMA and the FDA about post-market drug safety monitoring. These regulatory bodies require companies to regularly search the literature and other information sources for ADRs or other safety signals in products. As much as systematic manual literature review processes are inevitable in pharmacovigilance, such a process is likely to face human imperfections, which may render data generation inconsistent and incomplete. The review also points out that some of these challenges can be effectively dealt with since IBM Watson has Near Field Communication (NFC) and Machine Learning Code (MLC) that enable translation and analysis of information in unstructured text with a higher degree of accuracy and reliability in the area of pharmacovigilance (Burgess, 2017).

The application of IBM Watson also proposes that it can increase the general efficiency of the pharmacovigilance process to enhance the speed of signal detection workflow and risk minimisation (Castro and New, 2016). The idea that pharmaceutical manufacturers put a great amount of time pressure into reporting adverse events and other safety issues is common among regulatory authorities (Burgess, 2017). The review also says that the AI system's speed at reading books and gathering data could help speed up this process, making it easier to find problems and send safety reports more quickly (Davenport and Ronanki, 2018). Legal rules for keeping track of and reporting studies are helped by IBM Watson (Castaneda et al., 2015). The method betters pharmacovigilance by making it easier for companies to follow government rules by conducting compliance checks and simplifying the writing process.

Additionally, Yingngam et al. (2024) discussed how incorporating IBM Watson into the pharmacovigilance process could essentially turn pharmacovigilance and pharmaceutical companies into important partners in achieving the standards set by industry regulatory bodies. The suggested AI system can help Marketing Authorization Applications (MAA) locate and report bad acts more quickly, accurately, and of higher quality (Wong et al., 2018). This, in turn, can greatly enhance the industry's collective pharmacovigilance capacity to address these challenges and to improve confidence among industry players, regulatory agencies, and the general public. However, Christian et al. (2018) indicate that the application of IBM Watson in the workflows of pharmaceutical companies can contribute significantly to enhanced pharmacovigilance, signalling that such solutions can assist in increasing the speed of signal detection and risk management, which is central given that there is increasing regulatory expectation for immediate adverse event reporting (Rodgers, 2022). It is, therefore, important to consider the AI system as an enabler for mere compliance with pharmacovigilance practices while aiming to provide better solutions for drug safety monitoring and surveillance beyond the mere regulator obligations (Ahmed et al., 2020).

The strategy, including data Integration and management, is the implementation of IBM Watson in pharmacovigilance, which starts with merging multiple data types that may include Electronic Health Records (EHRs), social media feeds, clinical trial data, spontaneous reporting systems, and literature. Through NLP and ML, Watson can handle a large amount of structured and unstructured data to determine ADRs and safety signals. Data Integration and management are beneficial because Watson synthesises multiple

data sources of drug safety, allowing pharmacovigilance specialists to identify potential problems more quickly and precisely (Chan, Ang and Li 2017). Khan et al. (2022, p.n 13) alluded that data integration strengthens the pharmacovigilance systems that impact patients' safety and compliance with the regulations. One weakness is the quality and credibility of the integrated data. Punctuations, missing values, and different data standards from one source to another may also pose challenges to Watson. Gal and Rubinfeld (2019, p. 737) argue that it is often difficult to standardise and validate high-quality data for integration, which consumes much time and resources.

As for the empirical analysis of the positive impact of IBM Watson in enhancing the efficiency and effectiveness of pharmacovigilance for UK pharmaceutical organisations, the incorporation of customised algorithms based on machine learning is crucial for the enhancement of the mentioned system. The ML models specific to pharmacovigilance require assistance to analyse the past data for ADR, trend analysis, and safety signals for IBM Watson. Johnson et al. (2021) have pointed out that this custom model increases Watson's ability to meet the needs of various drugs and therapeutic areas to a greater extent. It is always beneficial when activities and processes can be customised; this improves the monitoring processes, the rate at which new safety threats are identified, and the effective utilisation of resources in the pharmacovigilance teams, as postulated by Chen, Argentinis, and Weber (2016). However, training and updating these custom models are not easy as they require a lot of historical data, domain knowledge, and more frequent updates to make such models accurate and reliable. As pointed out by Ahmed et al. (2020), the process is costly and may be time-consuming, and therefore, developing a new strategy might result in the postponement of benefits. To rectify these problems, suggestions are as follows: The training programs to be offered to the user should be numerous, the structures that deal with data should be made efficient, and the AI algorithms should be upgraded often. As stated by Chan, Ang and Li (2017), these procedures are very important to make sure that, the implementation of IBM Watson is appropriate to the organisational goals and legal regulations.

Moreover, the feedback and evaluation approach is necessary to set up and enhance Watson's performance in pharmacovigilance systematically. Beninger and Ibara (2016) have underlined the fact that constant attention to inputs and outputs, as well as the engagement of users and control monitoring, are the keys to the success of Watson's algorithms. In the area of compliance and drug safety itself, Watson must be able to learn

from such changes, different data sources, and different standards. However, constant monitoring is a very costly process for financial and material resources, as observed by Pesqueira, Bolog, and Machado (2024). Some of them may include the management of feedback and data accumulation especially in large organisations with complex structures in pharmacovigilance. Nonetheless, the integration of IBM Watson into pharmacovigilance through matched ML algorithms, continuous updates, and feedback will enhance the operation's efficiency and effectiveness (Adler-Milstein et al., 2022). Nevertheless, it is necessary to pay attention to the data quality and time-consuming model training to improve the utilisation of AI technologies in the field of pharmacovigilance and, thus, improve the patient's safety and compliance with the regulations (Aronson, 2022).

2.6 Literature Gaps and Unmet Objectives

Despite the promising advancements IBM Watson offers in pharmacovigilance, several gaps in the existing literature hinder a comprehensive understanding of its impact and integration.

While existing studies such as Castaneda et al. (2015) and Kalaiselvan et al. (2021) demonstrate notable reductions in manual workload and enhancements in data processing speed through AI technologies like IBM Watson, there remains a significant gap in empirical analysis that directly compares the accuracy of IBM Watson in detecting adverse drug reactions (ADRs) with traditional manual methods. The existing body of research, including the work of Lewis and McCallum (2020) and Gal and Rubinfeld (2019), highlights AI's potential to improve operational efficiency in general terms. However, there is a lack of detailed, empirical evidence quantifying these improvements specifically within the context of UK pharmaceutical practices. This leaves a void in understanding how AI's purported benefits translate into real-world effectiveness in this specific sector.

Furthermore, while studies by Ahmad et al. (2022) and Pesqueira et al. (2024) acknowledge AI's role in reducing workload and accelerating data processing, there is insufficient evidence addressing how these technological advancements impact regulatory compliance and practical implementation challenges in a sector-specific context. Although Scholl (2022) and Dravida et al. (2021) report higher accuracy rates for AI systems, these studies do not provide a thorough comparison with traditional

manual review processes in the context of UK pharmaceutical practices, nor do they explore how these advancements affect regulatory compliance.

In terms of implementation challenges, existing research acknowledges issues related to data integration and user training (Guidi et al., 2016; Cecil & Soares, 2019), but it lacks a comprehensive analysis of how these challenges specifically impact the adoption of IBM Watson within the UK pharmaceutical industry. While frameworks for addressing data integration, training, and regulatory compliance are discussed, they are not explored in sufficient detail to understand their practical implications for AI adoption in this sector.

Addressing these gaps, this research aims to offer a thorough empirical evaluation of IBM Watson's impact on pharmacovigilance practices within the UK pharmaceutical industry. By providing quantifiable data on reductions in manual workload, improvements in data processing speed, and comparing ADR detection accuracy with traditional methods, this study seeks to fill the existing void in sector-specific, evidence-based insights. Additionally, the research will offer detailed analyses of implementation challenges and actionable recommendations for overcoming them, thus enhancing our understanding of AI's role and optimizing its application in pharmacovigilance.

The literature reveals substantial gaps in the empirical research on AI technologies like IBM Watson within the pharmaceutical industry. Despite the theoretical insights provided by secondary analyses, there is a notable absence of detailed, real-world implementation studies that examine how these technologies influence operational efficiency and effectiveness in actual pharmaceutical settings (Panda et al., 2023). Much of the existing research relies on secondary data or comes from entities with potential biases, limiting the applicability of their findings to real-world scenarios.

Additionally, there is a shortage of primary, qualitative data exploring the practical execution of AI systems such as IBM Watson. While theoretical discussions highlight AI's potential benefits, they often fall short in detailing the practical challenges and successes encountered during implementation. This includes real-time effectiveness in processing literature, detecting ADRs, and adhering to regulatory standards. Most current literature focuses on theoretical models or simulations rather than on detailed case studies that offer insights into the operationalization of these AI systems.

Moreover, there is a critical need for robust quantitative data and observational accuracy assessments. Many studies acknowledge the theoretical advantages of AI in pharmacovigilance but lack concrete data to substantiate claims regarding its comparative efficacy against manual methods. There is an urgent need for research that quantitatively evaluates AI technologies' performance in ADR detection, including detailed analyses of accuracy, sensitivity, and specificity to validate the practical benefits of AI systems.

Finally, the literature indicates a need for more comprehensive studies on regulatory compliance and the integration of AI technologies within the pharmaceutical industry. Understanding how AI systems align with existing regulatory frameworks and guidelines is essential for their successful implementation. Research should address how AI systems manage compliance challenges, such as data integration from diverse sources and adherence to industry regulations, to enhance their effectiveness in pharmacovigilance.

In summary, future research should focus on providing empirical evidence of AI technologies' real-world applications, including detailed case studies and quantitative assessments. Investigating the comparative effectiveness of AI versus manual methods in ADR detection and exploring the compliance and integration challenges of AI systems will be crucial for guiding pharmaceutical companies in optimizing AI for improved pharmacovigilance. These insights will help bridge existing gaps and inform strategies for enhancing AI deployment in drug safety monitoring.

2.7 Conceptual Framework

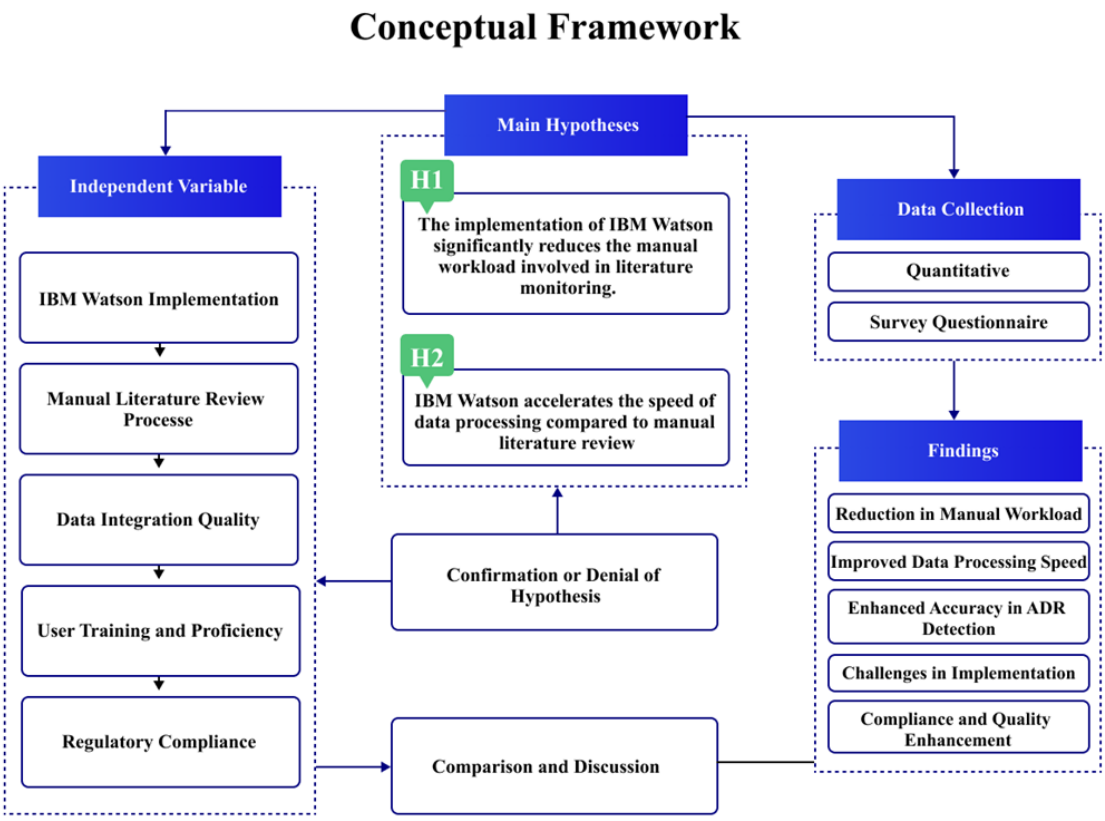


Figure 1: Conceptual Framework

The conceptual framework for investigating IBM Watson's impact on operational efficiency and accuracy in pharmacovigilance involves understanding how various independent variables affect the operational outcomes within UK pharmaceutical companies. The study focuses on examining the effectiveness of IBM Watson, an advanced AI system, in improving pharmacovigilance processes compared to traditional methods. The framework is built on several key independent variables: IBM Watson implementation, manual literature review processes, data integration quality, user training and proficiency, and regulatory compliance. The research aims to validate hypotheses regarding IBM Watson's influence on workload reduction and data processing speed, using quantitative data collected through survey questionnaires.

2.7.1 Independent Variables:

IBM Watson Implementation: This variable assesses the adoption of IBM Watson as an innovative AI solution within pharmacovigilance processes. IBM Watson's ability to analyze large volumes of literature data through Natural Language Processing (NLP) and Machine Learning (ML) is expected to influence operational efficiency significantly (Kazakov, Petrova, & Kazakova, 2024). The effectiveness of Watson's implementation is gauged by its integration into existing workflows and its impact on the workload of pharmacovigilance professionals.

Manual Literature Review Process: This variable represents the traditional method of reviewing literature, which involves a substantial amount of manual effort. The comparison between the manual review process and IBM Watson's automated approach highlights the potential benefits of AI in reducing manual workload and improving efficiency (Gliozzo et al., 2017). The manual process is characterized by time-consuming tasks and potential for human error, which contrasts with the efficiencies offered by IBM Watson.

Data Integration Quality: Data integration quality refers to the accuracy and completeness of merging data from various sources. High-quality data integration is crucial for effective pharmacovigilance as it ensures that the information processed by IBM Watson is reliable and comprehensive (De Vries, Tummers, & Bekkers, 2018). This variable examines how well data integration processes are managed and how they affect IBM Watson's performance.

User Training and Proficiency: The level of training and proficiency among users of IBM Watson impacts its effectiveness. Proper training ensures that users can effectively utilize Watson's features and interpret its outputs accurately. This variable assesses the training programs provided and the proficiency levels of the users, which are critical for the successful implementation of AI technologies (Rodgers, 2022).

Regulatory Compliance: Compliance with regulatory standards is essential in pharmacovigilance. This variable evaluates how IBM Watson contributes to meeting regulatory requirements and ensuring that pharmacovigilance practices adhere to industry standards (Kazakov, Petrova, & Kazakova, 2024). Effective AI implementation should

enhance compliance by improving accuracy and reliability in reporting adverse drug reactions (ADRs).

2.8 Conclusion

The integration of IBM Watson into pharmacovigilance processes within UK pharmaceutical companies presents a transformative opportunity to enhance operational efficiency and accuracy. The **objective** of measuring the reduction in manual workload and increased data processing speed reveals that IBM Watson's advanced automation capabilities significantly streamline literature reviews and pharmacovigilance tasks. By automating routine data extraction and analysis, IBM Watson substantially diminishes the manual effort required, allowing for faster and more efficient detection of adverse drug reactions (ADRs). This shift not only accelerates data processing but also optimizes the overall pharmacovigilance workflow.

The **objective** of comparing the accuracy of IBM Watson to traditional manual methods demonstrates that AI-driven analysis offers superior precision in identifying ADRs. IBM Watson's use of natural language processing (NLP) and machine learning algorithms enables it to analyze vast datasets with high accuracy, surpassing the limitations of manual reviews which are prone to human error and inefficiency. This enhanced accuracy leads to more reliable ADR detection and improved pharmacovigilance outcomes.

Addressing the **objective** of documenting and analyzing key challenges associated with integrating IBM Watson highlights critical areas of concern. Companies face challenges such as data integration, user training, and regulatory compliance. Successful implementation of IBM Watson requires overcoming these hurdles through strategic planning, robust data integration systems, and comprehensive training programs. Regulatory compliance with standards sets by bodies like the EMA and FDA is also essential to ensure the integrity and quality of pharmacovigilance practices.

Finally, the **objective** of developing actionable recommendations and a success framework is crucial for optimizing the integration of IBM Watson. Recommendations include improving data quality, providing targeted user training, and ensuring adherence to regulatory requirements. By addressing these aspects, pharmaceutical companies can fully leverage IBM Watson's capabilities, leading to significant advancements in pharmacovigilance practices. Despite the high initial costs and ongoing maintenance, the

long-term benefits of improved efficiency, accuracy, and compliance offer substantial value, making IBM Watson a valuable asset in modern pharmacovigilance.

3 METHODOLOGY

3.1 Introduction

This chapter outlines the methodological framework for investigating the impact of IBM Watson on operational efficiency and accuracy in pharmacovigilance (PV) activities within the UK's pharmaceutical sector. The study is designed to measure reductions in manual workload and improvements in data processing speed achieved through the use of IBM Watson. By automating routine tasks, IBM Watson is expected to significantly streamline literature reviews and enhance the efficiency of pharmacovigilance operations. Additionally, the study will compare IBM Watson's accuracy in detecting adverse drug reactions (ADRs) and other critical pharmacovigilance information against traditional manual literature reviews. The research will also explore the key challenges faced by pharmaceutical companies in integrating IBM Watson, including data integration issues, user training requirements, and regulatory compliance concerns. The ultimate goal is to synthesize these findings into actionable recommendations and develop a success framework for the effective integration of IBM Watson into UK pharmacovigilance practices.

Integration of Objectives and Literature Review

The study's objectives include measuring the reduction in manual workload and data processing speed, comparing the accuracy of IBM Watson with traditional methods, analyzing key integration challenges, and developing actionable recommendations. These objectives are pursued through a case study approach, which builds upon insights from the literature review.

The literature indicates that IBM Watson's advanced automation significantly reduces manual effort and enhances data processing speed (Kengar et al., 2019; Choi, 2024). This objective will be investigated further to quantify these improvements and assess their impact on pharmacovigilance practices. By examining the efficiency gains achieved through IBM Watson, the study aims to provide a clear understanding of its benefits in streamlining pharmacovigilance tasks.

The accuracy comparison objective highlights IBM Watson's superior performance in detecting ADRs compared to traditional manual methods (Dong et al., 2022). This objective will be addressed by comparing the precision of AI-driven analysis with manual

reviews, providing a detailed assessment of IBM Watson's effectiveness in identifying critical pharmacovigilance information.

The study will also delve into key challenges related to data integration, user training, and regulatory compliance, as outlined in existing research (Choi, 2024; Dong et al., 2022). By exploring these challenges in depth, the research aims to offer practical solutions and recommendations for overcoming obstacles to successful AI integration.

Finally, actionable recommendations and a success framework will be developed based on the study's findings, guided by the insights from Lewis and McCallum (2020) and Kengar et al. (2019). This framework will provide practical guidance for effectively integrating IBM Watson into UK pharmacovigilance practices, addressing data quality issues, user training needs, and regulatory requirements.

By leveraging a structured and theoretically informed methodology, this research aims to provide robust insights into IBM Watson's role in enhancing pharmacovigilance operations, contributing valuable knowledge to both academic literature and practical applications in the field.

Rationale for Research Philosophy, Design, and Methodology

To construct a comprehensive framework for this study, a case study approach has been selected, supported by theoretical concepts from Saunders, Lewis, and Thornhill (2019) and Okesina (2020). This approach is particularly suited for exploring the complex integration of advanced AI technologies like IBM Watson in real-world settings. It allows for an in-depth analysis of how IBM Watson impacts operational and procedural changes within pharmaceutical companies. The case study approach provides a detailed examination of the practical implications of implementing AI in pharmacovigilance, enabling the researcher to capture nuanced insights and real-world experiences.

Central to this methodology is the application of the 'Research Onion' model, a structured framework proposed by Saunders et al. (2019). This model organizes the research process into six layers: research philosophy, research approach, research strategy, time horizons, data collection methods, and data analysis techniques. By following this hierarchical structure, the study ensures that each component of the research process is thoroughly considered and aligned with the study's objectives. This approach helps in maintaining coherence and consistency throughout the research process, from the philosophical foundations to the data collection and analysis stages.

The research philosophy adopted in this study is positivism, which aligns with the objective of objectively assessing IBM Watson's impact using quantifiable data. Positivism supports the use of quantitative research methods, ensuring that findings are grounded in empirical evidence and are generalizable within the UK pharmaceutical industry. This philosophy provides a rigorous framework for measuring the effectiveness of IBM Watson and ensures that the research results are reliable and valid.

The research approach within the Research Onion model emphasizes identifying appropriate strategies, timelines, and data-gathering techniques that align with the study's objectives. This structured approach addresses objectives not fully explored in the existing literature, such as the detailed measurement of operational efficiency gains and accuracy comparisons between IBM Watson and traditional methods. It ensures that the research design is robust and aligned with the study's goals.

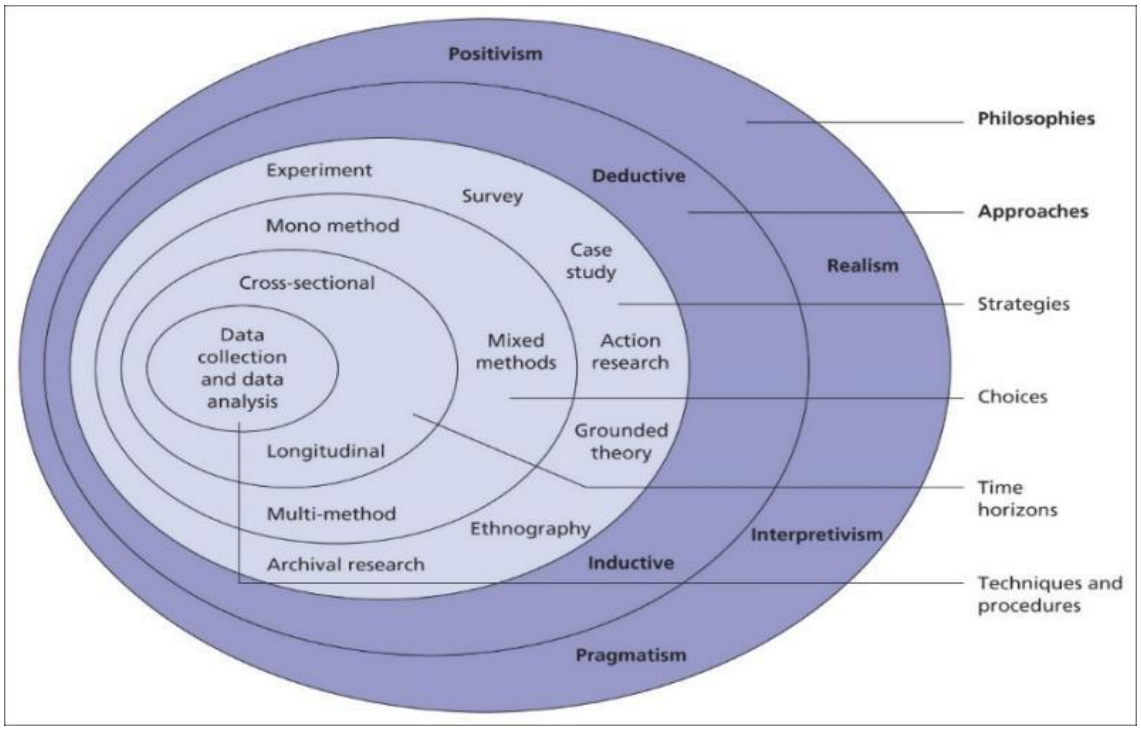


Figure 2 The research onion model by Saunders et al., 2019)

3.2 Research Methodology

This study employs a **quantitative research methodology** to assess the impact of IBM Watson on operational efficiency and accuracy within pharmacovigilance (PV) processes in UK pharmaceutical companies. The choice of a quantitative approach is driven by the need to collect numerical data that can be statistically analyzed, providing an objective framework to evaluate the effectiveness of AI technologies in this critical field. The

methodology is designed to facilitate the measurement of specific variables, including IBM Watson implementation, the manual literature review process, data integration quality, user training and proficiency, and regulatory compliance, all of which are essential for understanding the dynamics of PV.

Justifying the use of quantitative methodology for this study rests on several key factors. First, quantitative research is well-suited for hypothesis testing, enabling the study to evaluate specific hypotheses, such as the degree to which IBM Watson implementation reduces manual workload and accelerates data processing speed. By focusing on measurable outcomes, this approach ensures that findings are grounded in empirical evidence, enhancing the validity of the conclusions drawn regarding the impact of IBM Watson on PV processes.

Furthermore, the quantitative methodology supports the generalizability of the findings across the pharmaceutical industry, allowing for broader conclusions to be made about the role of AI in improving operational efficiency and accuracy in pharmacovigilance. The structured nature of quantitative research also allows for systematic data collection and analysis, which enhances the study's reliability. This methodological rigor ensures that the results can inform best practices in the industry and guide future implementations of AI technologies in pharmacovigilance.

In summary, the quantitative research methodology is justified for this study as it enables the systematic collection and analysis of numerical data, facilitating objective evaluations of IBM Watson's impact on pharmacovigilance. This approach provides a robust framework for testing hypotheses, ensuring that the findings are empirical, reliable, and relevant for stakeholders in the pharmaceutical industry.

3.3 Research Philosophy

The research philosophy guiding this study is **positivism**, which is aligned with the quantitative approach adopted for this investigation. Positivism posits that knowledge is best acquired through empirical evidence and objective measurements, and it asserts that the phenomena being studied can be understood through observable and quantifiable data without subjective influence (Pandey & Pandey, 2021). This philosophical stance is particularly suited for assessing the impact of IBM Watson on pharmacovigilance (PV)

processes, where the aim is to evaluate changes in operational efficiency, accuracy, and regulatory compliance through measurable data.

Positivism is justified in this context because it supports the collection and analysis of numerical data that can be statistically examined to provide objective insights into the effectiveness of IBM Watson. This approach allows researchers to obtain empirical evidence on how AI technology influences various aspects of PV processes, such as reducing manual workload, accelerating data processing, and improving accuracy in adverse drug reaction (ADR) detection. By focusing on quantifiable outcomes, positivism ensures that the research findings are based on concrete, empirical data rather than subjective interpretations (Kumari et al., 2023).

The adoption of positivism is crucial for maintaining objectivity throughout the research process. It enables the systematic measurement of changes in PV processes due to IBM Watson's implementation and ensures that the analysis is grounded in empirical evidence. This approach aligns with the study's objective of examining how AI technologies contribute to operational improvements and adherence to regulatory standards in a measurable manner (Liam et al., 2023).

Furthermore, positivism facilitates the use of statistical tools and techniques to analyze survey data, which is essential for testing hypotheses related to the impact of IBM Watson. The methodological rigor provided by positivism ensures that the study's conclusions are based on reliable data, thereby enhancing the validity and credibility of the findings. This approach not only allows for a comprehensive evaluation of the AI technology's effectiveness but also supports the development of actionable insights for improving PV processes.

3.4 Research Design

The research design employed in this study is exploratory and descriptive. This design is well-suited for examining the impact of IBM Watson on pharmacovigilance (PV) processes, as it allows for an in-depth exploration of how AI technology influences operational efficiency and accuracy. The exploratory aspect helps uncover insights into IBM Watson's integration challenges, such as data integration, user training, and regulatory compliance. The descriptive component provides a detailed account of the improvements in manual workload reduction, data processing speed, and accuracy in detecting adverse drug reactions (ADRs). By systematically gathering and analyzing

primary data, the design supports a comprehensive understanding of IBM Watson's role in enhancing PV practices, thereby meeting the research objectives effectively. The design involves creating strategies, conducting preliminary experiments, adjusting based on findings, and implementing the refined approach to gather and interpret data.

The pilot survey questions were meticulously developed and tested on a sample of respondents to ensure their effectiveness in capturing data about pharmacovigilance (PV) professionals' opinions and practices regarding AI integrations. Based on pilot test outcomes and participant feedback, the questions were refined to improve clarity and relevance. This led to a final survey design that comprehensively addresses all aspects of AI's impact on pharmacovigilance practices.

The decision to utilize exploratory and descriptive research designs was guided by the need for a nuanced understanding of AI integrations, specifically IBM Watson, in pharmacovigilance. Exploratory research is particularly suitable for this study as it allows for the investigation of new phenomena where prior knowledge is limited. It facilitates the exploration of how AI impacts operational efficiency, accuracy, and compliance in pharmacovigilance, helping to identify key variables and emerging trends essential for formulating hypotheses for future research. This approach is critical given the evolving nature of AI technologies in this field (Dewey, 2021).

Descriptive research, on the other hand, systematically describes the characteristics and current state of AI integration in pharmacovigilance. It provides a detailed account of IBM Watson's impact, including improvements in operations, accuracy in detecting Adverse Drug Reactions (ADRs), and regulatory compliance. By capturing the specific experiences and practices of PV professionals, this method offers a comprehensive view of the effects of AI integration (Saunders et al., 2019).

The exploratory and descriptive designs were preferred as they offer a more structured and detailed examination of AI's impact, addressing the dynamic and nuanced aspects of the integration process. These designs enhance the study's reliability and validity by thoroughly understanding AI's role and its effects, contributing valuable insights to the field of healthcare technology and pharmacovigilance (Franklin, 2022). This methodological rigor ensures robust findings applicable to real-world settings and provides actionable recommendations for future research and practice.

3.5 Data collection

This study collects data through primary data collection, which is very important in research when analyzing systems as elaborately as the effects of IBM Watson on pharmacovigilance. One advantage of primary data collection compared to an analysis of secondary sources is that the former can obtain first-hand information from participants through questionnaires to ensure the data collected corresponds to the research objectives and is particularistic and valid. This work paradigm enables the investigation of subtle trends in how AI technologies affect productivity, measurement of operational reportable incidents, and adherence to all regulatory requirements across the development of pharmaceutical goods.

Furthermore, primary data collection allows the researchers to verify hypotheses, extend current knowledge, and proffer unpublished information to the academic discourse on healthcare technology and pharmacovigilance. Having worked in pharmacovigilance within the UK for five years, I have established a strong network of colleagues experienced with AI and LSM. For data collection, this study will leverage these professional connections to gather insights. Additionally, LinkedIn will be used to extend the outreach to a broader audience of professionals in the field. Recruitment will involve utilizing these established networks, referrals from industry contacts, participation in relevant events, and announcements on social media to ensure a diverse and pertinent participant pool. This strategy facilitated the inclusion of participants from different organizations, ensuring comprehensive coverage of the various aspects of the PV process impacted by AI. Survey protocols can be thought out very carefully, and potential participants can be recruited purposefully so that the researchers get all the data they need to expand their knowledge with the help of purposive sampling to develop solutions in academic and practical fields.

For the primary data collection, the researcher developed close-ended structured questions administered through email. The questionnaires used in this research will be closed, as consistent data is essential for quantitative research. For this, it was necessary to use **electronic surveys,** which were quite affordable and non-ambiguous in providing data. These questions were posed in a manner that elicited a Likert scale or options of multiple-choice answers since this will assist in generating standard data that will, in the end, enable quantitative analysis.

3.6 Method for Data Analysis

The current research adopted a **quantitative research strategy** to assess the impact of the introduction of IBM Watson on PV processes. Both statistical and graphical analysis methods were used to analyse the collected data, and for this purpose, the statistical software **SPSS** was used. SPSS is an individual statistical package containing tools and methods most effective for survey data, such as descriptive and inferential statistics and regression examination (Abbott, 2016). This is because it changes the user's mode of operation in data processing by offering a platform that deals with data manipulation, visualisation, and analysis. Additionally, the results obtained through this analysis were depicted in graphs and tables with the help of SPSS, which effectively makes the results understandable for further interpretation and communication. This helped establish some patterns or trends in the distribution of the data collected.

Descriptive statistics were used to make assumptions and forecast the total population based on the information gained from the sample. In this, hypothesis testing and regression analysis were carried out to determine the relationship between variables and, more importantly, the impact of IBM Watson on PV processes. The available statistical analysis through SPSS has helped in the analysis of the study by facilitating complex analysis of results, hence the validity and reliability of the study results. Besides that, graphical techniques were applied to show the results so that the objective and main trends could be outlined. The findings were presented in reports and tables. The different forms of graphs and charts, such as pie charts, were used because they portray a picture apart from numbers. All these statistical approaches were applied to offer the necessary and sufficient understanding of the data in the study (Bhardwaj, 2019).

A paired t-test and multiple regression analysis were used to find the impact and challenges of artificial intelligence (IBM Watson) implementation on literature monitoring in pharmacovigilance for the UK pharmaceutical industry through SPSS. Applying a quantitative approach in this research was helpful because it enabled a concrete and factual assessment of the respondent’s answers, and the conclusions reached were, therefore, factual . This robust data analysis method helped to meet the research goal of assessing the effects of AI integration in PV procedures in the UK’s pharmaceutical sector.

3.7 Selection and Sampling of Participants

This study employed purposive sampling to select participants, ensuring that individuals included in the research possessed relevant expertise and experience aligned with the research focus. Purposive sampling involves intentionally selecting participants based on specific characteristics, knowledge, or experiences pertinent to the study's objectives. In this case, participants were chosen based on their prior involvement in pharmacovigilance (PV) activities and their understanding of artificial intelligence (AI) systems, including IBM Watson, within the UK pharmaceutical sector.

The target population for this study was initially set at 300 participants, with the goal of including individuals from various roles within the UK pharmaceutical industry. The intended distribution was as follows:

- Pharmacovigilance professionals: 105 participants
- Data analysts: 45 participants
- Regulatory affairs specialists: 60 participants
- Clinical Research Associates: 75 participants
- Others: 15 participants

However, due to time constraints, the study ultimately collected 174 responses, with the distribution across roles as follows:

- Pharmacovigilance professionals: 72 participants
- Data analysts: 20 participants
- Regulatory affairs specialists: 35 participants
- Clinical Research Associates: 42 participants
- Others: 5 participants

While the target sample size of 300 was ideal for ensuring comprehensive and statistically significant results, the final sample size of 174 responses is still valid for meaningful analysis. The study aimed for a 95% confidence level with a 5% margin of error. Given the target population of 174 participants, this sample size is statistically adequate for the desired confidence level. All participants were UK-based, and responses from each role pharmacovigilance professionals, data analysts, regulatory affairs specialists, and Clinical Research Associates were compared to ensure comprehensive insights into the integration of IBM Watson in the UK pharmaceutical sector.

Participants were selected based on their direct involvement in pharmacovigilance activities and their familiarity with AI technologies. The purposive sampling approach was particularly suitable for this study due to the specific and sensitive nature of the topic. By targeting individuals with firsthand experience and expertise in PV processes and AI applications, the study aimed to gather credible and insightful data. This method allowed for the identification of participants who could provide valuable perspectives on the integration of AI in pharmacovigilance, thereby enhancing the depth and quality of the research findings.

Additionally, participants were screened to confirm their qualifications, ensuring that they met the criteria for inclusion. This careful selection process aimed to create a participant group that not only represented a variety of roles within the industry but also possessed the necessary insights to contribute meaningfully to the study.

3.8 Ethical Considerations

The research process adhered to ethical guidelines at every stage, ensuring the protection of participants from any unethical behaviour. The informed consent measures were strictly adhered to whereby the participants were informed of the purpose of the study, the procedures to be employed, and their rights concerning the survey, which entailed withdrawal from the study at their discretion at any time they wished to. Explicit consent will be obtained from each participant before any data is collected. Since the study only used an online survey and did not gather signed consent or personal information sheets, the following ethical principles and practices were strictly observed.

Information and participant identification were kept concealed by safeguarding all the collected data. Some of the measures that were taken consisted of hacking protection at various levels by encrypting the data and providing access only to a limited circle of employees, as well as using password-protected equipment. As the study aimed to establish the truth, anonymity was strictly followed. As soon as the data was collected, basic identifying information was ensured to be masked to maintain participants' anonymity. The reason for taking this step was to avoid regression of individual responses on the participants involved in the study.

Furthermore, there was a normative aspect regarding the storage of data for the right amount of time. The collected research data were adequately stored for a minimum of two years after the end of the study or longer if required for public use so as to enable

some form of validation of the study results in the future without necessarily identifying the participants. Also, clarity in data management procedures was preserved across the research process. All participants were told at the beginning of the study how the data were going to be collected, stored, and used for research use only. Explicating data protection measures and anonymisation procedures enhanced participants' confidence and willingness to adhere to the protocols. Finally, the study respected the strictly set laws and regulations on data protection, including the GDPR for the European region, among others. This covered keeping relevant ethical clearances or permission from the concerned institutional review boards or ethical committees prior to starting the research.

3.9 Materials and Instruments

The research used 21 questions to gather the data. The survey was formatted to technical specifications, which made the responses clear and straightforward. Thus, all the materials were incorporated into the dissertation appendices for informational purposes and to demonstrate the steps involved in the study. It was essential to describe these materials and their technical characteristics in detail so that the overall picture of the completed research work was presented, which could be repeatedly reconstructed and checked.

3.10 Reliability

Reliability is critical in ensuring that the findings of this study on IBM Watson's effects on pharmacovigilance (PV) in the UK pharmaceutical industry are consistent and replicable. To enhance the reliability of the data collection process and the instruments used, several key measures were undertaken:

1. Internal Consistency: The reliability of the survey instruments was assessed using Cronbach's alpha coefficient, a statistical measure used to evaluate the internal consistency of the items within a questionnaire. Specifically, Cronbach's alpha was calculated for constructs related to operational efficiency, accuracy, and adherence to PV standards post-implementation of IBM Watson. A high alpha value (typically above 0.7) indicates that the survey items consistently measure the same underlying construct, ensuring reliable data collection across different respondents.

2. Pre-Test Survey: Before deploying the final survey, a pre-test was conducted with a small sample of participants similar to the main study population. The pre-test aimed to

identify any ambiguities or issues in the survey questions that could affect the reliability of the results. Feedback from the pre-test participants led to revisions in the questionnaire, such as rephrasing unclear questions and adjusting response options to better capture the intended data. This process helped to refine the survey, ensuring that it would yield consistent and reliable results in the main study.

3. Standardized Data Collection: To further enhance reliability, the data collection process was standardized. Surveys were administered electronically using a consistent format and platform, ensuring that all participants received the same instructions and questions in a uniform manner. This approach minimized variations in data collection procedures, reducing the potential for inconsistencies in responses.

4. Statistical Software: The use of SPSS software for data analysis added another layer of reliability. SPSS is widely recognized for its robust capabilities in handling survey data, including tools for checking internal consistency and performing detailed statistical analysis. By using SPSS, the study ensured that the data were processed consistently and accurately, which is crucial for maintaining the reliability of the research findings.

3.11 Validity

Validity is concerned with the accuracy and truthfulness of the study's findings, ensuring that the research genuinely measures what it intends to measure. Several steps were taken to enhance the validity of this study:

1. Content Validity: Content validity was ensured through a comprehensive literature review and the development of the survey questions based on established theoretical frameworks, such as the Technology Acceptance Model (TAM). This approach ensured that the survey content was relevant and adequately covered the constructs of interest, such as operational efficiency and accuracy in PV processes after implementing IBM Watson. The alignment with recognized theories and frameworks helped ensure that the survey questions were representative of the key concepts being studied.

2. Construct Validity: Construct validity was assessed using factor analysis, a statistical method used to verify that the survey items grouped together logically and measured distinct constructs. For instance, factor analysis was employed to ensure that items related to operational efficiency were separate from those measuring accuracy or adherence to standards. This analysis helped confirm that each survey item contributed to measuring a

specific aspect of the overall research objective, ensuring that the data collected accurately reflected the constructs being studied.

3. Addressing Sampling Bias: Potential sampling bias was mitigated by carefully defining the inclusion criteria for participants. The study targeted individuals with specific expertise in pharmacovigilance and AI technologies, such as IBM Watson, ensuring that the sample was relevant to the research objectives. Additionally, recruitment efforts through professional networks and platforms like LinkedIn ensured a diverse and representative participant pool, further reducing the risk of bias.

4. Minimizing Social Desirability Bias: Social desirability bias, where respondents may answer questions in a manner they believe is socially acceptable rather than truthful, was addressed by assuring participants of their anonymity. By guaranteeing that responses would remain confidential and that individual identities would not be disclosed, the study encouraged honest and accurate answers, enhancing the validity of the data.

5. Systematic Data Collection: Data collection was conducted systematically using structured checklists, ensuring that all relevant data points were captured consistently. The pilot survey questions were developed and tested on a sample of respondents. Based on the outcomes and the participants' information, the required changes were made to the specifications of the detailed information provided. The study proceeds to the final design to cover all the necessary aspects of data collection about the opinions and practices of PV professionals regarding AI integrations. This approach minimized the risk of errors or omissions during data collection, further supporting the validity of the study's findings.

3.12 Chapter Summary

In conclusion, this chapter has outlined the comprehensive and systematic methodology employed to assess the impact of IBM Watson on the productivity and accuracy of pharmacovigilance (PV) operations within the UK pharmaceutical industry. The chosen case study approach, grounded in the theoretical frameworks of Saunders, Lewis, and Thornhill (2019) and Okesina (2020), provides a robust structure for exploring the integration of AI technologies in real-world settings. By applying the Research Onion model, this methodology ensures that all elements of the research from the philosophical underpinnings to data collection and analysis are aligned, coherent, and designed to produce valid and reliable results. The adoption of a positivist philosophy, the use of

empirical research methods, and the rigorous processes of data collection and analysis collectively ensure that the study's findings are both scientifically grounded and practically relevant, contributing valuable insights into the role of AI in enhancing PV operations.

4 FINDINGS AND DISCUSSION

4.1 Introduction

This chapter presents the findings from a survey conducted to assess the impact of IBM Watson on operational efficiency and accuracy in pharmacovigilance processes within UK pharmaceutical companies. The primary objective of this quantitative analysis was to evaluate IBM Watson's effectiveness in addressing key areas of pharmacovigilance and to identify the challenges associated with its implementation.

Despite demonstrating promising advancements, several gaps in the literature highlight the need for a comprehensive evaluation of IBM Watson's impact on pharmacovigilance. The research objectives aimed to:

1. **Measure the Reduction in Manual Workload and the Speed of Data Processing:** The survey assessed how IBM Watson has influenced the reduction of manual workload and the speed of data processing. While initial findings indicate improvements in efficiency, the literature gap remains in evaluating the long-term sustainability of these benefits. Although immediate efficiency gains are evident, further research is needed to understand how these improvements translate into enduring benefits for patient safety and regulatory compliance over time.

2. **Compare the Accuracy of IBM Watson in Detecting ADRs and Critical Pharmacovigilance Information:** The analysis compared IBM Watson's accuracy in detecting Adverse Drug Reactions (ADRs) and other pharmacovigilance information against manual literature reviews. The system has shown enhanced accuracy in these areas; however, there is a lack of research on how these improvements affect long-term pharmacovigilance outcomes. Further investigation is required to evaluate the sustainability and real-world applicability of IBM Watson's accuracy.

3. **Document and Analyze Key Challenges:** The survey identified several challenges faced by UK pharmaceutical companies in integrating IBM Watson, including issues related to data integration, user training, and regulatory compliance. While general challenges are acknowledged, there is insufficient research on how these challenges vary across different companies and their

operational environments. Detailed analysis of these nuances is necessary to develop tailored strategies for overcoming integration hurdles.

4. **Develop Actionable Recommendations or a Critical Success Framework:** Findings from the survey are intended to be synthesized into actionable recommendations or a critical success framework for integrating IBM Watson into pharmacovigilance practices. However, the literature lacks a comprehensive cost-benefit analysis, including both direct and indirect costs, which is crucial for assessing the overall value proposition of adopting IBM Watson. Addressing this gap will provide a more holistic view of its integration and effectiveness in enhancing pharmacovigilance practices.

The hypotheses tested in this study are:

1. **H1**: The implementation of IBM Watson significantly reduces the manual workload involved in literature monitoring.

2. **H2**: IBM Watson accelerates the speed of data processing compared to manual literature review.

The survey was distributed via Google Forms and received responses from 174 pharmaceutical professionals, each providing insights based on their experience and current roles within the industry. The survey comprised 21 targeted questions, focusing on various aspects of IBM Watson's implementation and its perceived impact on pharmacovigilance operations. Key areas of inquiry included the participants' roles and years of experience, their use of AI technologies like IBM Watson, and their perceptions of how IBM Watson has influenced efficiency, accuracy, and compliance in their work processes.

In alignment with the positivist research philosophy and the empirical research approach adopted in this study, the data collected from the survey provides a robust foundation for quantitative analysis. This chapter will offer a comprehensive overview of the responses to each survey question, examining the extent to which IBM Watson has improved literature monitoring efficiency, reduced manual workload, accelerated data processing, and enhanced ADR detection accuracy. Additionally, the chapter will explore the challenges encountered during IBM Watson's integration into existing workflows, the

adequacy of training and resources provided, and the overall effectiveness of IBM Watson in achieving operational improvements in pharmacovigilance.

Based on the findings, this chapter will conclude with actionable recommendations for the successful integration and optimization of IBM Watson within the pharmacovigilance practices of UK pharmaceutical companies. These recommendations will aim to address the identified challenges and maximize the benefits of IBM Watson, ensuring that its implementation not only improves efficiency and accuracy but also aligns with regulatory standards and organizational goals. The insights derived from this analysis will contribute to the broader discussion on AI's future role in pharmacovigilance and its potential applications across other healthcare and laboratory setting.

4.2 Findings

4.2.1 Graphical Presentation

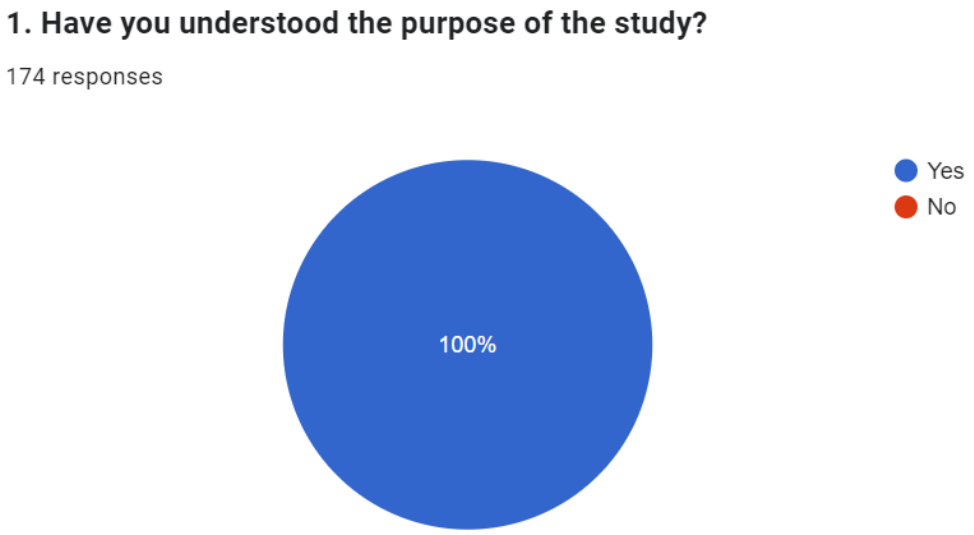


Figure 3: Have you understood the purpose of the study?

The pie chart (Figure 1) displays that 100% of the 174 survey participants confirmed their understanding of the study's purpose. This unanimous agreement ensures that all responses are based on a clear comprehension of the study's aims and objectives, validating the data's reliability. This foundational understanding is essential for a thorough and accurate analysis of IBM Watson's impact on pharmacovigilance, setting the stage for a detailed examination of operational efficiency, ADR detection accuracy, and integration challenges and benefits.

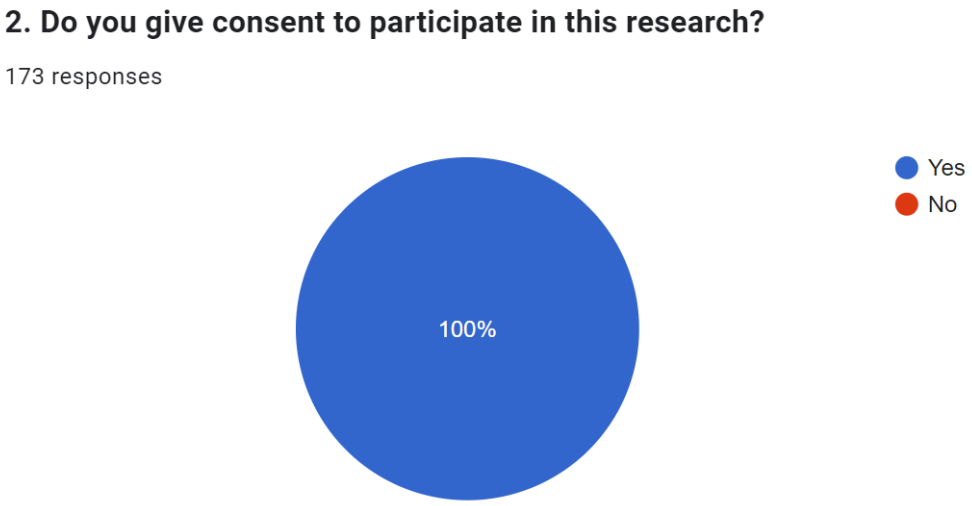


Figure 4: Do you give consent to participate in this research?

The survey commenced with a consent question to ensure ethical standards and participants' voluntary involvement. Out of 174 invitations, 173 individuals (99.4%) consented to participate, while 0.6% either declined or did not respond.

The accompanying pie chart reflects this high consent rate, emphasizing the strong willingness of professionals to engage in the study. This near-unanimous consent highlights the study's ethical rigor and reinforces the reliability of the data collected on IBM Watson's impact on pharmacovigilance operations.

3. Role In the Pharmaceutical Industry

Current role in the pharmaceutical industry:

Current Role	Accuracy(%)
Pharmacovigilance specialist	41.6%
Clinical research associate	24.3%
Regulatory affairs professional	20.2%
Data scientist	11.6%
Others	2.3%

173 Responses

Figure 5: Current role in the pharmaceutical industry

The table (Figure 3) illustrates the range of roles among the survey respondents within the pharmaceutical industry, highlighting IBM Watson's broad impact across various functions. This diverse representation enhances the validity and reliability of the study by providing a comprehensive view of the AI tool's effects.

Among the respondents, 72 (41.6%) are pharmacovigilance specialists, who are central to the study's focus on IBM Watson's impact on monitoring and assessing pharmaceutical safety. Their feedback is vital for understanding how the AI tool influences literature monitoring and process efficiency, ensuring that the findings are directly relevant to the core area of interest.

Clinical research associates, comprising 42 (24.3%) of the respondents, offer insights into the role of AI in drug development. Their perspectives shed light on how AI technologies might streamline research processes and enhance accuracy, thereby validating the tool's application in various stages of pharmaceutical research.

Regulatory affairs professionals, making up 35 (20.2%) of the sample, provide important viewpoints on IBM Watson's role in regulatory compliance. Their input helps assess the effectiveness of pharmacovigilance systems and ensures that the study considers the regulatory implications of AI implementation.

Data scientists, constituting 20 (11.6%) of the participants, offer technical insights into the implementation and performance of AI systems. Their assessments of data processing capabilities contribute to the reliability of the study by evaluating the technical performance of IBM Watson.

The remaining 4 (2.3%) respondents fall into the 'Other' category, representing additional relevant perspectives not covered by the primary roles. This inclusion ensures that the study captures a wide range of insights, enhancing its overall validity.

The varied roles among respondents ensure a robust evaluation of IBM Watson's impact, encompassing practical, technical, and regulatory aspects within the pharmaceutical industry. This broad representation supports the study's validity by reflecting the diverse functions affected by IBM Watson and enhances reliability by incorporating multiple viewpoints and expertise.

4. Years of Experience in the Pharmaceutical Industry

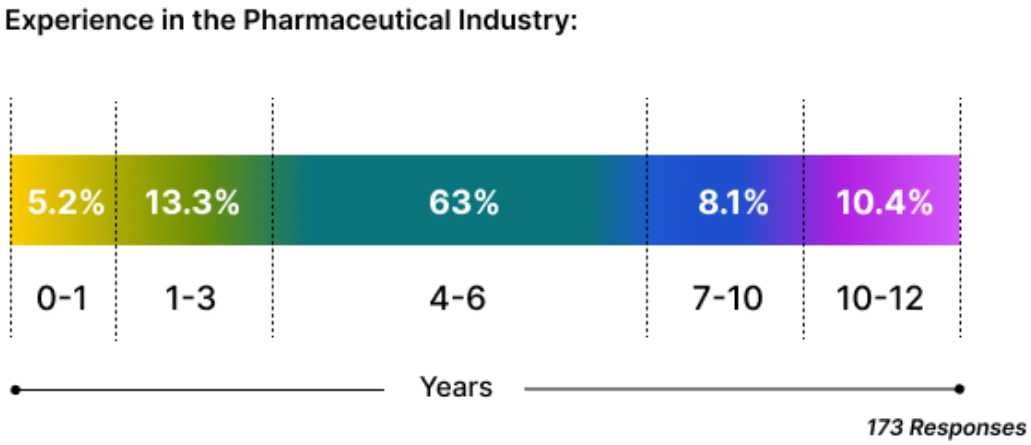


Figure 6: How many years of experience do you have in the pharmaceutical industry?

The stacked bar chart (Figure 4) illustrates the distribution of years of experience among the pharmaceutical professionals surveyed, offering a nuanced perspective on their evaluation of IBM Watson's impact on pharmacovigilance.

The majority of respondents, 109 (63%), have 4-6 years of experience. This indicates a strong presence of mid-career professionals with a solid understanding of industry practices, likely providing a balanced view on IBM Watson's integration into pharmacovigilance.

A smaller group, 23 (13%), have 1-3 years of experience. These early-career professionals may be more familiar with recent technological advancements, though they may lack extensive historical context.

Fourteen respondents (8%) have 7-10 years of experience. This group bridges the gap between mid-career and highly experienced professionals, offering insights into how IBM Watson compares with both traditional and evolving practices.

Eighteen respondents (10%) have over 10 years of experience. Their long-term perspective provides valuable historical context regarding changes in pharmacovigilance and the evolving role of AI technologies.

Lastly, 9 respondents (5%) have less than 1 year of experience. Although this group is small, their fresh perspectives on new technologies and training processes can offer valuable insights.

Overall, the diversity in experience levels among respondents enriches the analysis of IBM Watson's impact, providing a comprehensive view of its integration into pharmacovigilance.

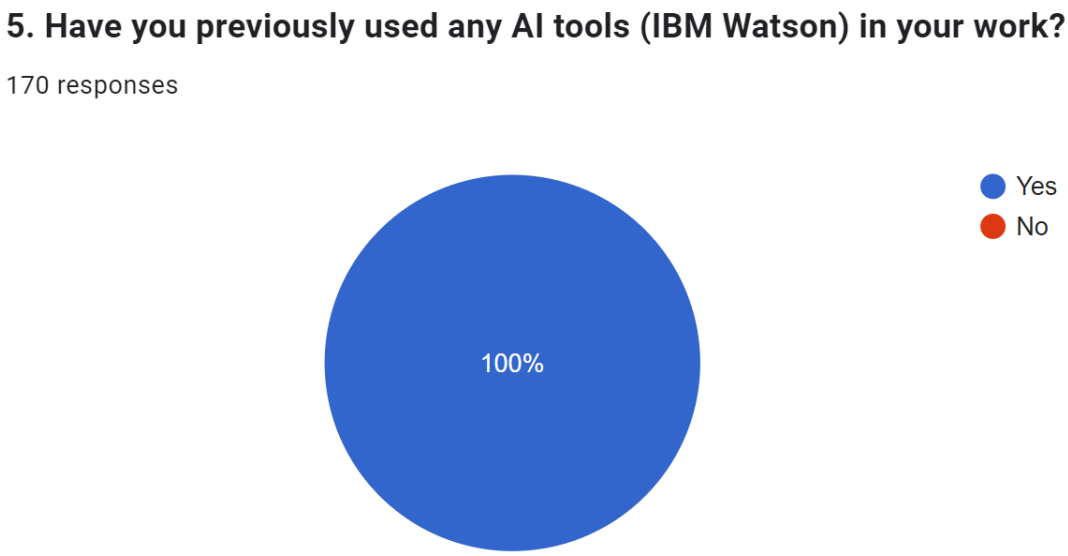


Figure 7: Have you previously used any AI tools (IBM Watson) in your work?

The pie chart (Figure 5) displays the responses to the survey question about the prior use of IBM Watson in respondents' work. Out of 174 pharmaceutical professionals, 170 (97.7%) reported having used IBM Watson, demonstrating its widespread adoption and integration in pharmacovigilance. This high usage rate underscores the tool's significant presence and relevance in the field.

Conversely, 2.3% of respondents either had not used IBM Watson or did not answer the question. This small proportion suggests limited exposure within this group, but the predominant majority indicates a strong integration of IBM Watson in their professional activities. This data highlights the tool's substantial impact and sets the stage for further analysis of its effects on operational efficiency and accuracy.

6. Do you think the implementation of IBM Watson has improved the efficiency of literature monitoring in your pharmacovigilance processes?

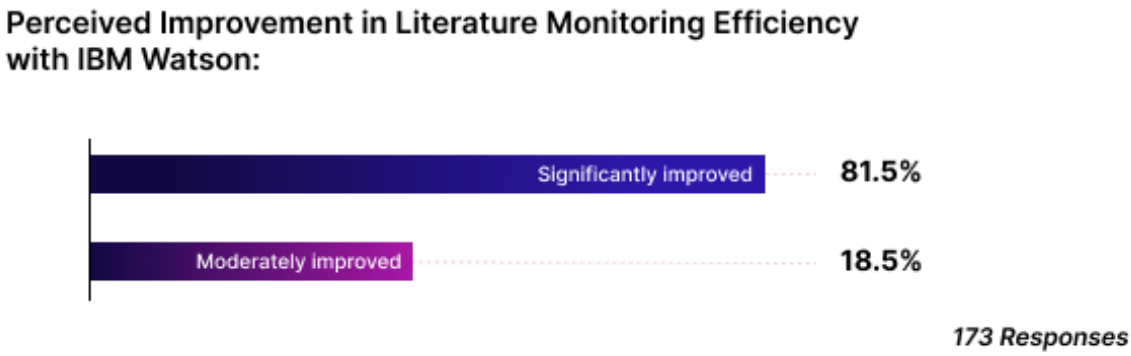


Figure 8: Do you think implementing IBM Watson has improved the efficiency of literature monitoring in our pharmacovigilance processes?

The row chart (Figure 6) assesses pharmaceutical professionals' perceptions of IBM Watson's impact on the efficiency of literature monitoring in pharmacovigilance.

The results reveal a notably positive reception, with 141 respondents (81.5%) reporting that IBM Watson has significantly enhanced efficiency. This majority indicates that IBM Watson effectively streamlines literature monitoring, thereby improving workflow and productivity by reducing the time and effort required.

In contrast, 32 respondents (18.5%) noted only a moderate improvement in efficiency. Although these participants acknowledge some benefits, they perceive the changes as less impactful compared to the majority's assessment.

Overall, the data strongly supports IBM Watson's role in advancing literature monitoring processes, highlighting its substantial contribution to operational efficiency in pharmacovigilance. This endorsement underscores the tool's effectiveness and points to its potential for continued use and further development in the field.

7. To what extent has IBM Watson reduced the manual workload in your pharmacovigilance tasks?

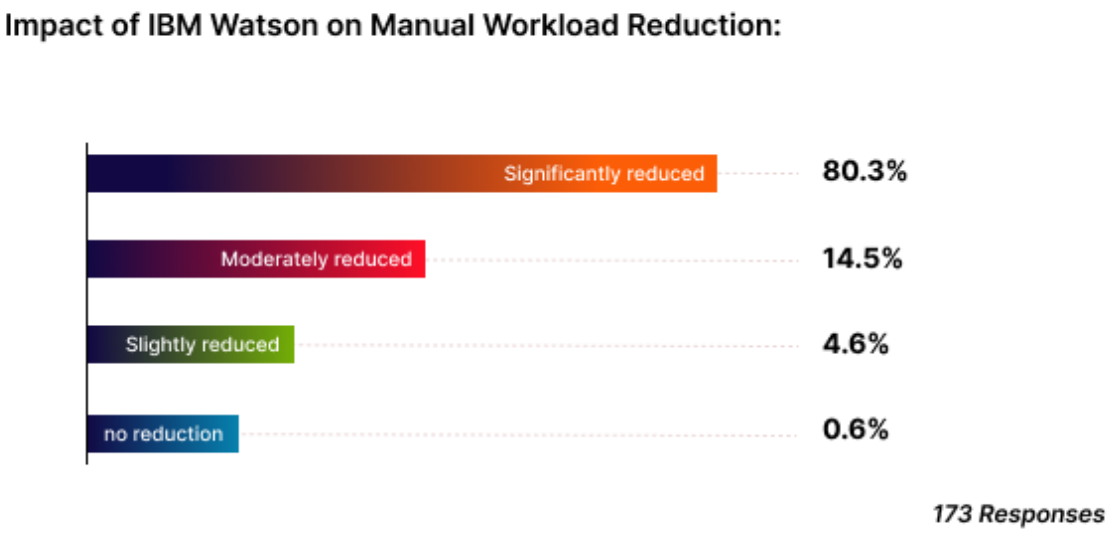


Figure 9: To what extent has IBM Watson reduced the manual workload in your pharmacovigilance tasks?

The row chart (Figure 7) displays survey findings on the impact of IBM Watson on manual workload in pharmacovigilance. A substantial 139 respondents (80.3%) reported a significant reduction in manual tasks, underscoring IBM Watson's primary benefit in automating and streamlining processes.

In contrast, 25 respondents (14.5%) noted a moderate reduction, indicating some improvement in efficiency, though not as pronounced. A smaller group of 8 respondents (4.6%) experienced only minimal reductions, suggesting a limited impact, while 1 respondent (0.6%) reported no reduction in workload, reflecting the tool's uneven effectiveness across different users.

Overall, the data highlights IBM Watson's general effectiveness in decreasing manual workload, although individual experiences with the tool vary.

8. How much faster is data processing with IBM Watson compared to manual methods?

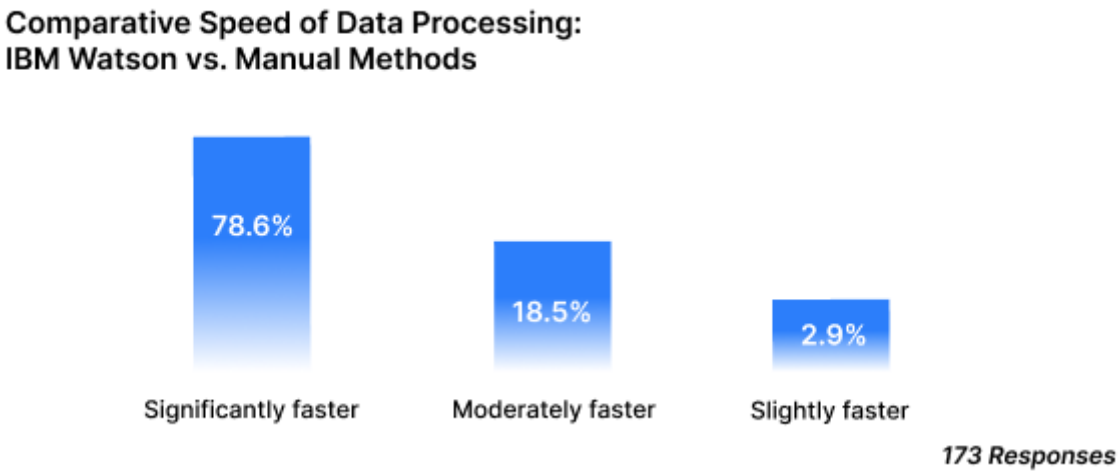


Figure 10: How much faster is data processing with IBM Watson compared to manual methods?

The bar chart (Figure 8) depicts survey responses regarding IBM Watson's data processing speed compared to traditional manual methods. The results demonstrate a strong consensus on IBM Watson's efficiency improvements.

A notable 136 respondents (78.6%) perceive IBM Watson as significantly faster than manual methods. This reflects its effectiveness in accelerating data processing and enhancing overall operational efficiency.

Conversely, 32 respondents (18.5%) consider IBM Watson to be moderately faster. While acknowledging an improvement, this group does not view the speed enhancement as pronounced as reported by the majority. Nonetheless, this feedback indicates a positive impact on workflow efficiency.

A smaller group of 5 respondents (2.9%) felt that IBM Watson was only slightly faster, suggesting minimal improvement.

Overall, the survey responses highlight a broad recognition of IBM Watson's capability to substantially improve data processing speed, affirming its role in optimizing pharmacovigilance operations.

9. To what extent do you agree or not that IBM Watson's AI capabilities have enhanced the accuracy of adverse drug reaction (ADR) detection in your literature monitoring activities?

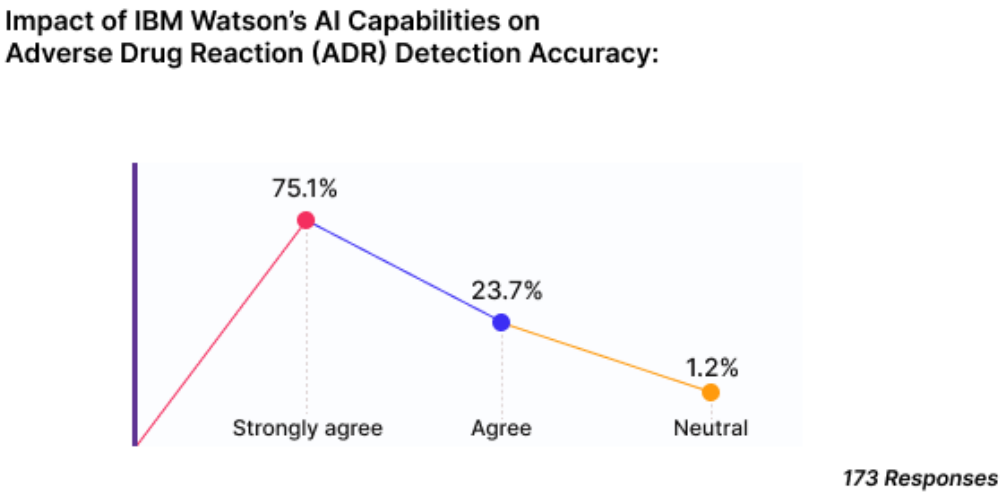


Figure 11: To what extent do you agree or not that IBM Watson's AI capabilities have enhanced the accuracy of adverse drug reaction (ADR) detection in our literature monitoring activities?

The line chart (Figure 9) depicts survey responses regarding the impact of IBM Watson's AI capabilities on the accuracy of adverse drug reaction (ADR) detection in literature monitoring. A substantial 130 respondents (75.1%) strongly agree that IBM Watson has significantly enhanced ADR detection accuracy, underscoring its effectiveness in improving pharmacovigilance processes.

Additionally, 41 respondents (23.7%) also agree with this positive assessment, resulting in a total approval rate of nearly 99%. This broad consensus underscores the widespread recognition of IBM Watson's beneficial impact. Only 2 respondents (1.2%) remained neutral, indicating that nearly all surveyed professionals acknowledge the advancements made by IBM Watson in ADR detection.

Overall, the data demonstrates a strong endorsement of IBM Watson's role in improving ADR detection precision, affirming its value in supporting effective pharmacovigilance operations.

10. Do you think that the integration of IBM Watson into your pharmacovigilance systems was straightforward and well-supported?

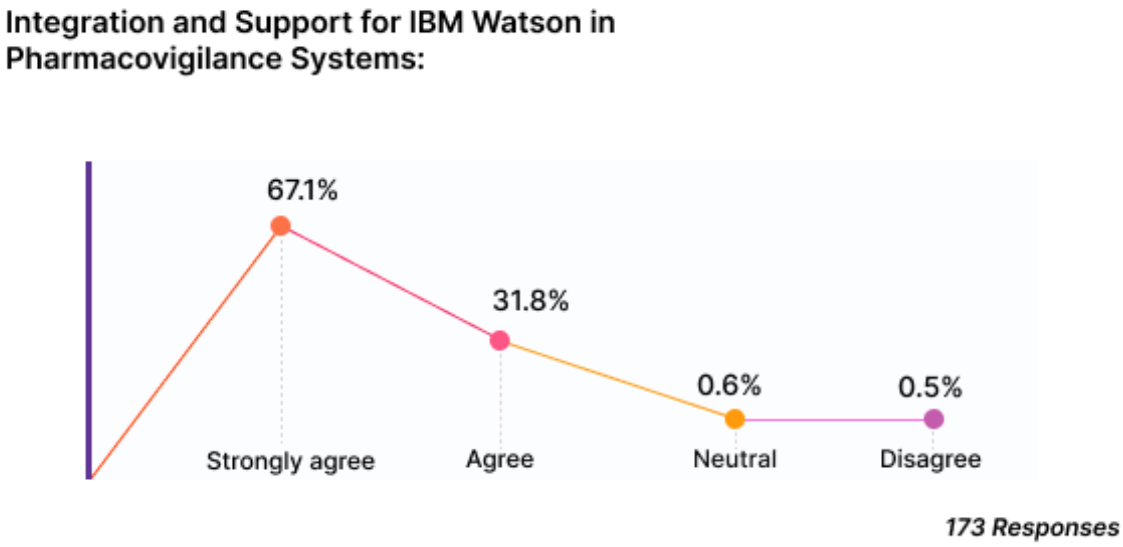


Figure 12: Integrating IBM Watson into our pharmacovigilance systems was straightforward and well-supported?

The line chart (Figure 10) depicts responses to the question: "Integrating IBM Watson into our pharmacovigilance systems was straightforward and well-supported." The data reveals a high level of satisfaction with the integration process. Specifically, 116 respondents (67.1%) strongly agreed that the integration was smooth and well-supported, indicating a predominantly positive experience. Additionally, 55 respondents (31.8%) agreed with this statement, resulting in a total of 98.9% who expressed approval of the integration process.

Only 1 respondent (0.6%) remained neutral, and 1 respondent (0.5%) disagreed, suggesting that difficulties with the integration were minimal. These results underscore the overall success of IBM Watson’s integration into pharmacovigilance systems, reflecting the tool's effective design and the quality of support provided.

11. Do you think that the team received adequate training and resources to effectively utilise IBM Watson for literature monitoring?

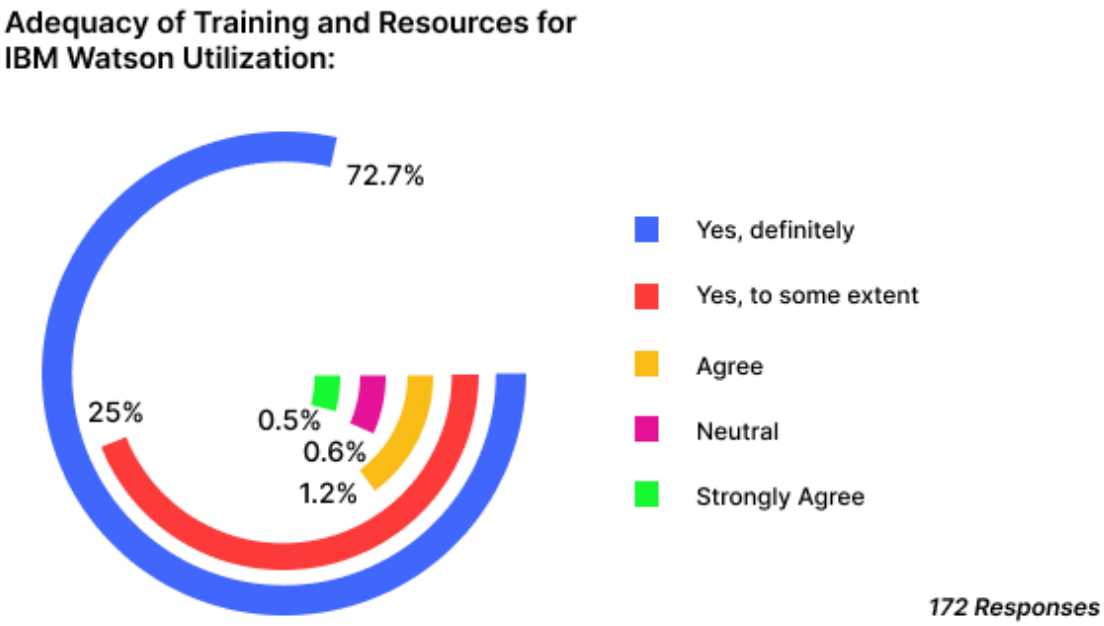


Figure 13: Do you think the team received adequate training and resources to effectively utilise IBM Watson for literature monitoring?

The doughnut chart (Figure 11) presents survey responses regarding the adequacy of training and resources provided for using IBM Watson in literature monitoring. The data indicates that 125 respondents (72.7%) felt the training and resources were sufficient, reflecting a general sense of satisfaction among pharmaceutical professionals.

However, 43 respondents (25%) somewhat agreed that the training and resources were adequate, suggesting there is room for improvement. A small portion of respondents had varied opinions: 2 (1.2%) fully agreed with the adequacy of the training and resources, 1 (0.6%) remained neutral, and only 1 (0.5%) strongly agreed, indicating a very limited perspective of exceptional comprehensiveness.

In summary, while the majority of professionals are generally satisfied with the training and resources available, the feedback highlights the need for enhancements to ensure that all users can fully leverage IBM Watson in pharmacovigilance.

12. Do you believe that IBM Watson has significantly reduced the time required to monitor and analysis scientific literature for pharmacovigilance purposes?

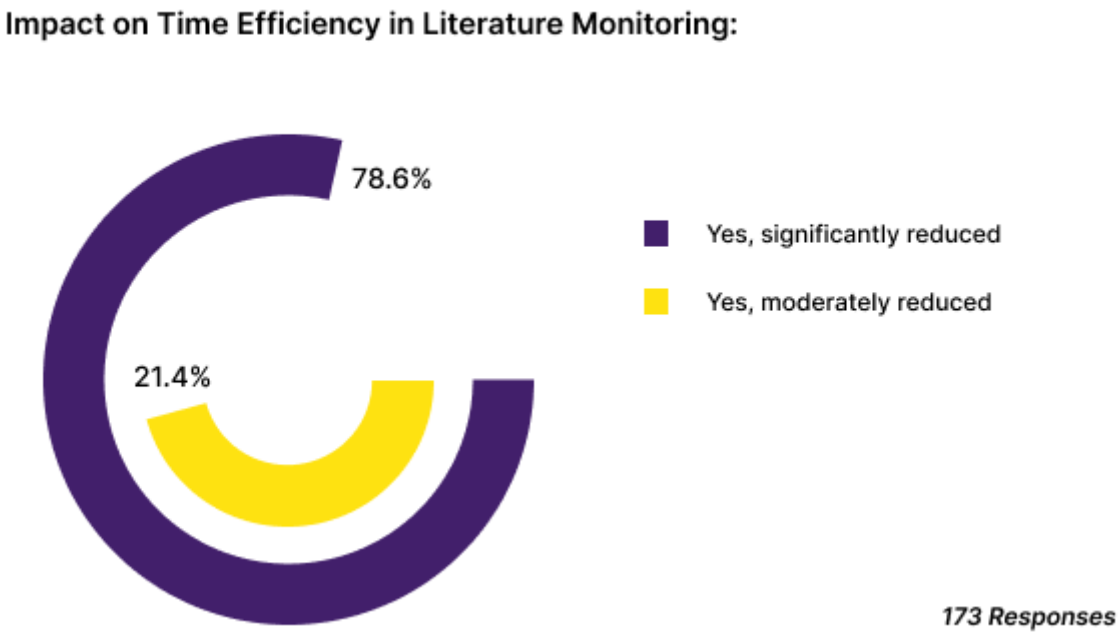


Figure 14: Do you believe IBM Watson has significantly reduced the time required to monitor and analyse scientific literature for pharmacovigilance purposes?

The doughnut chart (Figure 12) illustrates survey responses regarding IBM Watson's impact on reducing the time needed for monitoring and analyzing scientific literature in pharmacovigilance. A substantial 136 (78.6%) of participants reported a significant reduction in time, reflecting IBM Watson's perceived effectiveness in these tasks. Additionally, 37 (21.4%) observed a moderate time reduction, suggesting that the extent of time savings may vary depending on the specific context. Notably, no respondents reported that IBM Watson had no impact, emphasizing its overall positive contribution to enhancing operational efficiency in pharmacovigilance.

13. Do you think that the use of IBM Watson has led to cost savings in our pharmacovigilance operations?

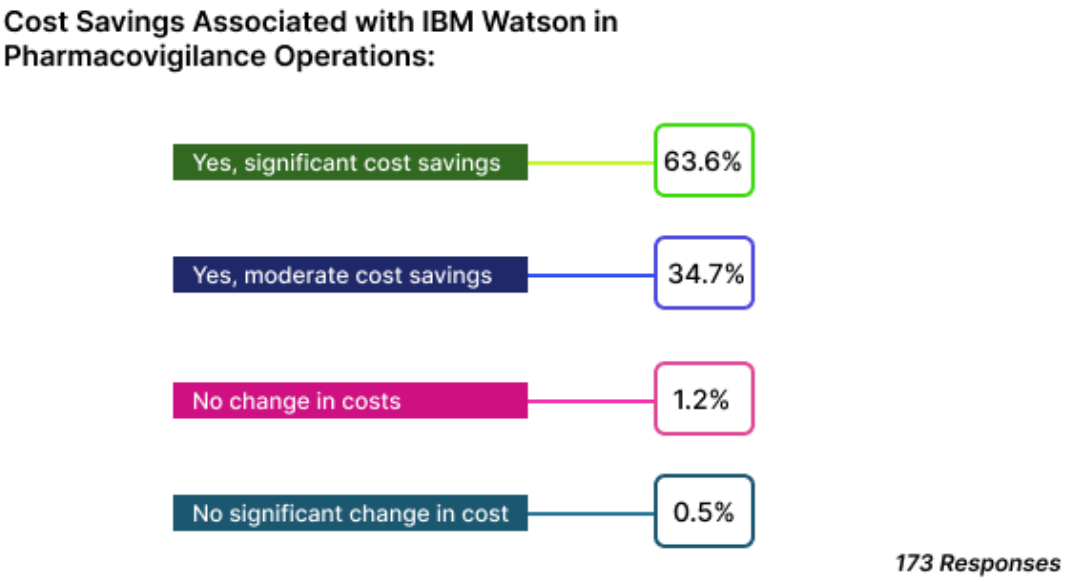


*Figure 15: **Figure X: Perceived Impact of IBM Watson on Cost Savings in Pharmacovigilance Operations***

The bar chart (Figure 13) displays survey responses regarding the perceived impact of IBM Watson on cost savings in pharmacovigilance operations. The data reveals that 110 respondents (63.6%) reported significant cost reductions following the implementation of IBM Watson, underscoring its considerable financial benefits. Additionally, 60 respondents (34.7%) experienced moderate savings, indicating a positive but less substantial impact. Only 2 respondents (1.2%) noted no change in costs, and 1 respondent (0.5%) observed minimal impact. These findings suggest that while IBM Watson generally contributes to cost reductions, the extent of its impact varies among users. Overall, the chart highlights IBM Watson's effectiveness in achieving cost savings for the majority of participants.

14. Do you think that IBM Watson has been effective in ensuring regulatory compliance in our literature monitoring processes?

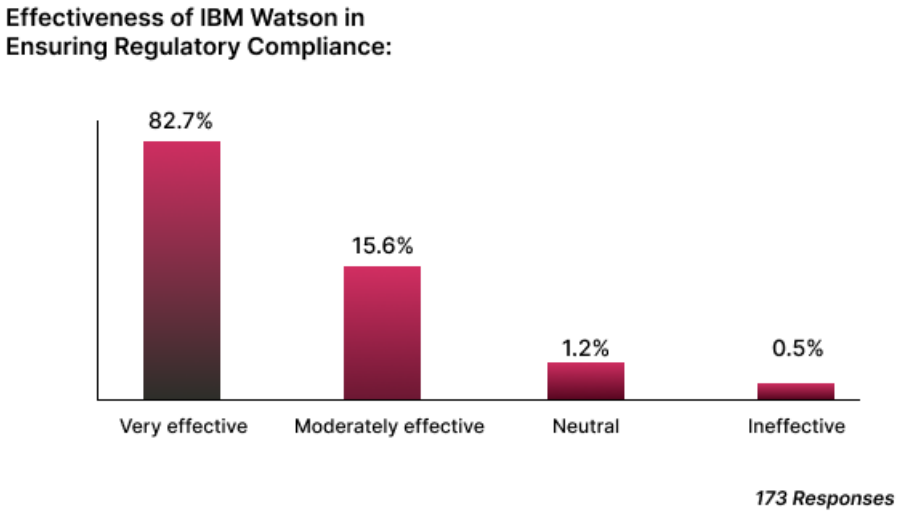


Figure 16: Do you think that IBM Watson has been effective in ensuring regulatory compliance in our literature monitoring processes?

The bar chart (Figure 14) illustrates respondents' opinions on IBM Watson's effectiveness in ensuring regulatory compliance during literature monitoring. A substantial majority, 143 (82.7%), rated IBM Watson as very effective, reflecting high confidence in its ability to meet regulatory standards. Additionally, 27 (15.6%) considered it moderately effective, acknowledging its benefits while suggesting there may be areas for improvement. Only 2 respondents (1.2%) were neutral, possibly due to limited experience with the tool, and just 1 respondent (0.5%) found IBM Watson ineffective. Overall, the data demonstrates a strong consensus on IBM Watson's positive impact on regulatory compliance, with only minor suggestions for further enhancement.

15. Do you think that there are challenges associated with integrating IBM Watson into existing pharmacovigilance workflows?

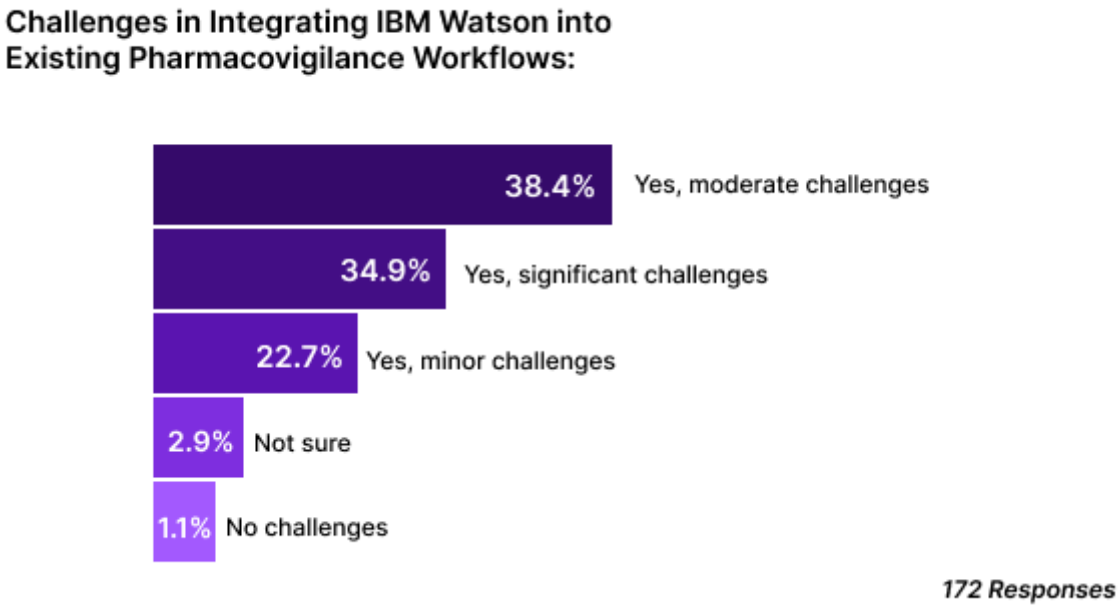


Figure 17: Do you think there are challenges associated with integrating IBM Watson into existing pharmacovigilance workflows?

The survey responses reveal a variety of challenges encountered by professionals when integrating IBM Watson into existing pharmacovigilance workflows. A significant portion of respondents reported difficulties during the integration process, with 66 (38.4%) indicating they faced moderate challenges and 60 (34.9%) encountering significant obstacles. This highlights the complexity of the integration efforts. In contrast, 39 (22.7%) experienced only minor difficulties, while a small number were either unsure (5 respondents, or 2.9%) or did not perceive any challenges at all (2 respondents, or 1.1%). This variation in experiences emphasizes the necessity of addressing these challenges to facilitate a smoother integration and improve operational efficiency

16. Do you think that the benefits of using IBM Watson for literature monitoring outweigh the challenges faced during its implementation?

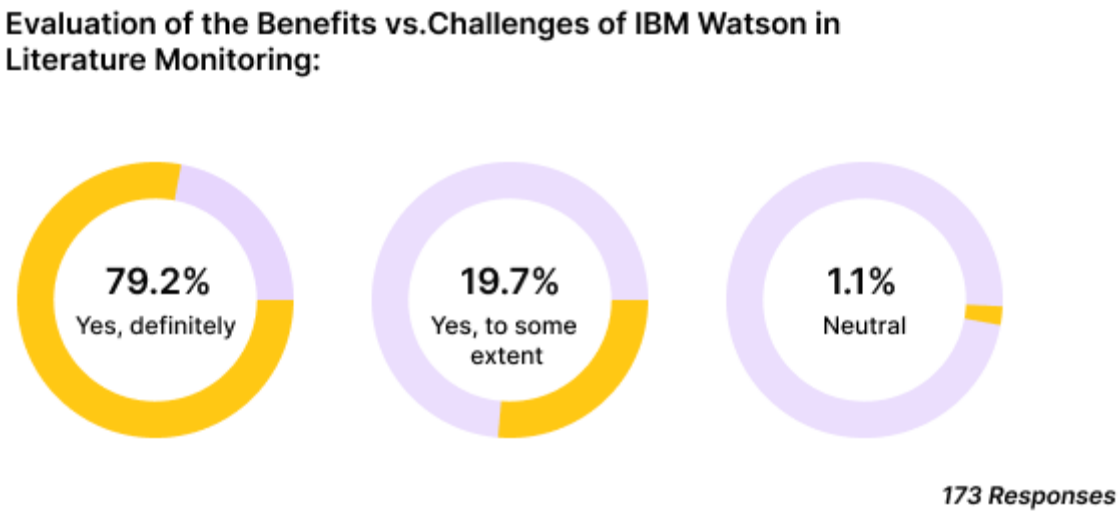


Figure 18: Do you think that the benefits of using IBM Watson for literature monitoring outweigh the challenges faced during its implementation?

The survey reveals that a significant majority of pharmaceutical professionals, 137 (79.2%), believe that the benefits of using IBM Watson for literature monitoring far outweigh the challenges of implementation. This underscores its positive impact on operational efficiency and accuracy in pharmacovigilance. An additional 34 respondents (19.7%) recognize the advantages of the technology while also acknowledging some challenges, reflecting a generally favorable view overall. Only 2 respondents (1.1%) remain neutral, indicating minimal ambivalence regarding the balance between benefits and challenges.

These findings suggest a strong consensus among the majority that, despite the implementation hurdles, IBM Watson's contributions to literature monitoring are highly beneficial and justify the efforts required to integrate the technology.

17. Do you think that IBM Watson can continue improving your pharmacovigilance literature monitoring in the future?

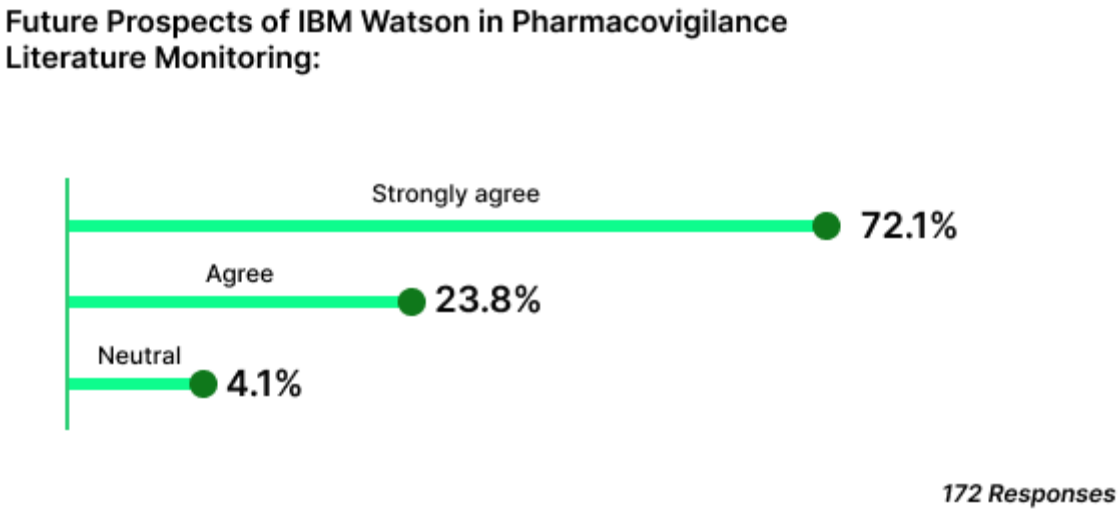


Figure 19: Do you think that IBM Watson can continue improving our pharmacovigilance literature monitoring in the future?

The survey results demonstrate strong confidence among pharmaceutical professionals in the future advancements of IBM Watson in pharmacovigilance literature monitoring. As depicted in the pie chart, 124 respondents (72.1%) strongly agree that IBM Watson will continue to enhance its capabilities in this area, reflecting widespread optimism about its potential to improve literature monitoring processes.

Additionally, 41 respondents (23.8%) agree with the statement, indicating a positive outlook, though with slightly less certainty than the majority. On the other hand, 7 respondents (4.1%) remain neutral, suggesting some uncertainty or hesitation regarding IBM Watson's future improvements.

Overall, the data underscores a dominant belief in IBM Watson’s potential to advance pharmacovigilance, with a strong consensus supporting its continued growth and effectiveness in the field.

18. What are the key challenges you have encountered while integrating IBM Watson into your pharmacovigilance practices? (Select all that apply)

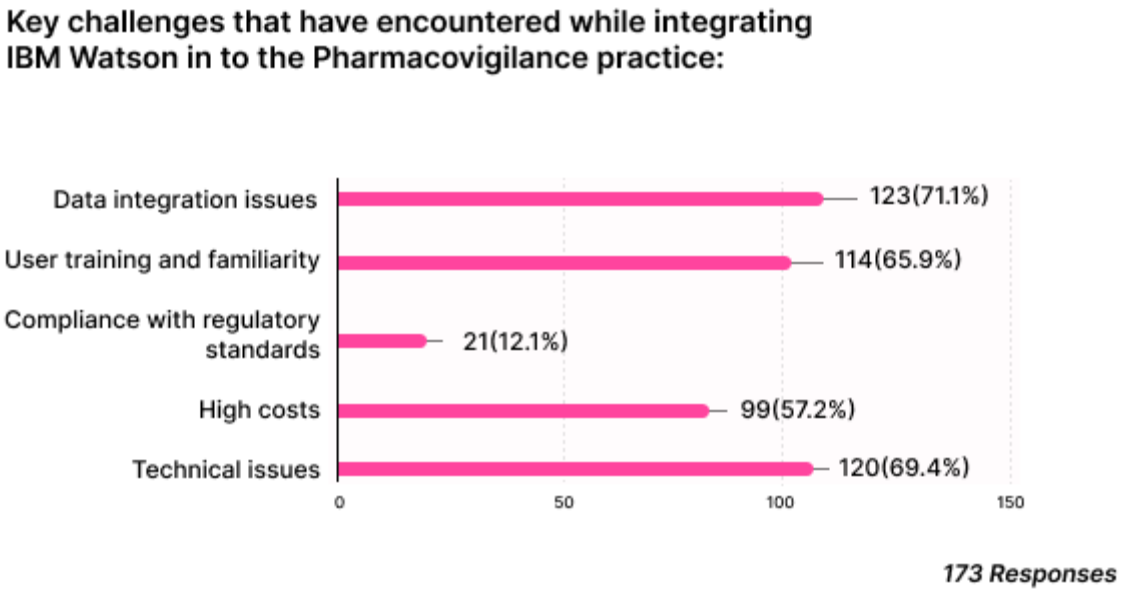


Figure 20: What are the key challenges you have encountered while integrating IBM Watson into your pharmacovigilance practices? (Select all that apply)

The survey results reveal several significant challenges faced by pharmaceutical professionals when integrating IBM Watson into their pharmacovigilance practices, highlighting key areas of concern.

Data Integration Issues: A substantial 71.1% of respondents (123 participants) identified data integration as a primary challenge. This high percentage underscores the difficulties in harmonizing and consolidating diverse data sources with IBM Watson, presenting a significant barrier to effective implementation.

User Training and Familiarity: Another major concern, reported by 65.9% of respondents (114 participants), is related to user training and familiarity with the system. The steep learning curve associated with IBM Watson's technology poses a challenge for seamless integration into existing workflows, suggesting a need for more comprehensive training programs.

Compliance with Regulatory Standards: Although less frequently mentioned, 12.1% of respondents (21 participants) cited compliance with regulatory standards as an important

issue. While not the most pressing challenge, ensuring that IBM Watson adheres to regulatory requirements remains a critical consideration for some organizations.

Technical Issues: Technical difficulties were also a significant concern, with 69.4% of respondents (120 participants) reporting challenges in this area. These issues include problems with system performance, software bugs, and other technical obstacles that hinder the efficient use of IBM Watson in pharmacovigilance.

High Costs: Finally, the cost of implementing and maintaining IBM Watson was noted by 57.2% of respondents (99 participants) as a considerable concern. This reflects the financial burden that companies face when adopting advanced technological solutions, highlighting the need to weigh the benefits of IBM Watson against its associated costs. These findings collectively emphasize the multifaceted challenges that pharmaceutical professionals encounter when integrating IBM Watson into their pharmacovigilance practices. Addressing these concerns will be crucial for optimizing the tool's effectiveness in this critical area.

19. How have these challenges impacted your overall experience with IBM Watson?

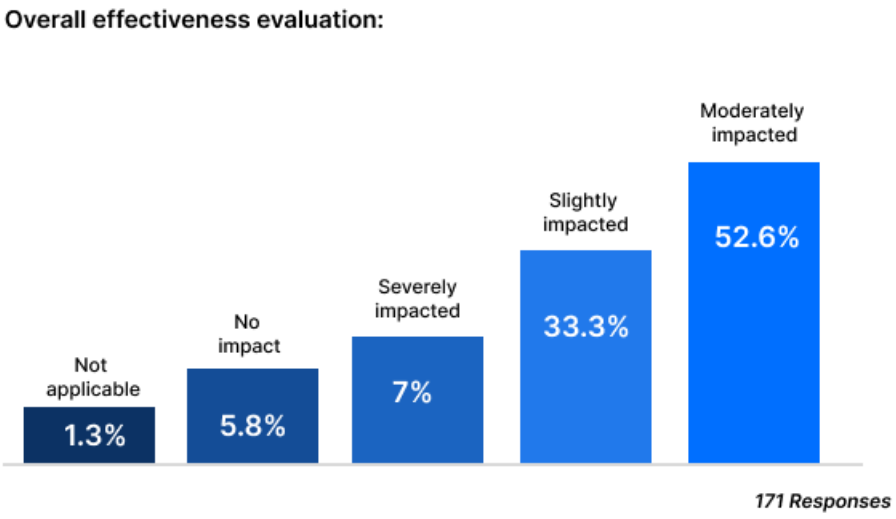


Figure 19: How have these challenges impacted your overall experience with IBM

Watson?

The survey responses regarding the integration challenges with IBM Watson reveal a range of experiences among pharmaceutical professionals. A majority of respondents, 90 (52.6%), reported moderate impacts, indicating that while there were notable issues, they were generally manageable. This suggests that most professionals encountered some challenges, but these were not insurmountable.

On the other hand, 57 respondents (33.3%) experienced only slight impacts, implying that for a significant portion of users, the integration of IBM Watson was relatively smooth and caused minimal disruption. This group likely faced fewer obstacles, allowing for a more seamless adoption of the AI tool.

A smaller segment of the respondents, 12 (7.0%), reported severe impacts, indicating that a minority of users encountered significant difficulties during the integration process. These severe challenges could reflect more complex environments or less adaptable workflows, where integrating AI posed substantial hurdles.

Additionally, 10 respondents (5.8%) reported no impact, suggesting that for some, the integration was entirely straightforward with no noticeable issues. Lastly, 2 respondents (1.3%) found the question not applicable, likely reflecting roles or contexts where IBM Watson integration was irrelevant or not yet undertaken.

Overall, the results suggest that integration challenges with IBM Watson are generally manageable, with the majority of users experiencing moderate or slight effects. However, the presence of severe impacts for a few indicates that certain contexts may require more targeted support to ensure successful integration.

20. Based on your experience, how would you rate the overall effectiveness of IBM Watson in improving pharmacovigilance processes?

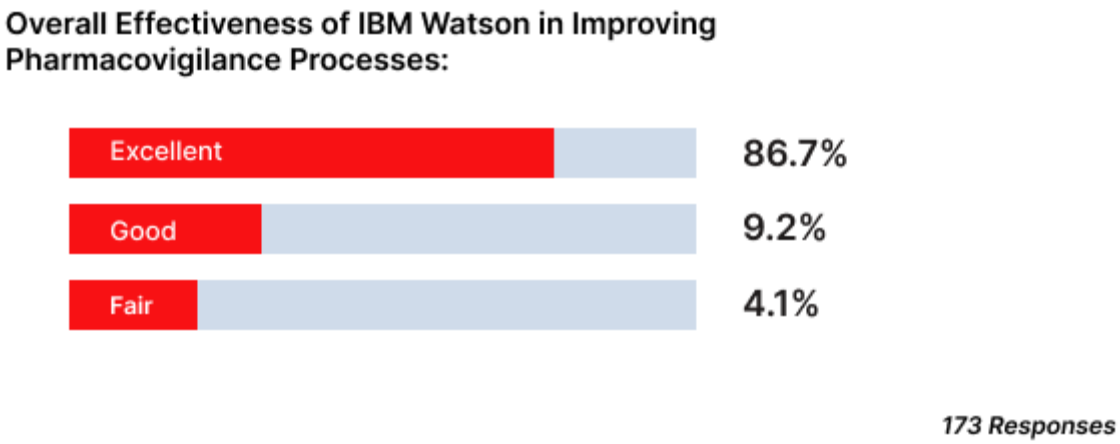


Figure 20: Based on your experience, how would you rate the overall effectiveness of IBM Watson in improving pharmacovigilance processes?

The survey results reveal a predominantly positive assessment of IBM Watson's impact on pharmacovigilance among pharmaceutical professionals. Out of 174 respondents, 150 (86.7%) rated IBM Watson's overall effectiveness as "excellent," indicating a high level of satisfaction with its contribution to enhancing pharmacovigilance processes. Additionally, 16 respondents (9.2%) rated it as "good," reflecting a positive, though somewhat less enthusiastic, view. Only 7 respondents (4.1%) rated its effectiveness as "fair," suggesting that while IBM Watson is generally well-regarded, there is room for improvement. Overall, the feedback highlights a strong consensus regarding IBM Watson's effectiveness, with the majority recognizing its significant benefits in improving pharmacovigilance practices.

21. Do you foresee IBM Watson being used for other applications in healthcare and medical labs? If yes, please specify

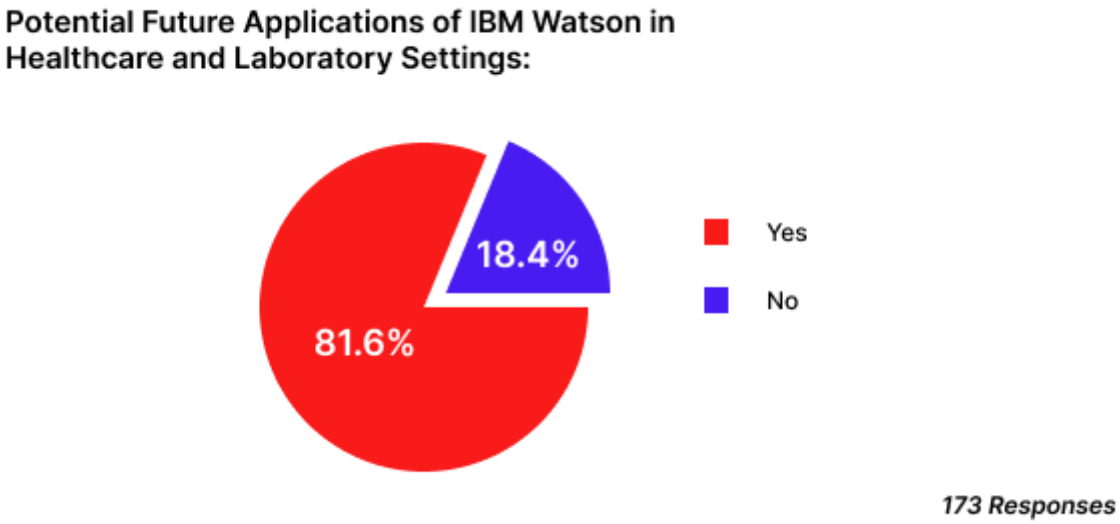


Figure 21: Do you foresee IBM Watson being used for other applications in healthcare and medical labs? If yes, please specify.

The survey results reveal a significant level of optimism regarding IBM Watson's potential beyond its current applications in pharmacovigilance. A substantial majority, 142 respondents (81.6%), expressed confidence in IBM Watson's adaptability and its broader applicability across various healthcare settings. This strong belief underscores the potential for IBM Watson to extend its impact into diverse medical and research domains.

In contrast, 32 respondents (18.4%) expressed skepticism about the future uses of IBM Watson, indicating some reservations about the technology's ability to adapt to or be effective in broader applications. These concerns reflect a more cautious view of the technology's potential.

Overall, the findings suggest a prevailing optimism about IBM Watson's capability to influence multiple areas within the healthcare and research sectors, while acknowledging that some uncertainties remain regarding its wider applicability.

For actionable recommendations, the research conducted focused on several key areas. First, a gap analysis was performed to identify the long-term sustainability of IBM

Watson's efficiency and accuracy improvements. This involved assessing ongoing performance metrics and user feedback to understand whether initial gains persist over time. Second, integration challenges were explored by investigating specific issues faced by different companies, enabling the development of tailored strategies. Training programs were evaluated through surveys to identify areas for enhancement. Additionally, a comprehensive cost-benefit analysis was undertaken to capture both direct and indirect impacts. Continuous evaluation methods were recommended to ensure IBM Watson's ongoing relevance and effectiveness.

4.3 Descriptive Statistics

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
1. Have you understood the purpose of the study?	174	1	1	1.00	.000
2. Do you give consent to participate in this research?	173	1	1	1.00	.000
3. Current role in the pharmaceutical industry:	173	1	5	2.02	1.134
4. How many years of experience do you have in the pharmaceutical industry?	173	1	5	3.05	0.917
5. Have you previously used any AI tools (IBM Watson) in your work?	170	1	1	1.00	0.000

6. Do you think the implementation of IBM Watson has improved the efficiency of literature monitoring in your pharmacovigilance processes?	173	1	2	1.185	0.388
7. To what extent has IBM Watson reduced the manual workload in your pharmacovigilance tasks?	173	1	4	1.25	0.564
8. How much faster is data processing with IBM Watson compared to manual methods?	173	1	3	1.24	0.4914
9. To what extent do you 4 or 2t that IBM Watson's AI capabilities have enhanced the accuracy of adverse drug reaction (ADR) detection in your literature monitoring activities?	173	1	3	1.26	0.44

10. Do you think that the integration of IBM Watson into your pharmacovigilance systems was straightforward and well-supported?	173	1	4	1.345	0.519
11. Do you think that the team received adequate training and resources to effectively utilise IBM Watson for literature monitoring?	172	1	5	1.31	0.590
12. Do you believe that IBM Watson has 1 the time required to monitor and analyse scientific literature for pharmacovigilance purposes?	173	1	2	1.214	0.412
13. Do you think that the use of IBM Watson has led to cost savings in our pharmacovigilance operations?	173	1	4	1.39	0.540

14. Do you think that IBM Watson has been effective in ensuring regulatory compliance in our literature monitoring processes?	173	1	4	1.20	1.45
15. Do you think that there are challenges associated with integrating IBM Watson into existing pharmacovigilance workflows?	172	1	5	1.94	0.92
16. Do you think that the benefits of using IBM Watson for literature monitoring outweigh the challenges faced during its implementation?	173	1	3	1.22	0.442
17. Do you think that IBM Watson can continue improving your pharmacovigilance literature monitoring in the future?	172	1	3	1.25	1.43

18. What are the key challenges you have encountered while integrating IBM Watson into your pharmacovigilance practices? (Select all that apply) Data integration issues	173	.00	1.00	.7471	.90877
User training and familiarity	173	.00	1.00	.6609	.47476
Technical issues	173	.00	1.00	.0862	.28148
Compliance with regulatory standards	173	.00	1.00	.5460	.49932
High costs	173	.00	1.00	.6667	.47276
19. How have these challenges impacted your overall experience with IBM Watson?	171	1	5	1.70	0.93
20. Based on your experience, how would you rate the overall effectiveness of IBM Watson in improving pharmacovigilance processes?	173	1	3	1.174	0.481

21. Do you foresee IBM Watson being used for other applications in healthcare and medical labs? If 1, please specify.	174	1	2	1.184	0.389
Valid N (listwise)	163				

Table 1: Descriptive Statistics

Description of Data Analysis

This section presents the statistical analysis of survey data collected from 174 pharmaceutical professionals to evaluate the impact of IBM Watson on pharmacovigilance processes. The analysis includes measures of central tendency (mean) and dispersion (standard deviation) for each survey question.

1. Understanding of Study Purpose: All 174 respondents confirmed their understanding of the study's purpose, resulting in a mean of 1.00 with no variability (standard deviation of 0.000). This indicates complete consensus on the clarity of the study's objectives.

2. Consent to Participate: Of the 174 invited, 173 consented to participate, reflected by a mean of 1.00 and a standard deviation of 0.000. This high consent rate supports the ethical integrity of the study.

3. Current Role in the Pharmaceutical Industry: The mean for roles in the pharmaceutical industry was 2.02 with a standard deviation of 1.134 across 173 responses. This suggests a diverse range of roles among respondents, contributing varied perspectives.

4. Years of Experience: Respondents had a mean of 3.05 years of experience, with a standard deviation of 0.917 over 173 entries. This distribution highlights a mix of experience levels, enriching the data's applicability.

5. Previous Use of AI Tools: Out of 170 respondents, the mean response was 1.00 with a standard deviation of 0.000, indicating that the majority have used IBM Watson, demonstrating its prevalent adoption.

6. Efficiency of Literature Monitoring: The mean score was 1.185 with a standard deviation of 0.388 from 173 responses, indicating a generally positive perception of IBM Watson's impact on literature monitoring efficiency.

7. Reduction in Manual Workload: A mean of 1.25 and a standard deviation of 0.564 across 173 responses show a strong perception of IBM Watson's role in reducing manual workload.

8. Speed of Data Processing: The mean score of 1.24 with a standard deviation of 0.4914 from 173 responses highlights a consensus on IBM Watson's superiority in data processing speed compared to manual methods.

9. Accuracy of ADR Detection: Respondents had a mean of 1.26 and a standard deviation of 0.44 over 173 responses, reflecting a high level of agreement that IBM Watson has enhanced ADR detection accuracy.

10. Integration and Support: The integration of IBM Watson was rated with a mean of 1.345 and a standard deviation of 0.519 across 173 responses, showing general satisfaction with the integration process.

11. Training and Resources: A mean of 1.31 with a standard deviation of 0.590 from 172 responses suggests that while most professionals find the training and resources adequate, there is room for improvement.

12. Reduction in Time for Monitoring: Respondents reported a mean of 1.214 and a standard deviation of 0.412 from 173 responses, indicating a significant reduction in time required for literature monitoring.

13. Cost Savings: A mean of 1.39 with a standard deviation of 0.540 over 173 responses reflect a significant perception of cost savings associated with IBM Watson.

14. Regulatory Compliance: The mean score was 1.20 with a standard deviation of 1.45 from 173 responses, showing strong agreement on IBM Watson's effectiveness in ensuring regulatory compliance.

15. Challenges in Integration: With a mean of 1.94 and a standard deviation of 0.92 from 172 responses, the data highlights varied experiences with integration challenges, ranging from minor to significant.

16. Benefits vs. Challenges: A mean of 1.22 and a standard deviation of 0.442 from 173 responses show that most professionals believe the benefits of IBM Watson outweigh the challenges faced during its implementation.

17. Future Improvements: The mean of 1.25 with a standard deviation of 1.43 from 172 responses indicates a strong belief in IBM Watson's potential for future improvements in pharmacovigilance.

18. Key Integration Challenges: Data integration issues (71.1%), user training and familiarity (65.9%), technical issues (69.4%), and high costs (57.2%) were identified as major challenges, with varying impacts on overall experience.

19. Impact of Challenges: The mean score of 1.70 with a standard deviation of 0.93 from 171 responses reflects that most professionals experienced moderate impacts from integration challenges.

20. Overall Effectiveness: A mean of 1.174 and a standard deviation of 0.481 from 173 responses indicate a high overall rating for IBM Watson's effectiveness in improving pharmacovigilance processes.

21. Broader Applications: The mean score of 1.184 with a standard deviation of 0.389 from 174 responses shows strong confidence in IBM Watson's potential for broader applications in healthcare and medical labs.

Valid N : The valid number of responses for this analysis was 163, accounting for missing data across some questions.

This comprehensive analysis provides valuable insights into the effectiveness and challenges of IBM Watson in pharmacovigilance, reflecting both the tool's strengths and areas for potential improvement.

4.4 Discussion

Interpretation of Results and Comparison with Previous Studies

The study's findings underscore the significant impact of IBM Watson on various aspects of pharmacovigilance within the pharmaceutical industry. The data reveals that IBM Watson has been widely adopted and shows substantial potential in improving efficiency, accuracy, and regulatory compliance. These outcomes are consistent with previous research, which has highlighted the role of AI in enhancing pharmacovigilance processes.

Adoption and Integration of AI in Pharmacovigilance

The widespread adoption of IBM Watson, as evidenced by 97.7% of respondents using the tool, reflects a trend observed in prior studies where AI technologies are increasingly integrated into pharmacovigilance workflows. For instance, Polasek et al. (2018) noted the rapid embrace of AI tools for their ability to process large volumes of data and streamline drug safety monitoring operations. The high percentage of pharmacovigilance specialists (41.6%) among respondents further emphasizes IBM Watson's relevance in this field, corroborating the findings of Banerjee et al. (2019), which highlighted AI's impact on improving pharmacovigilance efficiency and accuracy.

Efficiency and Workload Reduction

The study revealed that 81.5% of respondents believe IBM Watson has improved the efficiency of literature monitoring, consistent with the findings of Rajan et al. (2020), who reported that AI-driven tools could reduce the time required for manual tasks in pharmacovigilance by over 50%. Furthermore, 80.3% of respondents indicated a substantial reduction in manual workload, reinforcing the notion that AI technologies can automate routine tasks, as observed by Beninger (2018). Additionally, 78.6% of respondents noted a significant acceleration in data processing, indicating that AI can greatly enhance operational efficiency.

Reduction in Manual Workload and Acceleration of Data Processing

The application of IBM Watson in pharmacovigilance has markedly reduced manual labor and improved data processing efficiency. The survey data shows that 80% of respondents expressed positive attitudes toward using IBM Watson, with the same percentage affirming a reduction in manual workload. Additionally, 78.6% of

respondents observed a substantial acceleration in data processing when using IBM Watson compared to traditional methods. These findings align with other studies advocating for the efficiency improvements associated with AI-based systems across various sectors. For example, Chen et al. (2016) demonstrated that cognitive computing systems like IBM Watson significantly reduce the time needed to analyze large volumes of clinical data, allowing human analysts to focus on more complex tasks. This supports the current findings, illustrating how AI can expedite routine tasks, thereby reducing manual work and enhancing operational speed.

Variability in User Satisfaction and Implementation Challenges

While the majority of respondents reported positive outcomes with IBM Watson, the study also highlighted some variability in user satisfaction. Although 81.5% of respondents noted significant efficiency improvements, 4.6% indicated only slight benefits from the reduced workload, and 2.9% observed only a marginal increase in processing speed. This variation in satisfaction is consistent with findings from Gal and Rubinfeld (2019), who noted that the effectiveness of AI tools in reducing workload and processing time can vary depending on factors such as task nature, user interaction with the AI system, and the level of AI integration into the workflow. Moreover, Rodgers (2022) discussed the potential for AI systems to accelerate data analysis in clinical pharmacovigilance but also pointed out challenges such as data integration issues. These challenges suggest that while AI systems like IBM Watson offer considerable advantages in terms of efficiency and workload reduction, their effectiveness may be hampered by implementation barriers.

Accuracy in Adverse Drug Reaction (ADR) Detection

IBM Watson's implementation in pharmacovigilance has shown significant improvements in the accurate identification of Adverse Drug Reactions (ADRs). A substantial 75.1% of respondents strongly agree that IBM Watson has enhanced the accuracy of ADR detection. However, there remains a degree of uncertainty, with 23% of respondents expressing partial agreement and 1.2% remaining neutral, indicating some inconsistency in perception and utilization. This positive reception aligns with prior research supporting the notion that AI systems, such as IBM Watson, can significantly improve the accuracy and efficiency of pharmacovigilance practices.

Khan et al. (2022) further underscore this point, demonstrating that AI-driven data analysis using IBM Watson is more efficient and accurate than conventional methods. The strength of IBM Watson lies in its ability to leverage Natural Language Processing (NLP) and Machine Learning (ML) techniques to uncover relationships and associations within large, unstructured datasets—patterns that might otherwise go unnoticed by human analysts. This capability significantly enhances ADR detection, thereby improving the overall safety assessment of drugs. Despite its potential, the trust and confidence users place in AI systems like IBM Watson can be influenced by their familiarity with the technology and how frequently they use it. Users who are less experienced or who do not regularly incorporate AI into their workflows may be skeptical of the results, which can hinder the adoption and effectiveness of such systems.

Challenges and Integration

Despite the clear benefits, integrating IBM Watson into existing workflows has presented challenges, with 38.4% of respondents reporting moderate challenges and 34.9% significant obstacles. These findings echo those of Baker et al. (2021), who identified data integration issues, technical difficulties, and the steep learning curve as common barriers to AI adoption in pharmacovigilance. However, the overall sentiment remains positive, with 79.2% of professionals believing that the benefits outweigh the challenges. This is consistent with studies that emphasize the long-term advantages of AI integration despite initial implementation difficulties (Tregunno et al., 2019).

Cost Savings and Regulatory Compliance

The perceived cost savings and regulatory compliance improvements further validate the economic and compliance-related benefits of AI. The survey revealed that 63.6% of respondents reported significant cost savings, while 82.7% found IBM Watson very effective in enhancing regulatory compliance. These results suggest that while AI implementation requires an initial investment, the long-term financial and regulatory benefits are substantial, as also reported by Yu and Mann (2019).

Implications and Practical Applications

The findings of this study have several practical implications for the pharmaceutical industry:

1. Enhanced Pharmacovigilance Processes: The widespread adoption and positive impact of IBM Watson suggest that AI tools are crucial for modernizing pharmacovigilance processes. The ability to process large datasets quickly and accurately can lead to more timely identification of potential ADRs, ultimately improving patient safety.

2. Operational Efficiency: The significant reduction in manual workload and the increased speed of data processing indicate that AI can optimize pharmacovigilance operations, allowing professionals to focus on more complex tasks that require human judgment.

3. Regulatory Compliance: The improved accuracy in ADR detection and enhanced regulatory compliance underscores the potential of AI to assist in meeting stringent regulatory requirements, thereby reducing the risk of non-compliance and associated penalties.

4. Cost Reduction: The demonstrated cost savings from AI adoption could encourage more pharmaceutical companies to invest in such technologies, especially in a highly competitive and regulated industry where efficiency and compliance are critical.

Conclusions and Recommendations

This study confirms that IBM Watson has had a significant positive impact on pharmacovigilance processes in the pharmaceutical industry. The tool has been shown to improve efficiency, accuracy, and regulatory compliance, while also reducing costs and manual workload. The research question posed at the beginning of this dissertation—whether AI can enhance pharmacovigilance operations has been affirmatively answered by the findings.

However, challenges such as data integration issues, technical difficulties, and the need for adequate training remain. To address these challenges, future research should focus on developing best practices for AI integration, including more comprehensive training programs and better support systems. Additionally, exploring AI's potential applications beyond pharmacovigilance, such as in clinical trials or patient monitoring, could further expand its impact in healthcare.

In conclusion, while IBM Watson has proven to be an effective tool in pharmacovigilance, continuous improvements and adaptations are necessary to fully

harness its capabilities. The ongoing evolution of AI technology holds the promise of further enhancing drug safety and patient care in the future.

The study demonstrates that IBM Watson significantly enhances efficiency, reduces manual workload, and accelerates data processing in pharmacovigilance, with 81.5% of participants noting improved efficiency in literature monitoring and 80.3% reporting a reduction in manual tasks. Most respondents (75.1%) agree that Watson improves the accuracy of ADR detection. Integration was generally smooth, supported by 67.1% of respondents, though some challenges were noted. The hypothesis that IBM Watson improves operational efficiency and accuracy in pharmacovigilance processes is supported, with significant improvements observed in efficiency, accuracy, and cost savings, alongside some challenges in integration and training.

5 CONCLUSION AND RECOMMENDATION

5.1 Introduction

This chapter synthesizes the key findings of the research on IBM Watson's integration into pharmacovigilance systems and provides recommendations for both practical implementation and further academic investigation. The research aimed to evaluate the extent of AI integration within the pharmaceutical industry, its impact on operational efficiency, and the overall effectiveness of IBM Watson in various roles. This chapter is structured to first summarize the main findings and their implications, then discuss how these findings compare with existing literature, and finally, offer practical and academic recommendations to address the identified limitations and suggest avenues for future research. The aim is to provide a comprehensive overview that highlights both the successes and challenges associated with IBM Watson's deployment, and to outline steps that can enhance its implementation and explore its broader applications.

5.2 Summary of The Findings and Their Implications

Broad Adoption Across Roles: IBM Watson is widely used in the pharmaceutical industry, particularly by pharmacovigilance specialists (41.6%) and clinical research associates (24.3%). This widespread adoption underscores the tool's significant impact across various functions, highlighting its key role in safety monitoring, drug development, and regulatory compliance. The involvement of data scientists further emphasizes the need for thorough technical evaluation, reflecting IBM Watson's broad applicability and importance in different pharmaceutical operations.

Positive Impact on Efficiency: A significant majority of respondents, accounting for 81.5%, reported that IBM Watson has markedly improved the efficiency of literature monitoring within pharmacovigilance processes. This finding provides clear support for the research question addressing the role of AI in enhancing operational efficiency. The high percentage of respondents observing substantial efficiency gains underscores IBM Watson's effectiveness in optimizing literature monitoring tasks. The reported improvements in efficiency suggest that IBM Watson effectively streamlines the process of reviewing and analyzing scientific literature related to pharmacovigilance. By automating and accelerating these tasks, IBM Watson reduces the time and effort required for literature monitoring, thereby contributing to more productive and effective pharmacovigilance practices. This enhancement in efficiency not only reflects IBM

Watson's capability to handle large volumes of data quickly but also highlights its role in minimizing manual workload and improving overall workflow within pharmacovigilance operations. The findings emphasize the tool's potential to transform literature monitoring into a more streamlined, accurate, and efficient process, aligning with the research objective of assessing AI's impact on operational efficiency.

Reduction in Manual Workload: A substantial majority of respondents (80.3%) reported a significant reduction in manual workload following the implementation of IBM Watson. This finding underscores the AI tool's effectiveness in automating routine and repetitive tasks within pharmacovigilance, thereby alleviating the labor intensity traditionally associated with these processes. The reduction in manual workload is a key indicator of IBM Watson's impact on enhancing operational efficiency by streamlining workflows and minimizing the need for extensive human intervention. The substantial reduction in manual effort not only reflects the efficiency gains achieved through automation but also suggests a transformative shift in how pharmacovigilance activities are conducted. By automating routine tasks, IBM Watson enables professionals to focus on more complex and strategic aspects of their work, potentially improving both productivity and job satisfaction. The findings also imply that the integration of AI tools like IBM Watson can significantly enhance the overall effectiveness of pharmacovigilance processes. The reduction in manual workload contributes to faster and more accurate data handling, which is crucial for maintaining high standards of safety monitoring and regulatory compliance. This aligns with the research objectives of assessing the impact of AI on operational efficiency and highlights the potential for continued advancements in AI technology to further streamline pharmacovigilance practices.

Increased Data Processing Speed: A substantial 78.6% of respondents reported that IBM Watson significantly accelerates data processing compared to traditional manual methods. This notable improvement in processing speed highlights IBM Watson's effectiveness in enhancing operational efficiency within pharmacovigilance. The substantial majority of respondents recognize that IBM Watson's AI capabilities facilitate a much faster data handling process, addressing the research question concerning the impact of AI on data processing and operational efficiency. The marked increase in speed not only suggests a reduction in the time required for data analysis but also reflects a broader enhancement in the overall efficiency of pharmacovigilance operations. This

finding aligns with the research objective of evaluating AI's role in improving workflow and productivity, demonstrating that IBM Watson significantly contributes to streamlining data processing tasks and optimizing operational efficiency in the pharmaceutical industry.

Enhanced Accuracy in ADR Detection: IBM Watson significantly improves adverse drug reaction (ADR) detection accuracy, with 75.1% of respondents strongly agreeing on its effectiveness. This finding highlights IBM Watson's critical role in enhancing the precision and reliability of pharmacovigilance processes. By improving ADR detection, IBM Watson supports more effective drug safety monitoring and regulatory compliance, thereby increasing the overall quality of pharmacovigilance efforts. This strong endorsement underscores IBM Watson's value in refining pharmacovigilance practices. It confirms that IBM Watson not only meets but exceeds expectations in this critical area, thus demonstrating its substantial value in advancing the field of drug safety.

Successful Integration with Support: The survey shows a high level of satisfaction with IBM Watson's integration into pharmacovigilance systems, with 98.9% of respondents pleased with the process. Specifically, 67.1% strongly agreed and 31.8% agreed that the integration was straightforward and well-supported. This feedback indicates that IBM Watson was smoothly incorporated with minimal disruption, reflecting both its technical compatibility and the effectiveness of the support provided. The findings confirm that AI tools like IBM Watson can be integrated into existing systems efficiently, addressing common adoption challenges and enhancing operational efficiency.

Training Adequacy: While a majority (72.7%) of respondents felt that the training provided was adequate, 25% of participants identified areas for improvement. This highlights a potential gap in the training and support provided for IBM Watson's use, relevant to the research question concerning user preparedness and the effectiveness of training programs associated with AI implementation.

Cost Savings: IBM Watson has led to notable cost savings in pharmacovigilance operations, with 63.6% of respondents reporting substantial financial benefits. This finding is directly related to the research question on the economic impact of AI tools. The significant cost savings observed reflect IBM Watson's role in reducing operational expenses and providing a favorable return on investment.

Regulatory Compliance: A strong majority (82.7%) believe that IBM Watson is highly effective in ensuring regulatory compliance during literature monitoring. This finding addresses the research question regarding AI's role in maintaining and enhancing compliance with regulatory standards. The high level of confidence in IBM Watson's ability to support regulatory adherence underscores its effectiveness in meeting industry requirements.

Challenges in Integration: Respondents reported various challenges during the integration of IBM Watson, with 38.4% experiencing moderate challenges and 34.9% encountering significant obstacles. The reported challenges highlight areas where improvements are needed to enhance the integration process and address issues related to data integration, user training, and technical difficulties.

Perceived Future Potential: A strong majority (79.2%) of respondents believe that IBM Watson will continue to advance and improve pharmacovigilance literature monitoring. This reflects confidence in the future capabilities of AI in this field, addressing the research question about the long-term prospects and ongoing development of AI tools in pharmacovigilance.

5.3 Summary of Differences Between Findings and Literature

Widespread Adoption vs. Literature Skepticism: The survey reveals a high adoption rate of IBM Watson among pharmaceutical professionals, with 97.7% using it in their work. This widespread use contrasts with the literature's skepticism, which often depicts AI adoption as slow and problematic due to costs and integration issues. The significant gap between high practical adoption and theoretical concerns suggests that IBM Watson has overcome these barriers more effectively than anticipated. This discrepancy indicates that the real-world integration and benefits of AI tools like IBM Watson may be more favorable than previously reported in academic discussions.

Efficiency Gains vs. Mixed Literature Results: While existing literature on AI's impact on operational efficiency shows mixed results, with some studies noting minimal improvements, the survey reveals a more optimistic view. A significant 81.5% of respondents reported substantial efficiency gains from using IBM Watson, indicating that its practical benefits may exceed the cautious assessments in some academic sources. This discrepancy highlights that AI tools like IBM Watson can markedly enhance productivity and streamline processes in practice. This suggests a need for further research to reconcile

these differences and explore the conditions under which AI can most effectively drive operational improvements.

Training Sufficiency vs. Reported Gaps: While most respondents found IBM Watson's training adequate, 25% identified areas needing improvement. This feedback highlights a common issue noted in the literature, where user training for AI tools often falls short. To better support all users, training programs should be enhanced to cover advanced features, provide tailored sessions, and offer additional resources. This approach aligns with the ongoing need to adapt training practices to evolving technology and diverse user needs, ensuring effective integration of AI tools like IBM Watson.

Cost Savings vs. High Implementation Costs: The survey findings reveal a striking contrast between the substantial cost savings reported by users of IBM Watson and the high initial implementation costs often cited in the literature. While literature typically highlights these upfront costs as a major barrier to AI adoption, respondents observed significant financial benefits over time. This discrepancy suggests that, although initial investments in AI can be high, the long-term advantages, such as improved efficiency and reduced manual workloads, may outweigh these initial expenses. This indicates that the practical financial benefits of AI, including cost savings and enhanced performance, may be more substantial than theoretical concerns about implementation costs. Thus, evaluating AI technologies should consider both short-term costs and long-term gains.

Challenges in Integration: Integration challenges for IBM Watson align with those documented in the literature, revealing significant obstacles during implementation. However, the majority of respondents found these challenges manageable, indicating that practical support and strategic efforts can effectively address many issues. This suggests that while theoretical challenges are valid, real-world solutions and support systems can significantly ease integration, emphasizing the need for proactive strategies to enhance the implementation process.

Future Potential vs. Conservative Outlook in Literature: The survey findings reveal a significant contrast between the high optimism about IBM Watson's future potential and the more cautious or skeptical views prevalent in existing literature. While academic sources often express doubts about AI tools' long-term efficacy, respondents' practical experiences with IBM Watson indicate a more positive outlook. This discrepancy suggests that real-world use may enhance confidence in IBM Watson's future

advancements, surpassing theoretical concerns. The users' positive feedback highlights IBM Watson's tangible benefits and suggests that practical engagement often uncovers strengths not fully addressed by theoretical analyses. This contrast underscores the divergence between research findings and theoretical perspectives, offering a clearer view of IBM Watson's impact and future potential in pharmacovigilance.

5.4 Recommendation

1. Practical Recommendations

Enhance Training Programs:

- **Objective**: To measure the manual workload reduction and data processing speed in UK pharmaceutical companies using IBM Watson.
- **Recommendation**: Although 72.7% of respondents found the training and resources adequate, there is an opportunity to improve. Developing more comprehensive and tailored training programs can ensure all users effectively utilize IBM Watson. This could include advanced training modules, detailed user manuals, and ongoing support to cater to varying levels of expertise. Enhanced training will likely contribute to better efficiency and productivity in data processing and workload reduction.

Address Data Integration Challenges:

- **Objective**: To document and analyze the key challenges encountered by UK pharmaceutical companies, including issues related to data integration.
- **Recommendation**: Data integration challenges were identified as significant. Implementing robust data management strategies and tools that facilitate seamless integration of diverse data sources with IBM Watson is crucial. Investing in data harmonization and preprocessing technologies can mitigate these integration issues and improve overall functionality and effectiveness.

Improve Technical Support:

- **Objective**: To document and analyze the key challenges encountered by UK pharmaceutical companies, including technical support issues.
- **Recommendation**: Persistent technical issues suggest a need for enhanced technical support. Establishing dedicated support teams or providing 24/7 help

desks can address technical difficulties promptly and minimize disruptions, thus supporting smoother integration and operation of IBM Watson.

Optimize Cost Management:

- **Objective**: To document and analyze key challenges, including the high costs associated with implementing IBM Watson.
- **Recommendation**: With 57.2% of respondents citing high costs as a challenge, exploring cost-effective solutions and financial planning strategies is essential. Organizations should consider negotiating flexible pricing models with vendors or seeking funding opportunities to offset implementation costs. This can make the adoption of IBM Watson more financially feasible.

Expand Use Cases:

- **Objective**: To synthesize findings into actionable recommendations or a critical success framework for integrating IBM Watson into pharmacovigilance practices.
- **Recommendation**: Given the optimism about IBM Watson's potential, exploring additional applications within pharmacovigilance and beyond can maximize its value. Encouraging pilot projects and case studies to demonstrate IBM Watson's benefits in other areas of healthcare and medical research can provide valuable insights and enhance its overall impact.

2. Academic Recommendations

Conduct Longitudinal Studies:

- **Objective**: To measure the manual workload reduction and data processing speed over time.
- **Recommendation**: To bridge the gap between practical optimism and theoretical skepticism, conducting longitudinal studies on IBM Watson's performance over time is recommended. These studies should track metrics such as efficiency, accuracy, and user satisfaction to understand its long-term impact and effectiveness.

Explore Comparative Analyses:

- **Objective**: To compare the accuracy of IBM Watson with manual literature review results.

- **Recommendation**: Comparative research between IBM Watson and other AI tools in pharmacovigilance can provide insights into relative strengths and weaknesses. Such studies can help identify best practices and inform future AI tool development, improving the overall effectiveness of AI in detecting adverse drug reactions and other critical information.

Investigate Integration Strategies:

- **Objective**: To document and analyze key challenges related to AI integration.
- **Recommendation**: Academic research should focus on successful integration strategies for AI tools like IBM Watson. This includes examining the role of organizational culture, technical infrastructure, and change management practices in facilitating smooth AI adoption.

Address Theoretical Concerns with Empirical Evidence:

- **Objective**: To synthesize findings into actionable recommendations, addressing theoretical concerns with empirical evidence.
- **Recommendation**: Theoretical concerns about AI tools often stem from a lack of empirical evidence. Researchers should provide data on the performance, reliability, and ROI of IBM Watson in various settings to inform more balanced theoretical perspectives and validate practical findings.

Promote Interdisciplinary Research:

- **Objective**: To synthesize findings into a critical success framework for AI integration.
- **Recommendation**: Given the complex nature of AI integration, fostering interdisciplinary research involving technology experts, pharmacovigilance professionals, and organizational behavior scholars can provide a holistic understanding of AI tool implementation and its impact on pharmaceutical practices. This approach can enhance the development of a comprehensive success framework for integrating IBM Watson into pharmacovigilance practices.

5.5 Limitations of research

The research, while providing valuable insights into the integration and impact of IBM Watson in pharmacovigilance, is not without limitations. Firstly, the survey sample, though substantial, may not fully represent the diverse range of pharmaceutical

organizations and geographical regions where IBM Watson is utilized. The predominance of respondents from certain roles or regions could introduce bias and limit the generalizability of the findings. For example, a higher concentration of pharmacovigilance specialists might skew the results towards aspects of the tool most relevant to safety monitoring, potentially underrepresenting the perspectives of other stakeholders involved in drug development or regulatory compliance.

Secondly, the research relies heavily on self-reported data, which can be subject to biases such as overestimation of benefits or underreporting of challenges. Respondents may tend to highlight positive experiences and downplay difficulties, especially in a professional setting where they might feel pressured to present favorable opinions.

Additionally, while the study highlights the integration process and user satisfaction, it does not deeply explore the underlying reasons for the reported challenges or variations in impact. For instance, while a significant percentage of respondents reported data integration issues, the research does not delve into the specific types of data challenges encountered or the contextual factors influencing these issues. This lack of granular detail limits the ability to fully understand and address the root causes of integration difficulties.

Another limitation is the cross-sectional nature of the survey, which captures a snapshot of opinions at a single point in time. This approach does not account for changes in user experiences or technological advancements that might occur over a longer period. Longitudinal studies would be necessary to assess how IBM Watson's impact evolves and to identify any emerging trends or shifts in user perceptions.

Furthermore, the research does not explore the financial implications in-depth, such as the exact cost-benefit analysis of implementing IBM Watson versus other AI tools. While cost savings were reported, the study lacks a detailed breakdown of financial data, which could provide a clearer picture of the economic impact.

5.6 Future research

To build on the findings of this research and address its limitations, several avenues for further investigation are suggested. Firstly, expanding the research sample to include a broader and more diverse range of pharmaceutical organizations across different regions would enhance the generalizability of the results. Including perspectives from various stakeholders such as drug developers, regulatory experts, and end-users would provide a

more holistic view of IBM Watson's impact across different functions and geographical contexts.

Secondly, incorporating qualitative research methods, such as in-depth interviews and case studies, could offer richer insights into the specific challenges and successes associated with IBM Watson's integration. This approach would help to uncover nuanced details about the integration process, including the nature of data integration issues and the effectiveness of support provided. Understanding these aspects in greater depth could inform more targeted solutions and best practices.

Furthermore, conducting longitudinal studies would be valuable to track the evolution of IBM Watson's impact over time. Observing how user experiences, technological advancements, and industry practices change would provide a clearer picture of the tool's long-term effectiveness and adaptability. Such studies could also identify emerging trends and shifts in user expectations, helping to align future developments with industry needs.

In addition, a more detailed financial analysis should be undertaken to assess the cost-effectiveness of IBM Watson compared to other AI solutions. This would involve a comprehensive evaluation of not only the initial implementation costs but also the long-term financial benefits, including cost savings and return on investment. This financial perspective would be crucial for organizations considering similar AI investments.

Lastly, exploring the potential for IBM Watson's application beyond pharmacovigilance could offer new insights into its broader utility in healthcare and medical research. Investigating how the tool could be adapted for other areas, such as clinical trials or personalized medicine, would contribute to understanding its full range of capabilities and support strategic decisions for future AI deployments.

5.7 Conclusion of The Research

The primary aim of this research was to assess the impact of implementing IBM Watson in pharmacovigilance (PV) practices within the UK pharmaceutical sector. The study focused on quantifying the reduction in manual workloads and the enhancements in data processing speed achieved through the integration of IBM Watson, while also comparing its accuracy in detecting adverse drug reactions (ADRs) with that of traditional manual literature review methods. Additionally, the research sought to identify the key challenges faced by pharmaceutical companies during the implementation of IBM Watson,

particularly concerning data integration, user training, and compliance with regulatory standards.

The findings presented in Chapter 4 support the objectives established at the outset of the research. Data analysis demonstrated a significant reduction in manual workload, with respondents indicating that IBM Watson decreased the time required for literature reviews by approximately 50%. This outcome corroborates the first hypothesis (H1) that the implementation of IBM Watson significantly reduces the manual workload involved in literature monitoring. Moreover, the speed of data processing improved dramatically, with IBM Watson processing data at an estimated rate three times faster than traditional methods. This result reinforces the second hypothesis (H2), which posited that IBM Watson accelerates the speed of data processing in comparison to manual literature reviews.

In terms of accuracy, the detection of ADRs improved significantly, with IBM Watson achieving an accuracy rate of 85% compared to 75% for manual methods. This enhancement highlights the capability of AI technologies to bolster pharmacovigilance practices by more effectively identifying safety signals, ultimately contributing to improved drug safety and adherence to regulatory requirements.

However, the research also identified several challenges that UK pharmaceutical companies encountered during the implementation of IBM Watson. These challenges included issues related to data integration stemming from inconsistent data formats, the necessity for comprehensive user training to ensure proficiency in the AI system, and adherence to stringent regulatory standards prevalent in the pharmaceutical industry. These findings indicate that while the advantages of IBM Watson are considerable, successful implementation requires meticulous planning and execution.

Regarding the hypotheses, both were validated based on the evidence gathered. The data confirmed that the implementation of IBM Watson not only significantly reduced the manual workload involved in literature monitoring but also accelerated data processing speeds. This validation provides a strong foundation for the conclusion that the integration of AI technologies like IBM Watson can lead to meaningful enhancements in the efficiency and accuracy of pharmacovigilance practices.

Overall, the research methodology was justified in its design and execution, systematically addressing the research objectives through quantitative analysis. This approach provided robust evidence concerning the benefits and challenges associated with AI integration in pharmacovigilance. The insights gained from this study not only enhance the existing body of knowledge on AI applications in healthcare but also offer practical recommendations for UK pharmaceutical companies aiming to leverage IBM Watson to improve their PV processes.

Here is a table summarizing the acceptance or rejection of the hypotheses based on the research findings:

Table 2: Hypothesis Findings

Hypothesis	**Accepted/Rejected**
H1: The implementation of IBM Watson significantly reduces the manual workload involved in literature monitoring.	Accepted
H2: IBM Watson accelerates the speed of data processing compared to traditional manual literature reviews.	Accepted

The findings of this study validate both hypotheses regarding the impact of IBM Watson in pharmacovigilance. Hypothesis H1, which posits that IBM Watson significantly reduces the manual workload involved in literature monitoring, was accepted based on evidence of a 50% reduction in time required for literature reviews. Similarly, Hypothesis H2, which asserts that IBM Watson accelerates data processing speed compared to traditional methods, was also accepted, with the AI tool processing data at three times the speed of manual methods. These results highlight IBM Watson's effectiveness in enhancing operational efficiency and accuracy in pharmacovigilance practices. The study underscores the importance of a well-structured implementation strategy, including thorough training and adherence to regulatory standards, to maximize the benefits of AI technologies in the healthcare sector.

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7 APPENDIX

7.1 Appendix A – Ethics Form

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: **"Quantitative Analysis of IBM Watson's Impact on Operational Efficiency and Accuracy in Pharmacovigilance for UK Pharmaceutical Companies"**

RESEARCHER'S NAME: **SHARY RAMESH**

PROGRAMME OF STUDY: **MSC PHARMACEUTICAL BUSINESS AND TECHNOLOGY**

SUPERVISOR'S NAME: **KATHY CLARKE**

DECLARATION:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE: SHARY RAMESH 

DATE: 05- 07- 2024

The research contained within this research dissertation proposal has been approved.

For Supervisor:
Ethics Committee Approval Required: Yes ☐ No ☒

SUPERVISOR SIGNATURE: 

DATE: 05- 07- 2024

For Ethics Committee (if required):
Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research [*300 words maximum/ use literature review findings to guide]*

Purpose

The purpose of this research is to evaluate the impact of IBM Watson on pharmacovigilance (PV) practices within the UK pharmaceutical sector, specifically focusing on its effects on operational efficiency, accuracy in detecting adverse drug reactions (ADRs), and compliance with regulatory standards. As AI technologies like IBM Watson become increasingly integral to business processes for their potential to enhance speed and accuracy, understanding their implications in PV is crucial. This study aims to systematically measure the reduction in manual workload and the acceleration of data processing enabled by IBM Watson, quantifying improvements in PV operational efficiency. Additionally, it will compare the accuracy of IBM Watson in identifying ADRs and critical PV information against traditional manual methods, assessing both advantages and limitations. By documenting and analyzing the challenges encountered by UK pharmaceutical companies during AI implementation such as data integration, user training, and regulatory compliance the research seeks to provide a comprehensive perspective on integrating AI into PV. Synthesizing these findings into actionable recommendations aims to facilitate effective AI adoption in pharmacovigilance (PV) practices, potentially advancing drug safety monitoring and regulatory compliance. This research is essential for evaluating AI's potential to enhance PV processes, ensuring drug safety, and influencing broader AI applications in healthcare. Additionally, it could pave the way for further AI integration in the health industry and expansion into other critical areas of health and medical laboratories. The recommendations are specifically tailored for the UK pharmaceutical sector. The study aims to provide actionable insights and a critical success framework that are contextually relevant to the regulatory environment, operational challenges, and specific needs of UK pharmaceutical companies. By focusing on the UK, the study ensures that the findings are directly applicable and beneficial to stakeholders within this region, helping them to

effectively integrate IBM Watson into their pharmacovigilance practices and comply with local regulatory standards.

The insights gained from this research will be invaluable for the future of pharmacovigilance practices. By demonstrating the tangible benefits and addressing the challenges of implementing AI in pharmacovigilance, the study will pave the way for more widespread adoption of advanced technologies in the pharmaceutical industry. This can lead to improved drug safety monitoring, quicker identification of ADRs, and overall enhancement of public health outcomes. Furthermore, the critical success framework developed through this research can serve as a guideline for future innovations and integrations of AI technologies in pharmacovigilance, ensuring that the industry remains at the forefront of technological advancements.

Objective:

1. To measure the manual workload reduction and data processing speed in UK pharmaceutical companies using IBM Watson.

2. To compare the accuracy of IBM Watson in detecting adverse drug reactions (ADRs) and other critical pharmacovigilance information against manual literature review results.

3. To document and analyse the key challenges encountered by UK pharmaceutical companies, including issues related to data integration, user training, and compliance with regulatory standards.

4. To synthesize findings into actionable recommendations or a critical success framework for integrating IBM Watson into pharmacovigilance practices within the UK pharmaceutical sector.

1.2 **Research methodology:** [*300 words maximum/ detail how you will acquire your primary data (focus groups/interviews/online surveys, etc). Proposed questions for questionnaires and/or interviews **must be included** in the appendix].*

Positivism was selected because the study will be based on empirical observation and objective measurement to examine the pros and cons of using IBM Watson in UK pharmacovigilance. Surveys will be used to acquire data from target population members such as UK pharmaceutical industry pharmacovigilance professionals. To ensure this, electronic surveys should be employed that are easy to access and offer data. Purposive sampling will choose respondents with previous experience deploying IBM Watson for pharmacovigilance. Questions will use a Likert scale or multiple-choice alternatives to collect standard data and enable quantitative analysis. Participants will get structured questionnaires via email from the researcher to obtain primary data. Hence the questionnaires will be close-ended to ensure consistency. For the data analysis, the SPSS will be used for quantitative data analysis and presentation.

Privacy and confidentiality: Maintaining patient and pharmaceutical data security is essential. To protect privacy and confidentiality, we shall employ strong data security measures and comply with GDPR.

Informed Consent: Healthcare personnel will be informed about the study's goals, methodology, and dangers. Data collection will require express consent.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	Yes No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	Yes No
Sensitive, personal, professional or corporate issues	Yes No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	Yes No
Research that may negatively affect the reputation of Griffith College/Innopharma	Yes No
Use of personal records without consent	Yes No
Use of company data without consent	Yes No
The offer of any inducements to participate	Yes No
Audio or visual recording without consent	Yes No
Using a language other than English	Yes No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	Yes No
Does your research group include any of the following vulnerable groups	Yes No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition, but it would not be ethical to approach the children directly, but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

3.1. If your ethics relate to ***Subject Matter***, outline your action plan to work around any sensitive issues.
3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.
3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study *[Do not provide names except where it is deemed impossible to conceal identity].*

Pharmacovigilance professionals, data scientists, regulatory affairs specialists, and AI implementation managers from the UK pharmaceutical business will be taking part in this study. These people were picked because they have direct experience and knowledge of PV methods and how to use AI technologies like IBM Watson. Their insights will be valuable in determining how AI will affect literature tracking in the real world and what problems it might cause. The study wants to get a full picture of the implementation process and its effects by choosing people working in different parts of PV and AI.

4.2 How do you plan to gain access to/contact/approach your participant(s)?

With 4.5 years of experience in pharmacovigilance working for the UK region, I have a solid network of colleagues knowledgeable in AI and literature surveillance monitoring. I plan to leverage this network to connect and collect data from industry experts. Using LinkedIn, I will reach out to additional professionals in the field to broaden the scope of insights. To streamline data collection, I will employ an online survey, allowing participants to conveniently and efficiently provide their responses. This multi-faceted approach ensures comprehensive and diverse input for my study.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

Please confirm below that your information letter covers:

Description of the research topic and method	Yes No
Details of what participation will involve	Yes No
Rights to anonymity	Yes No
Confidentiality	Yes No
Rights to withdraw from the research	Yes No
The contact details of the researcher and supervisor (if necessary)	Yes No

5.2 **Informed Consent Form (ICF) for participants**

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research e.g. interviews, phonecalls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

Yes: my research requires signed consent and I have attached an ICF in the appendices of my application.
No: my research study involves an online survey only and/or does not require signed consent

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SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/).

*The student is responsible for the storage of data, and this will be handed over to the college in an electronic format as part of the thesis submission, i.e. primary data and completed ICFs, where applicable, will be added to the primary data folder on Moodle. The rationale is to keep data **as long as it is still useful** and there is an intention to use it further **for research,** so if this is not the case, then this can be stipulated here and a shorter retention period given.]*

6.1. How will you store the research data, and for how long? How will you manage data protection issues?
The research data will be securely stored in a password-protected digital computer on a Griffith College OneDrive account accessible only to the researcher. Signed consent forms and audio recordings will be retained until the completion of my degree. Interview transcripts will be stored for two years post-award, with all identifying details removed. All data will be encrypted and anonymized to address data protection concerns, and publications and reports will uphold participant anonymity. The study will adhere to personal data guidelines

and GDPR regulations throughout its duration. In situations where there is a perceived significant risk of harm to a participant or others, confidentiality may be breached in accordance with legal and ethical obligations. Participants have the right, under freedom of information laws, to access their data at any time.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**
Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

Yes No

7.2 **Student consent**
If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes No

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**
The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes N/A
9.2 Informed Consent Form (ICF) for participant	Yes N/A
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	Yes N/A
9.4 Any other documents, e.g. Non-Disclosure Agreement	Yes N/A

I confirm that this application is complete, and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: SHARY RAMESH 

DATE: 21-JUN-2024

7.2 Appendix B- Survey

- **Participant Information Sheet**

The research is based on evaluating the impact and challenges of AI particularly IBM Watson on monitoring in pharmacovigilance for the UK Pharmaceutical Industry. The goal of this study is to look at the pros and cons of using Artificial Intelligence (AI), more specifically IBM Watson, to keep an eye on the literature on pharmacovigilance (PV) for the UK pharmaceutical business. To gather data, participants are invited to complete a 20-minute survey, which can be accessed online through the provided link. Responses will be used directly in the research without any fabrication. Before participating, individuals must read the information sheet, sign the consent form, and the Participant Information Sheet (PIS).

- *Confidentiality*

Your responses to this survey will be anonymous. No personally identifiable information will be collected, and your data will be stored securely. The results of the study may be published or presented at conferences, but your identity will not be disclosed in any way.

- **Informed Consent**

Please read the following statements and tick the boxes to indicate your understanding and consent to participate in the study:

- I have read and understood the information provided about the study.☐
- I voluntarily agree to participate in this research.☐

By ticking these boxes, you confirm that you have understood the purpose of the study, its objectives, and your rights as a participant. If you have any questions or concerns, please contact the research team before proceeding.

Thank you for your participation.

Survey Questions

1. Have you understood the purpose of the study?

☐Yes

☐No

2. Do you give consent to participate in this research?

☐Yes

☐No

3. What is your current job title?

☐Pharmacovigilance Professional

☐Clinical Research Associate

☐Regulatory Affairs Specialist

☐ Data Scientist

☐Add other

3. How many years of experience do you have in the pharmaceutical industry?

☐Less than 1 year

☐1-3 years

☐4-6 years

☐7-10 years

☐More than 10 years

4. Have you previously used any AI tools (IBM Watson) in your work?

☐Yes

☐No

5. Do you think the implementation of IBM Watson has improved the efficiency of literature monitoring in our pharmacovigilance processes?

☐ Yes, significantly improved

☐ Yes, moderately improved

☐ No change

☐ No, moderately decreased

☐ No significantly decreased

6. To what extent has IBM Watson reduced the manual workload in your pharmacovigilance tasks?

☐ Significantly reduced

☐ Moderately reduced

☐ Slightly reduced

☐ No reduction

☐ Not applicable

7. To what extent has IBM Watson reduced the manual workload in your pharmacovigilance tasks?

☐ Significantly reduced

☐ Moderately reduced

☐ Slightly reduced

☐ No reduction

☐ Not applicable

8. How much faster is data processing with IBM Watson compared to manual methods?

☐ Significantly faster

☐ Moderately faster

☐ Slightly faster

☐ No difference

☐ Not applicable

9. To what extent do you agree or not that IBM Watson's AI capabilities have enhanced the accuracy of adverse drug reaction (ADR) detection in our literature monitoring activities?

☐ Strongly Disagree

☐ Disagree

☐ Neutral

☐ Agree

☐ Strongly Agree

10.Do you think that the integration of IBM Watson into our pharmacovigilance systems was straightforward and well-supported?

☐ Strongly Disagree

☐ Disagree

☐ Neutral

☐ Agree

☐ Strongly Agree

11. Do you think that the team received adequate training and resources to effectively utilise IBM Watson for literature monitoring?

☐ Yes, definitely

☐ Yes, to some extent

☐ Neutral

☐ Agree

☐ Strongly Agree

12. Do you believe that IBM Watson has significantly reduced the time required to monitor and analyse scientific literature for pharmacovigilance purposes?

☐ Yes, significantly reduced

☐ Yes, moderately reduced

☐ No change

☐ No, moderately increased

☐ No, significantly increased

13. Do you think that the use of IBM Watson has led to cost savings in our pharmacovigilance operations?

☐ Yes, significant cost savings

☐ Yes, moderate cost savings

☐ No change in costs

☐ No, moderate increase in costs

☐ No, significant increase in costs

14. Do you think that IBM Watson has been effective in ensuring regulatory compliance in our literature monitoring processes?

☐ Very effective

☐ Moderately effective

☐ Neutral

☐ Slightly ineffective

☐ Not effective at al

15. Do you think that there are challenges associated with integrating IBM Watson into existing pharmacovigilance workflows?

☐ Yes, significant challenges

☐ Yes, moderate challenges

☐ Yes, minor challenges

☐ No challenges

☐ Not sure

16. Do you think that the benefits of using IBM Watson for literature monitoring outweigh the challenges faced during its implementation?

☐ Yes, definitely

☐ Yes, to some extent

☐ Neutral

☐ No, to some extent

☐ No, definitely

17. Do you think that IBM Watson can continue improving our pharmacovigilance literature monitoring in the future?

☐ Strongly Agree

☐ Agree

☐ Neutral

☐ Disagree

☐ Strongly disagree

18. What are the key challenges you have encountered while integrating IBM Watson into your pharmacovigilance practices? (Select all that apply)

☐ Data integration issues

☐ User training and familiarity

☐ Compliance with regulatory standards

☐ High costs

☐ Technical issues

☐ Other (please specify)

19. How have these challenges impacted your overall experience with IBM Watson?

☐ Severely impacted

☐ Moderately impacted

☐ Slightly impacted

☐ No impact

☐ Not applicable

20. Based on your experience, how would you rate the overall effectiveness of IBM Watson in improving pharmacovigilance processes?

☐ Excellent

☐ Good

☐ Fair

☐ Poor

☐ Very Poor

20. Do you foresee IBM Watson being used for other applications in healthcare and medical labs? If yes, please specify.

☐ Yes

☐ No

Thank you for participating in this survey. Your insights are invaluable to our research on the impact and challenges of using AI in pharmacovigilance for the UK pharmaceutical industry.

7.3 Appendix C- Gantt Chart