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“The applications of AI (Machine learning & RPA) Phase III Clinical trials in India”

Qualification: MSc in Pharmaceutical Business and technology

Institute: INNOPHARMA/Griffith College Dublin

UNDER THE GUIDANCE OF
Dr. Sue Mulhall
Assistant Professor at Griffith College Dublin, Ireland

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Year: Sep 2022-Sep 2023

DECLARATION BY THE CANDIDATE

This is to state that the work embodied in this thesis titled "**The Application of AI (Machine Learning & RPA) Phase III Clinical Trials in India**" forms our own contribution to the research work carried out under the guidance of Dr. Sue Mulhall, Assistant Professor in Griffith College Dublin**.** This work has not been submitted for any degree for this University or any other University. Whenever references have been made to previous work of others it has been clearly indicated as such and included in the Bibliography.

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Lists of Tables

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List of abbreviations

AI- Artificial Intelligence

ML- Machine learning

RPA- Robotic Process Automation

CT- Clinical trials

DDI- Drug-Drug Interaction

DL- Deep Learning

NLP- Natural Language Processing

OCR- Optical Character Recognition

RWE- Real-World Evidence

EHR- Electronic health record

EMR- Electronic medical record

EDC- Electronic Data Capture

RMP- Risk Management Plan

Q/A- Question answers

CROs- Clinical research organizations

CRMs- Clinical research managers

CDT- Clinical research management

SPSS- Statistical package for the social sciences

IBM- International business machines

PC- Personal computer

GDPR- General data protection regulation

KPIs- Key performance indicators

PIL- Participant information letter

CDM- Clinical data manager

ABSTRACT:

Rapid developments in machine learning (ML) and robotic process automation (RPA), both aspects of Artificial intelligence (AI), have resulted in a major change in several sectors, including the pharmaceutical and healthcare industries. After receiving regulatory permission and being made available on the market, phase III clinical studies are essential for assessing the safety, effectiveness, and side effects of new drugs and medical treatments. To improve their efficiency and effectiveness, however, these experiments frequently need a lot of time and money and are at risk of human error.

This research makes valuable contributions by filling the highlighted research gap through a thorough examination of the viability, challenges, and benefits associated with the implementation of artificial intelligence (AI), machine learning (ML), and robotic process automation (RPA) technologies in Phase III Clinical Trials. By conducting a comprehensive analysis of academic work, relevant approaches, and practical instances, this study highlights the inherent capabilities of these technologies in enhancing functional efficacy, data accuracy, and well-informed decision-making processes within the field of clinical trials.

The integration of different aspects of the research is facilitated by the identification of a research gap and a thorough examination of the existing literature. The research aims aim to evaluate the suitability of artificial intelligence (AI), machine learning (ML), and robotic process automation (RPA) in Phase III Clinical Trials within the India. The research enquiries aim to explore and identify the difficulties that exist and viable solutions to address them. The research technique combines qualitative interviews with key stakeholders and quantitative analysis of historical trial data.

The findings highlight the positive effects of combining AI, ML, and RPA, focusing improved patient enrolment, improved monitoring practices, and more trustworthy data analysis. The analysis of these data situates the outcomes within the distinct framework of clinical trials conducted in India, taking into consideration the regulatory, cultural, and technological complications that are relevant to the area.

The main goal of this research is to provide detailed information on the implementation of artificial intelligence (AI), machine learning (ML), and robotic process automation (RPA) in Phase III Clinical Trials conducted in India. It offers practical suggestions for key stakeholders such as pharmaceutical companies, regulatory agencies, and researchers, empowering them to effectively adopt and leverage new technological breakthroughs.

In conclusion, this study offers important new information about the possible influence of AI (ML & RPA) in Phase III clinical trials in India. Stakeholders in the pharmaceutical sector, researchers, and regulatory agencies can make well-informed judgments on the use of these technologies by considering the advantages and limitations of AI adoption. To ensure the successful incorporation of AI in the effort of increased clinical research quality in India, the study also highlights the significance of addressing ethical concerns and embracing technical breakthroughs.

Chapter 1: Introduction

This research initiative aims to examine the application of AI, specifically machine learning and robotic process automation, in India's phase III clinical trials. This chapter includes the title and explanation how AI is helping in phase III clinical trials in India and about the emerging technologies and their use specifically about Machine learning (ML) & Robotic process automation (RPA). In recent years, a rapid increase in AI has resulted in innovative changes in many different sectors, including healthcare. According to developments of AI, machine learning and robotic process automation indicate huge opportunities for enhancing efficiency, accuracy, and decision-making processes. By applying these technologies, it is planned that the clinical trial process can be improved, resulting in the development and approval of safe and effective treatments developing with greater speed. Finally, the implementation of AI in clinical trials has the potential to benefit both researchers and patients.

Title: The Application of AI (Machine Learning & Robotic process automation) Phase III Clinical Trials in India

Hypothesis: The use of AI (Machine Learning & robotic process automation) in Phase III Clinical Trials in India will improve trial efficiency, accuracy, and efficacy, resulting in better patient outcomes and faster treatment.

This hypothesis proposes that using AI (Machine Learning & robotic process automation) technology in Phase III clinical trials in India will have an advantageous effect on several parts of the trial procedure. It indicates that using AI algorithms and models for data analysis, patient recruitment, adverse event monitoring, treatment response prediction, and overall trial management will result in better outcomes.

Modules the topic is linked to:

- Clinical research management (CRM)
- 21st-century dynamics in emerging trends (CDET)

Overall Aim:

The primary objective of this research is to evaluate the possibility and effectiveness of applying AI, more especially machine learning and robotic process automation (RPA), in phase III clinical trials in India. The specific areas of focus for this research are located in India. The results of the study will be beneficial to researchers as well as pharmaceutical companies, regulatory

authorities, and healthcare professionals who are involved in the design, administration, and monitoring of clinical trials. The aim is to give scientific advice and guidelines for harnessing AI technology to improve clinical trial procedures, which will lead to greater efficiency, lower costs, and enhanced patient outcomes

1.1 Background:

The goal of this research is to give people an understanding of the background and circumstances surrounding the use of AI, machine learning, and RPA in phase III clinical trials in India. It makes a contribution to the academic field by analyzing the history, current trends, and difficulties surrounding the topic. It also highlights the necessity and significance of looking into the use of AI technologies in the particular in India.

Phase III clinical trials are essential for evaluating the safety, efficacy, and adverse effects of new pharmaceuticals and medical treatments. Before regulatory approval and market release, these trials involve a lot of research on human subjects and are considered an important phase. Still, standard phase III clinical trial procedures are usually time-consuming, costly in terms of resources, and highly susceptible to human error. The need for new approaches to speed up and improve the clinical trial process is becoming more evident. The implementation of AI, specifically machine learning and RPA, has the potential to solve these obstacles and revolutionize clinical trials.

In India, phase III clinical trials involve using AI, machine learning, and RPA to enhance efficiency, accuracy, and cost-effectiveness. These technologies automate repeated tasks and reduce human error, to the advantage of pharmaceutical industry stakeholders. This study investigates the use of AI, machine learning, and RPA in phase III trials in India, providing pharmaceutical companies, researchers, and regulatory agencies with information on the benefits and limitations of implementing these technologies for improved clinical research quality.

Justification for the research:

The purpose of this research is to investigate the potential applications of AI in phase III clinical trials in India. The selection of this topic was influenced because of a need for solving existing obstacles and problems in clinical trial procedures. This research aims to fill the knowledge gap regarding the benefits and limitations of applying AI in clinical trial procedures by investigating how to make use of AI technologies. Also, as India is a center for clinical research and has a large patient population, it is essential to understand the implications, opportunities, and challenges of implementing AI in th healthcare centre of India.

Purpose & Aim:

The primary objective of this research is to evaluate the possibility and effectiveness of applying AI, more especially machine learning and robotic process automation, in phase III clinical trials in India. The specific areas of focus for this research are located in India. The results of the study will be beneficial to researchers as well as pharmaceutical companies, regulatory authorities, and healthcare professionals who are involved in the design, administration, and monitoring of clinical trials. The aim is to give scientific advice and guidelines for harnessing AI technology to improve clinical trial procedures, which will lead to greater efficiency, lower costs, and enhanced patient outcomes.

1.2 Research Objectives:

1. **The purpose of this research is to look into the particular applications of AI (machine learning and robotic process automation) in Phase III clinical trials in India.**

   To realise the research aim set out to identify and investigate the areas of Phase III clinical trials that can benefit from the use of AI technologies. This research will provide valuable information into the possible benefits and challenges connected with implementing AI in Phase III clinical trials by evaluating the particular uses of AI, such as predictive analytics, data processing, and decision support systems. This objective will help understand AI's function and impact in clinical trials in India through deep literature reviews, case studies, and data analysis.

2. **This study aims to determine the benefits and drawbacks of using AI (machine learning and robotic process automation) for real-time monitoring and safety analysis in Phase III clinical trials in India**

   With the aim of realizing the outlined research objective is to determine the benefits and drawbacks of using AI (machine learning & robotic process automation) for instant monitoring and safety evaluation in Phase III clinical trials in India. This goal focuses on investigating the possible advantages and disadvantages of using AI technology for immediate safety analysis and monitoring during Phase III clinical studies.

3. **The purpose of this study is to investigate how AI (including machine learning and robotic process automation) can help with patient care and adherence monitoring during Phase III clinical trials in India.**

   In order to accomplish the stated research goal to explore the role of AI in enhancing patient management and adherence monitoring, which are critical aspects of successful clinical trials. By analyzing case studies, and patient data, and comparing AI-assisted approaches with conventional methods, this research will provide insights into the potential benefits and challenges of implementing AI technologies in patient management. The outcomes of this objective will contribute to optimizing patient care, enhancing treatment adherence, and improving the overall quality and efficiency of Phase III clinical trials in India.

4. **In terms of India's healthcare system, investigate the ethical considerations and challenges connected with the use of AI (machine learning and robotic process automation) in Phase III clinical trials.**

   Recognizing the significance of ethical implications when implementing AI technology in clinical trials, to achieve the research objective established aims to investigate the ethical issues and problems particular to the India healthcare system. It will identify and examine any potential ethical issues and challenges generated by the presence of AI in Phase III trials through a complete analysis of current ethical frameworks, regulatory guidelines, and case studies. This goal will help to better understand the ethical issues and promote the development of ethical standards and processes for AI implementation in clinical trials in India by including appropriate individuals and experts.

5. **This study also aims to investigate the possibilities of future developments and prospects for AI (machine learning and robotic process automation) in Phase III clinical trials in India.**

   To realise final objective of this study is to explore the potential future advancements and opportunities for AI (Machine learning & robotic process automation) in Phase III clinical trials in India. This objective aims to predict and analyze the future trends and developments in AI technologies and their potential applications in Phase III clinical trials. By reviewing emerging technologies, research trends, and expert opinions, this research will provide information on the opportunities for using AI in enhancing the efficiency, accuracy, and effectiveness of clinical trials in India.

1.3 Research Questions:

The clinical trials perspective, particularly Phase III trials in India, are experiencing a significant transformation due to the introduction of Artificial Intelligence (AI) and Robotic Process Automation (RPA). These technology innovations have the capacity to effectively tackle the basic obstacles involved with such studies, although also providing a variety of advantages. This section provides an in-depth analysis of the transformative impact, expected benefits, current challenges, and prospects offered by artificial intelligence (AI) and robotic process automation (RPA) in the field of Phase III clinical trials conducted in India. The objective is to highlight how these advancements are positioned to transform the area of clinical research and enhance patient outcomes.

Influence and Benefits of AI in Clinical Trials

1. What influence does AI machine learning & RPA have on Phase III clinical trials' effectiveness and efficiency in India?
2. How has the adoption of AI and machine learning (ML) & RPA in clinical trials grown in recent years?
3. Why is India regarded as one of the most important clinical trial markets, particularly in the context of AI/ML applications?
4. What are the possible benefits of using AI and machine learning in clinical trial preparation, execution, and analysis?

Challenges and Obstacles in Implementing AI in Clinical Trials

5. What are the challenges and obstacles to applying AI machine learning in India's Phase III clinical trials?
6. What insights can be gained from individuals with experience in clinical trials, particularly those who have worked or are currently working in Phase III clinical trials in India, regarding the use of AI machine learning & RPA in these trials?

AI and RPA for Improving Clinical Trial Efficiency

7. How can AI and RPA help to reduce clinical trial failure rates in India?
8. How should AI and machine learning increase clinical study efficiency and cost-effectiveness?
9. How can machine learning-based predictive models help in the early detection and

prevention of drug-drug interactions (DDIs) in Phase III clinical trials?

10. What are the possible benefits of employing AI and RPA for developing personalized therapy plans?
11. Are there any other issues that you feel may be relevant to this discussion that you would like to explore?
12. What kind of potential future developments and opportunities exist for AI (Machine Learning & Robotic Process Automation) in Phase III clinical trials in India?

1.4 Ethics:

For recruiting participants for surveys, Google forms were conducted and send them with the help of emails, LinkedIn, and through WhatsApp. It will not take so much time so participants will fill in the answers according to their pace. While for interviews it needs to reach participants first through LinkedIn and emails to discuss my idea and to get their consent only then need to schedule an interview with them. For recruiting participants for surveys, It should be conducted by Google forms and send them with the help of emails, LinkedIn, and through WhatsApp. It will not take so much time so participants will fill in the answers according to their pace. While for interviews, to reach participants first through LinkedIn and emails to discuss the idea and to get their consent only then I can schedule an interview with them.

The primary objective of this research effort is to analyze the application of artificial intelligence (AI), specifically machine learning and robotic process automation (RPA), inside Phase III clinical trials conducted in India. The objective is to improve effectiveness, precision, and decision-making procedures, ultimately speeding the progression and authorization of secure and affordable treatments. This research aims to look into the possible advantages, obstacles, and ethical implications related to the implementation of artificial intelligence (AI) technology in the field of clinical trials. With investigation of multiple aspects, including patient recruitment, safety analysis, treatment response prediction, and overall trial management, the research attempts to offer valuable perspectives on the potential transformative impact of artificial intelligence (AI) on the clinical trial environment in India. The main objective is to provide research-based suggestions for adopting artificial intelligence (AI) in order to enhance trial protocols, which will help researchers, pharmaceutical companies, regulatory agencies, and health care professionals. The project aims to investigate the impact of artificial intelligence (AI) on clinical trials, with a focus on specific research objectives and issues. This will be achieved by a detailed review of existing literature, evaluation of relevant case studies, and accurate data

analysis. The research will explore various aspects, including the influence of AI on clinical trials, the problems associated with its implementation, potential improvements in efficiency, implications for patient care, ethical considerations, and future prospects.

The primary objective of this research effort is to analyze the application of artificial intelligence (AI), specifically machine learning and robotic process automation (RPA), inside Phase III clinical trials conducted in India. The objective is to improve effectiveness, precision, and decision-making procedures, ultimately speeding the progression and authorization of secure and affordable treatments. The next chapter contains the detail discussion about the existing literature about clinical trials specifically focusing on ML & RPA phase III in India.

Chapter:2 Literature Review

This chapter discusses how Phase III clinical trials have changed medication development by integrating AI. Machine learning and robotic process automation support AI's potential to transform essential trial processes. AI's applications are diverse and promising, from predictive modelling and real-time monitoring to patient recruiting and safety research. India is a major player in worldwide clinical research; hence AI's Phase III trials are highlighted.
However, this combination is complicated. The chapter compares AI-driven efficiencies to ethical concerns about data veracity, patient privacy, and algorithmic bias. To maximize AI's benefits while protecting patient autonomy and guaranteeing equitable treatment, a delicate balance is needed.

The chapter addresses the need to overcome obstacles as AI grows. AI system accessibility, algorithmic fairness, and adaptability to changing regulations are key. These obstacles present growth and innovation opportunities in this sector. Precision medicine and blockchain technology for safe data sharing are examples of progress. In conclusion, this chapter covers AI's implementation in Phase III clinical trials, including practical applications, ethical issues, biases, and future plans. It explains how AI and clinical trials have changed drug discovery and patient care through an in-depth literature review.

2.1 Overview of AI in Clinical Trials

2.1.1 Evolution and Adoption of AI in Clinical Trials:

AI is being used to enhance the data-driven approach in clinical trial design and execution, offering essential assistance for its possible use in clinical trial design. Additionally, it is resolving possible issues with and uses AI and included tools and devices in clinical trials for a hypothetical Pharma 4.0 approach. (Cascini et al., 2022)

The characteristics of clinical trials using AI in the healthcare industry are examined in this research study. The study is focused on the usage of data-driven learning algorithms and how they are applied to different illness areas. The evaluation attempts to offer insights into the nature and extent of AI applications in healthcare research by examining a variety of clinical studies listed on ClinicalTrials.gov. (Wang *et al.*, 2022)

2.2 Key Components of AI: Machine Learning & Robotic Process Automation:

Machine learning could be used to improve clinical trial planning, execution, and analysis. Machine learning has the potential to increase the productivity and output of

preclinical research and clinical trial preparation. (Weissler et al., 2021)

Robotic process automation, or RPA, is a technology that performs routine tasks and procedures using software robots. By replicating human activity on computer systems, it helps to raise efficiency, accuracy, and productivity (UiPath Inc, 2017).

Advanced robotics is utilizing AI, machine learning (ML), and deep learning (DL) to enhance autonomous navigation, object recognition and manipulation, natural language processing, and preventative maintenance. Robotic intelligence is expanding thanks to the incorporation of AI and ML, and accurate machine learning techniques are being utilized to teach robots and boost accuracy. AI in robots enables real-time updates to rapidly plan its route and detect obstacles in its way. The use of AI in robots is anticipated to increase by about 54% year and reach a forecasted value of $22.6 billion. (Soori, Arezoo and Dastres, 2023)

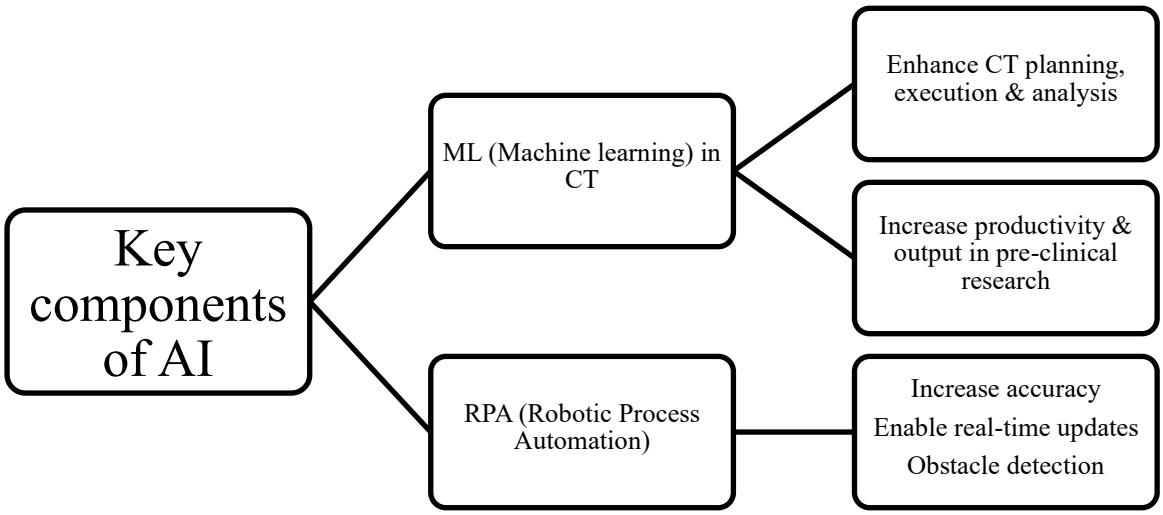

Figure 1: Key components of AI

2.3 Current Trends and Applications of AI in Clinical Trials Phase III:

The implementation of AI into clinical trials presents both opportunities and challenges. By analyzing diverse data sources, AI can improve patient selection, enhance data analysis through the identification of patterns, and accelerate trial management processes. (Askin et al., 2023)

AI has the potential to change clinical trial behaviour, particularly in terms of research

design, planning, and conduct of clinical trials. One of the applications of AI in clinical trials is the use of machine learning (ML), deep learning (DL), natural language processing (NLP), and optical character recognition (OCR). (The Role of AI in Clinical Trials, 2023)

The potential of AI technologies in enhancing Real World Evidence (RWE) generation in clinical trials is explored in an article. It concentrates on five important applications of AI, including natural language processing, machine learning, and predictive analytics. AI is capable of effectively managing vast quantities of data, identifying patient cohorts, and predicting outcomes. In addition, explores the obstacles and considerations to be made when implementing AI technologies in clinical trials. (*5 Applications of AI to Enhance RWE Generation,* 2019)

Drug development time and expense can be decreased in India through the use of AI-driven algorithms in clinical trials. AI may recreate data to find more effective statistical outcome measures, forecast participant outcomes, and identify participants who are most likely to advance quickly and reach endpoints quickly, resulting in shorter trial durations. Additionally, AI can be utilized to enhance patient monitoring during clinical trials, improving patient safety and speeding up the medication development process. By collecting subject information, screening and filtering possible participants, and informing medical professionals and patients about clinical trial chances, the application of AI, automation, and machine learning can improve clinical trials.(*The power of AI to transform clinical trials,* 2018)

Phase III clinical trials in India	Importance: Evaluate safety, efficacy and adverse effects of new drugs and treatments Challenges: Time consuming and costly
Evolution and Adaption of AI in clinical trials	AI used to enhance data driven approach in clinical trial design and execution Resolving possible issues with the AI and included tools and devices for pharma 4.0 approach
Key components of AI	Machine learning: Improves clinical trial planning, execution and analysis RPA: Automates routine tasks, increasing efficiency, accuracy and productivity
Current trends and applications of AI in Phase III	AI improves patient selection, data analysis, and trial management Real-time monitoring enhances patient safety and identifies protocol deviations AI based electronic data capture improves data capture and speed
Specific applications of AI in Phase III clinical trials in India	Data analysis and predictive Modelling
	Machine learning to estimate drug-drug interactions
	Patient recruitment and eligibility assessment: AI enabled solutions to identify suitable cohorts

Table 1: Current trends & application of AI in CT

2.4 Specific Applications of AI in Phase III Clinical Trials in India

2.4.1 Data Analysis and Predictive Modelling:

The development of machine learning-based predictive models that incorporate several

pharmacological features, such as therapeutic, chemical, and genetic data, to estimate the likelihood of DDIs (drug-drug interactions). (Cheng and Zhao, 2014)

2.4.2 Patient Recruitment and Eligibility Assessment:

The adoption of AI-enabled patient recruitment solutions in clinical trials is a promising research topic. Using AI can enhance the effectiveness and cost-efficiency of conventional clinical trial procedures. By identifying suitable cohorts for clinical trials by analyzing medical records and social media content, AI can be used to increase the success rate of clinical trials by redesigning them. (Ali, 2010)

Analyzing medical records and social media content, AI can identify cohorts suitable for clinical trials. Using AI technologies to alert medical staff and patients about trial opportunities and simplifying entry criteria to make them more accessible for potential participants may speed up trial recruitment. (Fultinavičiūtė, 2022)

The outcomes of this research show that patient recruitment in clinical trials can be facilitated by using predictive modelling as a tool. Comparing this strategy to conventional rule-based systems, it has a number of important benefits. One benefit is its independence from particular interpretations of eligibility standards and electronic health record (EHR) data, allowing for more adaptability to various trial settings. Predictive modelling also has the ability to automate, expediting the hiring procedure and lessening the demand on trial coordinators. These results show that predictive modelling has the potential to be an efficient tool for assisting patient recruitment in clinical trials. (Köpcke *et al.*, 2013)

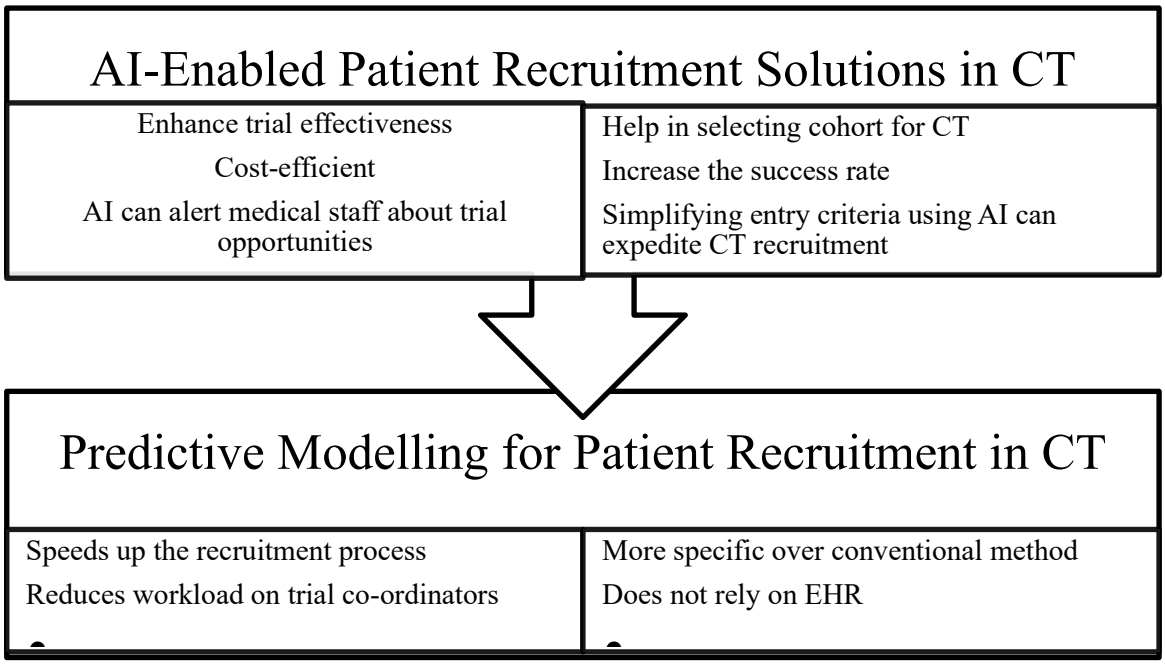

Figure 2:Patient Recruitment & Eligibility Assessment

2.5 Real-time Monitoring and Safety Analysis:

AI can enhance clinical trial execution by monitoring patient efficacy and safety in real time, spotting probable protocol deviations, and anticipating patient dropout rates. (Bhatt, 2021)

Real-time clinical trial monitoring is growing since monitors don't have to visit sites to transfer or assess data. Data is captured digitally. CROs, hospitals, clinics, study sponsors, and research directors can view data from practically anywhere. Monitoring has five goals: keeping participants safe and accepting their rights, having reliable data, ensuring the study is being done as intended, enhancing the experiment, and preventing issues before they arise. AI and machine learning can increase clinical trial monitoring efficiency and accuracy. Investigators can monitor safety via real-time reporting. (*Why Real-Time Monitoring is Saving Clinical Trials*, no date)

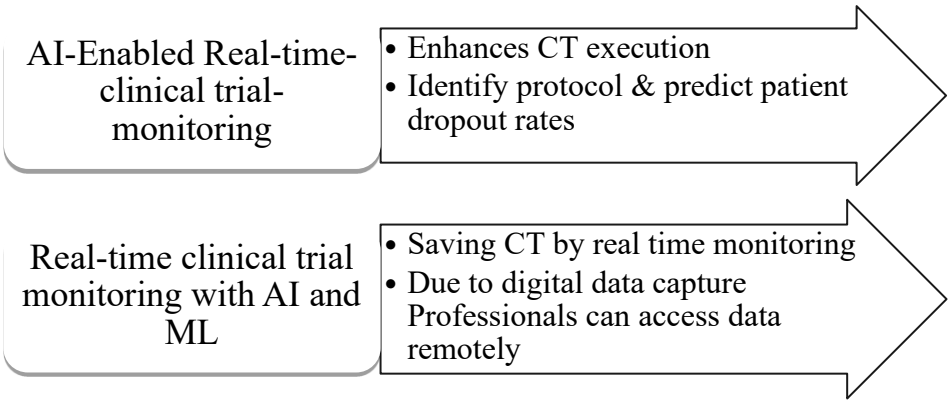

Figure 3: Real-time-monitoring & Safety Analysis

2.6 Electronic Data Capture and Management Systems:

The studies that have been investigated provide significant knowledge into the future directions and capabilities of AI and ML in Phase III clinical trials. They underline the necessity of investigating advanced machine learning approaches such as deep learning, which have shown promise in a variety of applications. Researchers can discover new possibilities and improve the use of AI and ML in Phase III clinical trials by exploring further into these advanced approaches. (Dana et al., 2018)

EDC tools are superior to manual clinical data collecting and analysis. Validation tests and automated error detection ensure data accuracy and integrity, improving data quality. EDC tools streamline data gathering, enable real-time data capture, and speed data availability, improving performance and efficiency. EDC tools minimize transcription, storage, and remote data access expenses for paper-based data. EDC tools also enable proactive data monitoring and resolution of inconsistencies and protocol violations. A centralized data management platform helps stakeholders collaborate and communicate. EDC tools improve productivity, data quality, and cost, making clinical research more effective. (Sahoo and Bhatt, 2004)

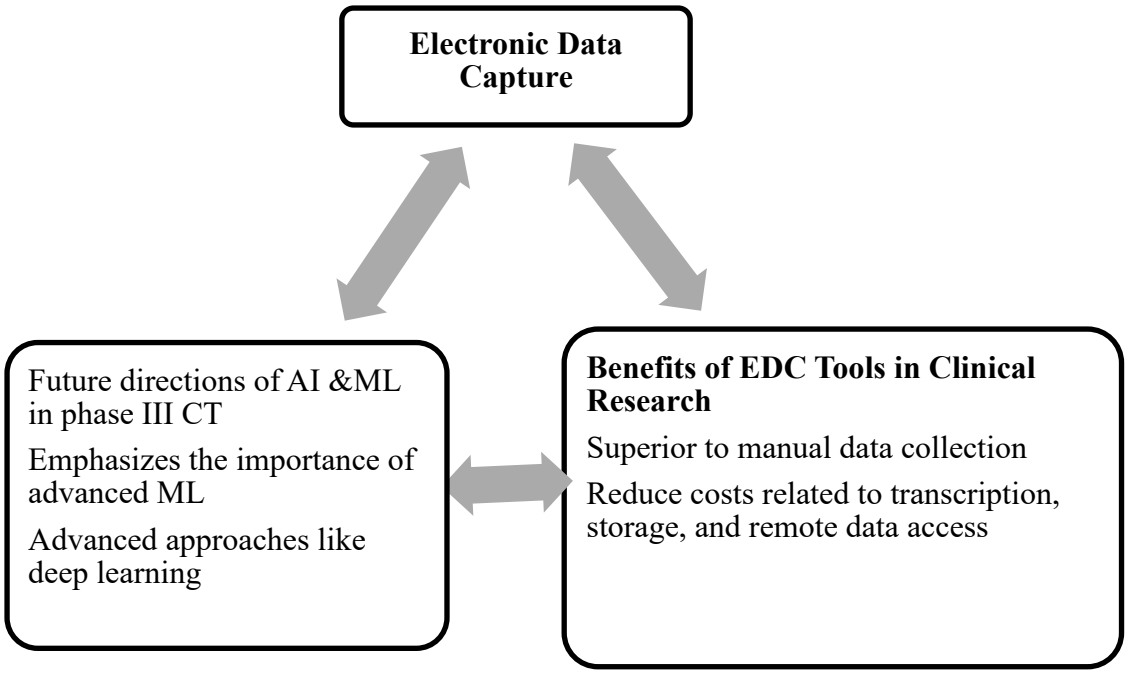

Figure 4: Electronic Data Capture

2.7 Risk Assessment and Quality Control:

The pharmaceutical sector may undergo a technological revolution called robotic process automation (RPA). In order to improve claim processing and boost efficiency, RPA can automate registration processes, maintain, and manage medical information, and carry out repetitive data entry. RPA deployment is a strong option for several pharmaceutical industry-specific operations because it can save a lot of money and ensure compliance. (Schiraldi, 2021)

Clinical Practice on patient safety, rights, and trial results. Comprehensive questionnaires analyze risk and offer on-site monitoring strategies. Risk-proportionate monitoring activities and methodologies must be used in trials. Real-time monitoring is becoming common in clinical trials because it allows stakeholders to access data from many places. (Brosteanu *et al.,* 2009)

2.8 Advantages and Disadvantages of AI Adoption in Phase III Clinical Trials

2.8.1 Improved Efficiency and Cost-effectiveness:

The potential of AI in clinical trials is examined in the study "AI Powered Clinical Trials". According to the research, AI has the ability to enhance patient monitoring, reduce expenses and time, and simplify statistical analysis. The amount of time and money spent on clinical trials can be cut in half with the use of AI. (Majie, 2021)

AI can speed up clinical trials, cut costs and time, and enhance patient monitoring. But when using AI in clinical trials, it's important to carefully analyze all of the ethical, legal, and regulatory obligations as well as any possible sources of bias and injustice. (Chien et al., 2022)

2.8.2 Enhanced Data Accuracy and Quality:

AI/ML can reduce the high failure rates in clinical trials. The advantages of automating data collection, verification, and monitoring order to save time, and money, and reduce the possibility of human mistakes. It covers the possibility of enhancing trial success through data analysis from earlier studies to enhance clinical trial protocol development. (Sahoo and Bhatt, 2004)

2.8.3 Potential Ethical and Legal Implications:

While using AI and ML in Phase III clinical trials has many possible benefits, it also brings a few challenges and ethical concerns that must be properly handled. Sinha, Singh, and Sharma (2020) provide light on multiple important issues that occur in the context of AI and ML applications in the medical business, such as data privacy, algorithmic bias, and ML model interpretability. When it comes to using AI and ML in clinical studies, data privacy is a major concern.

AI (AI) integration in healthcare has ethical concerns that need to be addressed, such as informed consent for data use, safety and transparency, algorithmic fairness and biases, and data privacy. The ethical integration of AI in healthcare can be guided by well-known notions from research ethics. Although the application of AI in medical applications holds significant potential for enhancing healthcare, it also raises ethical issues that must be recognized and addressed. Patient autonomy, informed permission, and threats to privacy and confidentiality are only a few of the ethical issues that arise with the use of AI in healthcare. To maximize the potential benefits of AI while minimizing its possible drawbacks, the ethical concerns surrounding AI in healthcare must be recognized and dealt with methodically. (McCradden, Stephenson and Anderson, 2020)

2.8.4 Challenges and Limitations of AI Integration:

The implementation of AI and ML in Phase III clinical trials has the potential to change the field of medicine by offering personalized approaches to treatment. Previous clinical trials sometimes use an approach called one-size-fits-all, in which therapies are tried on a large sample of patients without considering individual differences. But with developments in AI and ML, researchers may now use the power of these technologies to design individualized treatment methods based on patients' particular characteristics and reactions. However, implementing AI in the design of clinical trials requires careful consideration of ethical, legal, and regulatory requirements and addressing the challenges of data privacy, security, and workforce training. (Harrer et al., 2019)

Challenges and benefits of using AI (AI) in clinical trials are Data quality, ethical considerations in AI implementation, retrospective data, data bias, interpreting AI-generated data, data regulation, integrating AI with existing systems, and technical limitations are highlighted. Addressing these problems, AI in clinical trials may improve patient care, trial design, and data processing. (Joshi, 2023)

Advantage/Disadvantage	**Key Features**
Improved Efficiency and Cost-effectiveness (Advantage)	-AI can enhance patient monitoring -Reduce expenses -Improve Patient Monitoring -AI adoption can half the money and time on CT
Enhanced Data Accuracy and Quality (Advantage)	-It reduces high failure rates in CT -Data analysis from previous studies enhances CT protocol development

	-Automation of data collection, verification, and monitoring saves time and reduces human errors
Potential Ethical and Legal Implications (Disadvantage)	-Ethical issues include data privacy, algorithms bias in medical AI/ML applications
	-Recognizing and addressing ethical issues is crucial to maximize AI's benefits while minimizing drawbacks.

Table 2: Advantage & Disadvantage of AI (ML) In CT

2.9 AI in Patient Management and Adherence Monitoring

2.9.1 Remote Patient Monitoring and Personalized Interventions:

AI and robotics can enhance healthcare delivery, patient outcomes, and costs. However, implementing these technologies requires careful consideration of ethical, legal, and regulatory requirements, as well as addressing data privacy, security, and workforce training challenges. (Deo and Anjankar, 2023)

The use of digital health technology in clinical trials to improve medication adherence is explored in the article. It highlights how wearable technology and mobile health apps have the ability to increase adherence and reduce the risks brought on by non-adherence. The article also discusses the difficulties of integrating digital health technologies in clinical trials, including issues with data security and privacy. Overall, the report emphasizes the need of utilizing digital health technologies to improve medication adherence in clinical trials and stresses the need for more research to determine these technologies' efficacy in this situation. (Zijp *et al.*, 2019)

2.9.2 Medication Adherence and Compliance Tracking:

It highlights the potential of AI in clinical trials. The whole comprehensive literature review concluded that AI has the potential to reduce the duration and cost of clinical trials, identify drug efficacy, and enhance patient monitoring. (Balsundaram, 2021)

The importance of tracking participant adherence in clinical trials is explained in the paper. It examines the several tools employed to assess adherence, such as patient diaries, electronic records, and residual tablet counting. To guarantee the reliability of the participant data acquired, adherence measurement is essential. The article recognizes that clinical trial participants can have requirements beyond just taking the drug as directed. They might have to follow particular test and exam clinic visit schedules. Overall, the article highlights the significance of keeping an eye on participant compliance in clinical studies to guarantee correct and reliable information collecting. (dp_admin, 2016)

2.9.3 Intelligent Decision Support Systems for Clinicians:

AI can transform clinical trials in four ways: by improving patient selection, increasing clinical trial efficacy, reducing trial duration and costs, and facilitating drug discovery. (Lange, 2021)

It discusses EHRs for clinical decision assistance. It shows how EHRs contain demographics, medical history, prescriptions, test results, and diagnoses. The article acknowledges EHR data difficulties such as different data kinds and characteristics. It focuses on using EHR data to enhance healthcare quality and lower costs, especially in acute and chronic conditions. (Venugopalan, 2020)

2.9.4 Patient Engagement and Empowerment:

The research shows that AI can speed up clinical trials, cut costs and time, and enhance patient monitoring. But when using AI in clinical trials, it's important to carefully analyze all of the ethical, legal, and regulatory obligations as well as any possible sources of bias and injustice. (Chien et al., 2022)

Patient involvement and empowerment in personal healthcare. discusses and compares and contrasts these notions. It examines related terminology and their role in patient involvement and healthcare decision-making. The essay emphasizes active patient participation and autonomy in personal healthcare by addressing patient engagement and empowerment. The paper promotes patient engagement and empowerment in personal healthcare settings. (Hickmann, Richter and Schlieter, 2022)

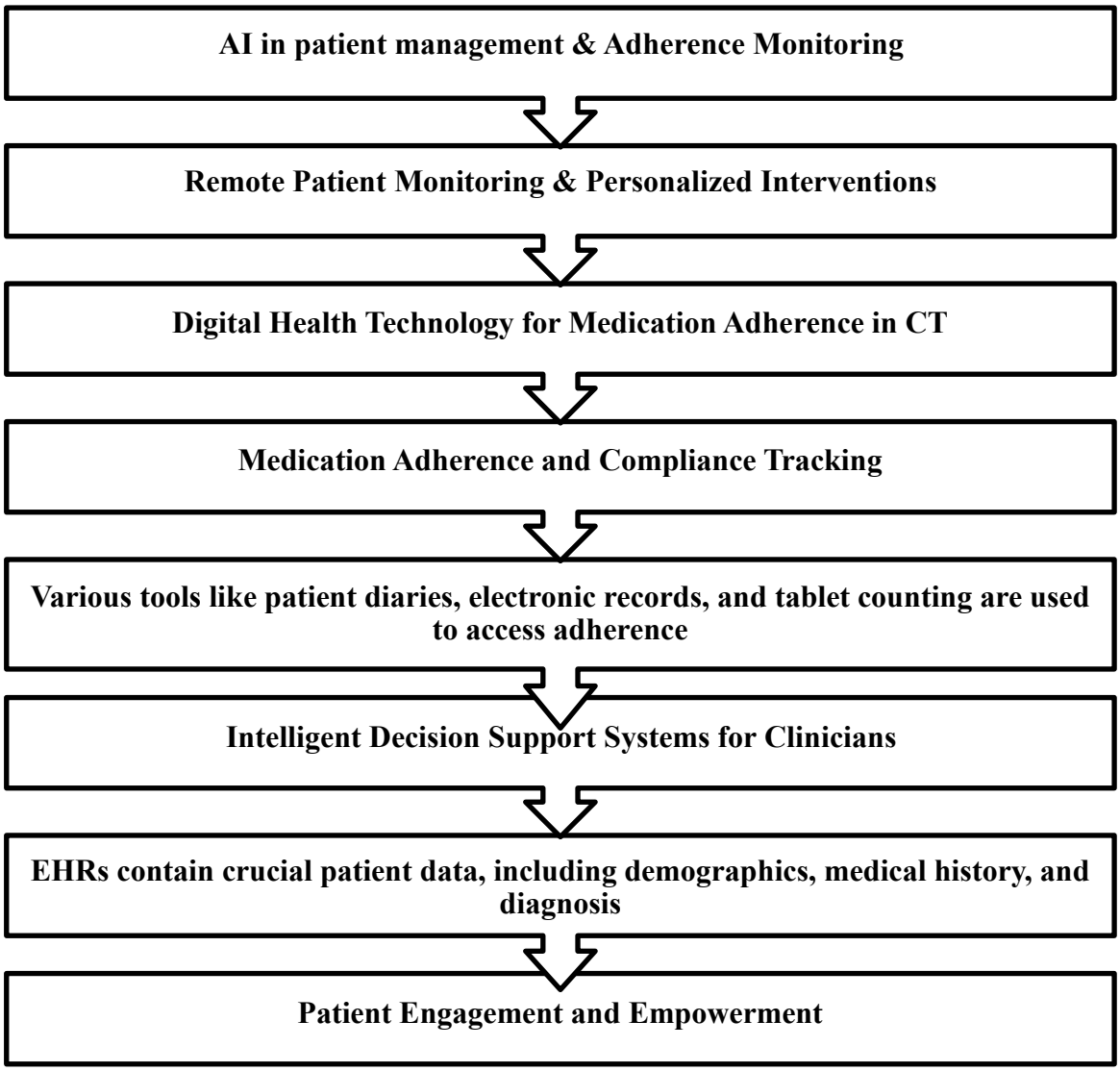

Figure 5: AI in Patient Management

2.10 Ethical Considerations and Challenges in AI-enabled Clinical Trials

2.10.1 Privacy, Security, and Data Governance:

The implementation of AI and ML in Phase III clinical trials presents both opportunities and challenges. Assuring data privacy and security, according to regulatory guidelines, is a significant challenge. To solve these challenges, strong management of data, algorithm transparency, and collaboration between stakeholders is required. (Askin et al., 2023)

When it comes to using AI and ML in clinical studies, data privacy is a major concern. Patient data is extremely sensitive and must be treated with extreme caution in order to maintain confidentiality and comply with privacy standards. Because clinical trials need the collection and analysis of large volumes of sensitive health information, it is critical to put in place strong data protection procedures to preserve patient privacy. (Yin, Ngiam

and Teo, 2021)

2.10.2 Informed Consent and Patient Autonomy:

The potential of AI in clinical trials is examined in the study "AI Powered Clinical Trials". The paper discusses the potential benefits and challenges of utilizing AI in healthcare, including ethical and regulatory considerations. (Majie, 2021)

It covers clinical trial informed consent and ethics. Patients need clear and accessible information to make clinical trial decisions, according to the article. Language and cultural limitations make informed consent difficult. The article discusses informed consent in clinical trials and ethical considerations to protect study participants. (Sabry *et al.*, 2022)

2.10.3 Bias and Fairness in AI Algorithms:

But when using AI in clinical trials, it's important to carefully analyze all of the ethical, legal, and regulatory obligations as well as any possible sources of bias and injustice. (Chien et al., 2022)

In clinical trials in India, the study highlights fairness, prejudice, and appropriate use of AI and machine learning in global health. It shows how AI biases and fairness issues affect low- and middle-income groups. These issues stem from technical incapacity, social biases against minorities, and weak legal protections. The research emphasizes the necessity to proactively address these concerns to enable fair and unbiased use of AI and machine learning technologies, particularly in clinical trials. The study recommends that AI and machine learning can be used more effectively and equitably in global health, including clinical trials, by recognizing and mitigating biases, improving technical capability, fostering inclusion, and providing legal safeguards. (Fletcher, Nakeshimana and Olubeko, 2021)

2.10.4 Transparency of AI Systems:

The studies that have been investigated provide significant knowledge into the future directions and capabilities of AI and ML in Phase III clinical trials. They underline the necessity of investigating advanced machine learning approaches such as deep learning, which have shown promise in a variety of applications. Researchers can discover new possibilities and improve the use of AI and ML in Phase III clinical trials by exploring

further into these advanced approaches. (Dana et al., 2018) (Joshi, 2023)

Advantages of AI adoption in Phase III Clinical trials	**AI adoption in Phase III Clinical trials**
Improved efficiency and cost effectiveness with AI	Ethical and legal implications, including data privacy and biases
Enhanced data accuracy and quality through automation	Challenges in implementation such as technical issues and data bias
AI in patient monitoring & adherence monitoring	Ethical considerations and challenges in AI enabled clinical trials
Remote patient monitoring and personalized interventions	Privacy, security, and data governance: Ensuring data protection
AI driven medication adherence and compliance tracking	Informed consent and patient autonomy: Ethical AI implementation
	Transparency of AI system: Understanding AI generated data

Table 3: AI Adoption in Phase III CT

2.11 Future Advancements and Opportunities for AI in Phase III Clinical Trials

2.11.1 Integration of AI with Wearable Devices and IoT:

AI can transform clinical trials in four ways: by improving patient selection, increasing clinical trial efficacy, reducing trial duration and costs, and facilitating drug discovery. AI can assist in predicting patient outcomes and identifying potential safety hazards. Clinical trial planning can be made more efficient with AI by automating processes like site selection, patient enrolment, and data gathering. (Bhatt, 2021)

It covers blockchain and IoT use in healthcare, with a focus on clinical trials. Blockchain technology is examined for data storage, data sharing, medicine traceability, and remote patient monitoring. Blockchain transparency, security, and decentralization can improve data integrity, interoperability, and patient privacy in healthcare. IoT devices and blockchain technology offer real-time data collecting, processing, and monitoring in clinical trials, improving efficiency and accuracy. The paper addresses the potential

benefits and opportunities of blockchain and IoT in healthcare, particularly clinical trials. (Sharma, Kaur and Singh, 2021)

The utilization of machine learning for predicting complications in critical care patients using diverse clinical data is examined in this paper. The study focuses on the incorporation of complex metabolic states and clustering techniques to monitor patient outcomes. It helps to understand the potential of machine learning in forecasting patient outcomes and enhancing the effectiveness of critical care. In summary, it offers valuable insights into the application of machine learning in critical care and the predictive capability of heterogeneous clinical data for patient outcome prediction. (Vijay Huddar *et al.,* 2021)

2.11.2 Blockchain Technology for Secure Data Sharing:

There is a correlation between the effect of data transparency on scientific publications and the concept of black box warnings in clinical trials. The article discusses the initiatives taken by pharmaceutical companies, regulatory bodies, and other industry decision-makers to make clinical trial data accessible through multiple access points, including clinical trial disclosures, clinical study reports, plain language summaries, and scientific publications. (Joshi and Bhardwaj, 2018)

Blockchain technology is applied to clinical trials in this systematic review. Blockchain technology being examined in clinical trial data management, biological research, and education. Blockchain's decentralized, transparent, and immutable nature helps healthcare organizations improve data security, privacy, and interoperability. Blockchain technology in clinical trials could improve data integrity, expedite operations, and promote stakeholder participation. The article discusses blockchain technology's potential benefits and opportunities in healthcare, especially in clinical trials. (Elangovan *et al.,* 2022)

This article highlights the importance of informed consent in clinical research and explores its core concepts and areas. It emphasizes the need for clear standards and procedures guiding informed consent from study participants, especially in various situations. The article also discusses clinical research informed consent ethical issues. The article highlights the necessity of informed consent in sustaining ethical norms and defending clinical research participants' rights and autonomy. (Gupta, 2013)

2.11.3 AI-driven Drug Discovery and Target Identification:

The use of AI/ML in phase III clinical trials in India has the potential to increase clinical trial efficiency and efficacy. The evaluation of the literature focuses on the potential benefits of AI/ML in predicting trial failure and success, lowering the time and expense associated with more traditional trials, and enhancing the data-driven approach in clinical pathway development and implementation. (Admin, 2019)

AI and machine learning algorithms' ability to evaluate huge biomedical datasets and identify drug targets and prospects. It helps to understand AI's role in improving drug research and deep learning's promise. AI is also identifying new therapeutic targets, improving safety and efficacy throughout the drug development life cycle, and lowering drug development time and cost. The article discusses AI's role in improving drug discovery and target identification in clinical trials in India. (McLaren, 2023)

2.11.4 Precision Medicine and Treatment Personalization:

The implementation of AI and ML in Phase III clinical trials has the potential to change the field of medicine by offering personalized approaches to treatment. With developments in AI and ML, researchers may now use the power of these technologies to design individualized treatment methods based on patients' particular characteristics and reactions. (Harrer et al., 2019)

AI improves and optimizes drug discovery. In particular, deep learning-based technologies can revolutionize target identification, chemical screening, and optimization in drug discovery. AI and machine learning can speed up medication discovery and improve drug efficacy. The essay discusses AI's potential to revolutionize medication research. (Sarkar *et al.,* 2023)

2.12 Summary of Key Findings:

The implementation of AI (AI) into clinical trials presents both opportunities and challenges. By analyzing diverse data sources, AI can improve patient selection, enhance data analysis through the identification of patterns, and accelerate trial management processes. But assuring data privacy and security, according to regulatory guidelines, and combining AI with existing systems are significant challenges. (Askin et al., 2023)

2.12.1 Identification of gap in the literature:

The studies that have been investigated provide significant knowledge into the future directions and capabilities of AI and ML in Phase III clinical trials. They underline the necessity of investigating advanced machine learning approaches such as deep learning, which have shown promise in a variety of applications. Researchers can discover new possibilities and improve the use of AI and ML in Phase III clinical trials by exploring further into these advanced approaches. (Dana et al., 2018)

Lack of efficacy, safety concerns, a lack of money, protocol changes, and difficulties with recruitment and retention can all cause clinical studies to fail. To increase the success rate of clinical trials, it is crucial to optimize every step of the research process. Digital solutions for data gathering, remote monitoring, and patient involvement can help overcome obstacles and boost trial efficiency. Digital techniques and tools can help clinical research be productive and benefit patient communities. According to the review, data analysis and predictive modelling can raise the success rates of clinical trials. (Fogel, 2018)

COVID-19 research is now going in India and how evidence-based medicine is essential for pandemic management. It draws attention to the difficulties in managing mild and moderate COVID-19 as well as the lack of information from medication trials. The paragraph focuses on the value of clinical research in conventional medicine and the demand for more of it. It offers details about the patterns shown by COVID-19 research that was registered with the Clinical Trials Registry - India. Overall, the paragraph offers insightful information about the state of COVID-19 research in India at the moment and the necessity of evidence-based medicine for pandemic management. (Rao *et al.*, 2021)

The Cochrane Handbook is a thorough manual that offers guidance on the typical procedures that apply to every review, including planning a review, looking for and choosing studies, extracting data, and analyzing data. For academics performing systematic reviews of healthcare interventions, it is a crucial resource. The guide, which is accessible online, offers thorough information on the procedures followed in Cochrane systematic reviews, including the use of advanced robotics, AI, machine learning, and deep learning, which can increase the precision and effectiveness of clinical trials. (Tianjing, PT Higgins, and Deeks, 2022)

Safety monitoring in clinical trials is crucial throughout the drug development life-cycle. Pharmaceutical sponsors must adopt a systematic approach to ensure patient safety. Regulatory requirements for risk management plans and evaluation strategies have evolved. The goal of safety monitoring is to identify, evaluate, minimize, and manage risks. Risk Management Plans (RMPs) are required in Europe, serving as the basis for pharmacovigilance and risk minimization activities. Safety surveillance plays a vital role in developing efficient and safe treatments, starting from preclinical toxicology studies. Methodological challenges and the need for reliable drug safety signals in clinical trials are also discussed. (Yao *et al.,* 2013)

Clinical trial monitoring is an essential component of trial conduct that enhances participant safety, data quality, and trial integrity. The goal of monitoring can be summed up in five principles: protecting participants and upholding their rights; obtaining reliable data; ensuring that the trial is being conducted as intended; enhancing the trial's conduct; and avoiding issues before they arise. Trial monitoring guidance is dispersed among several sources both inside and between organizations, is frequently written in technical language, and does not provide specifics on how to carry out the monitoring goals. The effectiveness and precision of clinical trial monitoring can be increased by incorporating AI and machine learning. (Molloy and Henley, 2016)

Clinical trial real-time data capturing and analytics could transform medication development. Virtual data capture and real-time analytics allow researchers to see trends and make informed conclusions. This increases risk-averse monitoring and clinical trial efficiency. AI and ML increase data analysis and pattern identification, streamlining workflows and improving patient outcomes. AI and ML improve medication development, patient selection, and trial design in clinical trials. (Stempel, 2018)

Advantages of AI adoption in Phase III Clinical trials	Disadvantages & Challenges in AI adoption in Phase III Clinical trials
Future advancements & opportunities for AI in phase III clinical trials	
Integration of AI with wearable devices &IoT: Personalized patient monitoring and interventions	Summary of Key findings: AI enhances clinical trials but has challenges
Blockchain technology for secure data sharing: Enhancing data integrity and privacy	Implications for practice and research: Need for further investigation
AI driven drug discovery and target identification: Improving drug research and efficacy	Recommendations for future studies: Addressing challenges and maximizing AI benefits
Precision medicine and treatment personalization: Individualized treatment approaches	

Table 4: Advantages and Disadvantages in Phase III trials

The next stage of our study takes us to the research approach and procedures, building on the insights we've gained in this chapter. Here, we'll go into the methods that enabled us to conduct an empirical investigation of AI's influence on Phase III clinical trials. The insight gained here will help establish the path for a comprehensive understanding of the based on artificial intelligence future of drug research and patient care because of the mutually beneficial connection between the chapters.

Chapter 3: Methodology

3.1 Research Design:

This chapter describes the research design and methodology used to examine the application of AI (ML & RPA) in phase III clinical trials in India. Using a mixed methodology approach, the study combines surveys and interviews to obtain a comprehensive understanding of this complicated topic.

To resolve the complexity of the research topic, a mixed methodology is selected. Implementing AI in phase III clinical trials requires both quantitative and qualitative data to get a vast level of information. By combining surveys and interviews, the study aims to combine data and offer a detailed interpretation, which improves the overall validity of the research.

The following steps outline the methodology employed:

1. **Selection of key participants**: The initial step involved identifying and selecting key participants in clinical trials in India. This group comprised, researchers, CROs, CRMs, Clinical data mangers, university students etc. These participants were chosen due to their significant roles and expertise in the clinical trial process.

2. **Data collection through interviews, surveys & Q/A format**: To collect data, a combination of google form survey, zoom audio/video calls and Q/A format interviews was conducted with the selected participants. This approach allowed for a diverse range of perspectives and provided a conducive environment for relevant information.

3. **Google form survey & interview protocol**: To ensure consistency and uniformity in data gathering, an interview protocol and survey was developed and adhered to throughout the process. This protocol consisted of a set of carefully crafted questions aimed at gaining insights into the challenges and environmental factors influencing use of AI (ML & RPA) Phase III clinical trials in India.

4. **Probing inquiries**: To dive deep into deeper into the concerns raised and acquire comprehensive information, probing inquiries were used during the interviews. These open-ended questions encouraged participants to elaborate on their responses, leading to more valuable qualitative data.

5. **Data Saturation**: Interviews and surveys were conducted until data saturation was achieved, meaning that further interviews were no longer producing significant new information. This ensured that a comprehensive understanding of the participant perspectives was attained.

6. **Zoom audio/video call interviews**: A total of seven participants to part in qualitative research of the project of which five zoom audio/video call and two were Q/A format. These zoom meetings and Q/A format gave vital insights into the difficulties, situations, and problems related to use of AI (ML & RPA) Phase III clinical trials in India.
7. **Framing research phases**: The knowledge gained from the interviews played a pivotal role in shaping the subsequent phases of the research, including survey and Q/A format, as well as data analysis.

Overall, mixed methodological approach (abductive method) involving zoom video/audio calls, surveys and Q/A format with targeted participants in use of AI (ML & RPA) Phase III clinical trials in India provided valuable first-hand experiences and opinions. The data collected served as a comprehensive basis for the research, aiding in understanding the challenges, perspectives, and potential improvements in managing phase III clinical trials in India. The combination of qualitative insights from interviews and quantitative data from surveys ensured a robust and well-rounded analysis of the research topic.

Furthermore, the conceptual framework (figure 16) provides a structured and comprehensive overview of the role of AI, ML, and RPA in Phase III clinical trials, highlighting their potential to revolutionize clinical research in India while acknowledging the importance of addressing ethical concerns and technological advancements for effective implementation.

3.2 Research Methods:

For data collection, mixed-method approach was used, qualitative data was collected through audio-visual recordings of interviews with participants, including clinical data managers, AI experts, university students, and employees with experience in clinical trials and quantitative data was collected through google form survey by the targeted participants. These interviews and survey provided the information about their perspectives and experiences related to the application of AI (ML & RPA) Phase III clinical trials in India. In these interviews and survey, the primary focus was on the RPA and ML on clinical trials. As most of the participants are experts and currently conducting clinical trials with RPA and ML in India. So, that really

helped to gather the significant and accurate information about the implementation of AI in clinical trials in India.

To effectively structure the survey, the research identified recurring themes and significant areas of interest based on research questions. These questions served as the foundation for formulating the survey form. The questions were carefully designed to cover a wide range of topics, encompassing the application of AI (ML & RPA) phase III clinical trials in India which include challenges encountered, benefits, regulatory compliance, resource allocation, protocol development, data management, patient recruitment, personalized treatment, and collaboration among stakeholders. To ensure the survey's clarity and relevance for the target audience, the questions were customized. The survey employed a combination of multiple-choice, Likert scale, and open-ended questions. This approach allowed for quantitative evaluations insights to be gathered.

While for the qualitative approach, interviews were conducted through Zoom audio/video calls and Q/A format through emails. The target participants that were included researchers, CROs, CRMs, clinical trial coordinators (Data co-ordinator & Research co-ordinator) or managers, university students, and AI experts, Clinical experts & data managers. The gathered information clarified the concept of ML & RPA on clinical trials in India. The interview protocol was designed based on research questions to collect the relevant information. The questions were aimed to focus on the areas like patient recruitment, personalized treatment, patient data analysis, concept of ML & RPA and future perspective of AI etc. The interviews provided enough data for qualitative evaluation insights.

In a mixed-methods approach that is abductive method was used, a sampling plan can use parts of both probability sampling and non-probability sampling. Sequential sampling is when you use probability sampling for one step (like random sampling for qualitative interviews) and non-probability sampling for the next step (like a survey). Triangulation uses different sample methods for qualitative and quantitative parts, such as purposive sampling for qualitative research and probability sampling (e.g., simple random sampling, stratified sampling) for quantitative research. With embedded sampling, one type of data collection is put inside another. One way uses probability sampling, and the other uses purposive sampling. Setting quotas for characteristics of interest and choosing participants on purpose to meet those quotas is how quota sampling ensures diversity and fair representation.

3.3 Protocols before data collection

The target participants that were included researchers, CROs, CRMs, clinical trial coordinators (Data co-ordinator & Research co-ordinator) or managers, university students, and AI experts. The reason behind this was the topic is inclined toward the healthcare sector and getting information for healthcare, clinical trials is possible only with the people who already work there or have worked there. As the information that is needed was difficult for the common man to answer without experience.

By engaging in interviews and surveys with these experienced professionals, the aim was to obtain in-depth information about their first-hand experiences and perspectives regarding the use of AI machine learning & RPA in Phase III clinical trials. By Conducting both interviews and surveys increased the chance of getting more data and at least a response rate of 50-60%. For getting a better response rate. Surveys and interviews are kept anonymous for participants so they will feel free to answer the questions.

As part of participant recruitment strategy, Google forms were conducted. This procedure enables the design and distribution of the survey questionnaire to many individuals. The Google form survey URLs were distributed via multiple channels, including emails, LinkedIn, and WhatsApp, in order to maximize the reach. For directly contacting potential participants who have experience in the topic or who are experts in the field by using these channels. Personal emails explaining the purpose of research and requesting their participation in interviews were conducted. This strategy helped in more communication and increased the possibility of receiving responses from individuals with expertise in AI in clinical trials.

For conducting interviews, the (Interview questionnaire) was prepared for participants & this section provides an in-depth analysis of the transformative impact, expected benefits, current challenges, and prospects offered by artificial intelligence (AI) and robotic process automation (RPA) in the field of Phase III clinical trials conducted in India. The objective is to highlight how these advancements are positioned to transform the area of clinical research and enhance patient outcomes.

LinkedIn was used as a second source for participant recruitment. For contacting more participants professional network like LinkedIn was used for posting or send direct messages containing the survey link. LinkedIn provided a platform where interaction with the pharmaceutical industry, clinical research, and related professionals became easy. This strategy allowed to access a wide range of potential participants with useful information and opinions.

For interviews, a more personalized approach is necessary. After contacting potential participants through LinkedIn or email, initiation to contact for discussing the research idea was conducted and requested their permission to arrange an interview. Interview's purpose and scope, highlighting the value of their knowledge and contribution to the research were discussed. After that interview sessions were scheduled at mutually convenient times following their approval. Accurate communication and respect participants' time and preferences throughout the recruitment process were guaranteed. Respecting participants time, they may have busy schedules, so their participation in surveys and interviews was ensured according to their own time and convenience.

Google forms, emails, LinkedIn, and WhatsApp were used to reach a wide variety of participants who provided valuable points of view regarding the use of AI in Phase III clinical trials in India. The consent of participants was the most important aspect of interviews to approach those interested to guarantee a respectful and consent-based recruitment process.

3.4 Conduct during data collection

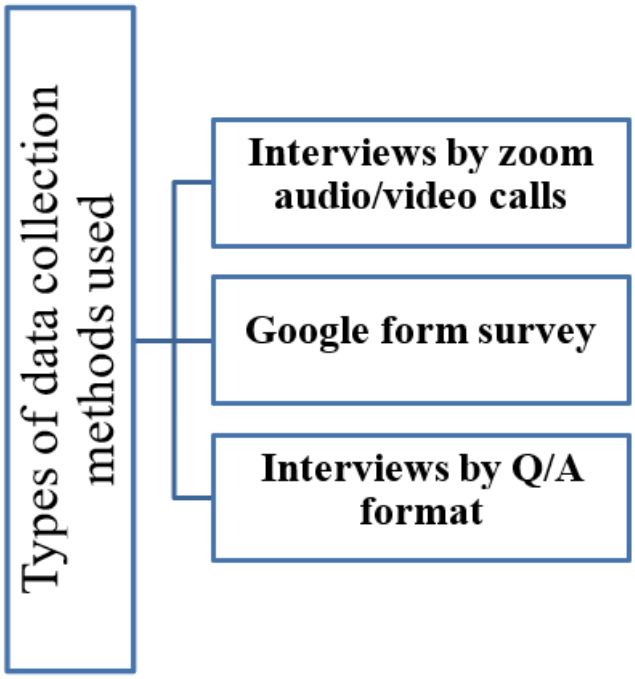

Figure 6: Types of Data Collection Methods

For the quantitative component, a structured survey questionnaire was prepared to collect data on AI's influence on trial efficacy and outcomes. The qualitative component consisted of semi-structured interviews with researchers, clinicians, regulators, and AI technology providers involved in phase III clinical trials in India.

Google forms was used for collecting responses from participants. This allowed the survey questionnaire to be designed and distributed to many people. The survey provided the quantitative data from twenty-five respondents in percentage values. For analyzing the data descriptive analysis method was used with the help of SPSS software. Basically, SPSS is an open source analyzing software provided by IBM. Once the data was imported to software in excel format, there are lots of tools available to analyze the data and represent it our required format.

It was decided that interviews required a more personal approach. After contacting potential participants through LinkedIn or email, the first call was made to discuss the research concept and request permission to conduct interviews. There were seven total interviews that was conducted which include five zoom video interviews and two were in Q/A format. The purpose and scope of the interview were described, highlighting the significance of their knowledge and contribution to the research. Following their approval, interview sessions were scheduled at mutually convenient periods. Throughout the recruitment procedure, participants' time and preferences were respected, and accurate communication was ensured. Recognizing that participants may have busy schedules, efforts were made to ensure that they could complete

surveys and interviews at their own time.

Google Forms, emails, LinkedIn, and WhatsApp were used to reach a large number of participants who could offer valuable input on the use of AI in Phase III clinical trials in India. To assure a respectful and consent-based recruitment process, personal contacts were made with those interested.

The audio-visual recordings were initially stored on a digital device, such as a personal computer, during the interview sessions for extracting the relevant data. Once the recordings were saved and transferred to their supervisors, they will be deleted from researchers PC to ensure data security and privacy. Additionally, to ensure data backup, a copy of the recordings will be saved on Griffith's One Drive, a secure cloud storage platform. For data analysis, transcripts of the interview conversations were prepared in Microsoft Word. These transcripts captured the interviews and provided a textual representation of the data. Like the audio-visual recordings, the transcripts are stored on researchers PC and backed up on Griffith's One Drive.

3.5 Protection of dissertation data

Information was collected and stored using password protection. The information was proposed to be stored for two years before being destroyed. Data was handled using General Data Protection Regulation (GDPR) and national Data protection laws. Information provided by the participant was stored adhering to Griffith College Dublin/ Innopharma Education policies and in alignment with GDPR and Data Protection. Data retention is transparent and lawful in this research. All raw data obtained including signed consent forms and audio recordings stored confidentially until the end of the research and until the exam board confirms the results of the dissertation. This raw data will be stored in an appropriate folder on Moodle for archiving purposes. Limited personnel have access to these files, but they can be reviewed by myself, my supervisor, a second reader, or an external examiner if required during the retention period.
Personal data was anonymized at the earliest opportunity in this research study. Data will not be shared with anyone without the prior consent of the supervisor or the college authority. GDPR and national data protection guidelines were followed for the protection of individual information. As this research is for a dissertation, all collected data, including signed informed consent forms, participant information letter, original audio recordings, and interview transcriptions kept in password-protected files on researcher laptop, which is locked with

restricted access, and will be stored for a period of two years following the end of the research and post conferral of results of the dissertation by the exam board. Raw data including transcripts of interviews in which all personal identifying information has been removed will be uploaded to Moodle in a password-protected folder and will be accessible to the supervisor, the second reader, or an external examiner. The results of this study will be submitted in final dissertation.

3.6 Ethics-Related Factors:

For recruiting participants for surveys, Google forms were conducted and send them with the help of emails, LinkedIn, and through WhatsApp. It did not take so much time so participants filled in the answers according to their pace. While for interviews it needs to reach participants first through LinkedIn and emails to discuss idea and to get their consent only then need to schedule an interview with them.

The interview participants were provided with a document named the "Participant Information Letter," which clarified the methodology of the research and outlined the nature of their involvement in the study. Participants were additionally requested to provide their signature on a "Informed Consent Form" as an indication of their comprehension and voluntary agreement to participate in the research.

Before disclosing any information, all participants provided their signatures on the Informed Consent Form. The participants were aware of their authority to withdraw their involvement at any given moment or not respond to specific inquiries without facing any negative consequences. In case individuals decided to withdraw the collection of the interview data, a specified timeframe of two weeks was provided for them to communicate their decision. Afterward, their information would be deleted from our records.

All participants were aware that their personal information would be held under strict confidentiality. In distributing the findings of our research, strict procedures were implemented to ensure the confidentiality and anonymity of all participants, thereby safeguarding their true names and personal information from disclosure. The names of the individuals involved were altered and measures were taken to ensure that no identifying information was disclosed during the interviews. The participants consented to the audio recording of their interviews, with the possibility of selected parts being included into the dissertation and presentation. Several

participants expressed a preference for responding to interview questions by email rather than engaging in video or audio calls. Additionally, the participants provided their signatures on the consent forms.

The researchers had no expectation that participants would disclose any material that would violate their company's policies or reveal confidential information. In case that an individual expresses concern for their own or another person's safety, it is essential to notify the appropriate authorities, irrespective of their consent. The completed consent forms and original recordings were securely stored on a laptop protected by a password for a duration of two years subsequent to the interview. The interview transcript, with all personally identifiable information removed, will be retained until September 2025.

The decision made to use a mixed-method approach was motivated by the certainty that it would allow to not only respond to the fundamental "why" questions that underlie the based-on AI transformation of Phase III trials, but also to the "what" and "how" questions that support them. The base for a firm conclusion that include both actual proof and specific insights are established by this methodological approach.

The combination of quantitative data and qualitative narrations helped to structure as the next chapter, "Findings and Analysis." A broad perspective of AI's impact on clinical trials is provided by the combination of the factual and conceptual aspects. A complete understanding of the implications, difficulties, and opportunities presented by AI in regard to Phase III clinical trials made possible by the conclusion of this study approach and resulting findings.

Chapter 4: Findings & Analysis

This chapter reveal the conclusion of our study on AI and Phase III clinical trial characteristics through quantitative and qualitative analysis. The quantitative findings show statistically significant trends, proving AI's revolutionary potential, while participants' qualitative perspectives highlight ethical problems, operational challenges, and future prospects. This chapter expands the study of AI's impact on Phase III trials and leads to the next chapter, where these insights form the basis for informed recommendations and a conclusive summary of our research study.

4.1 Survey enabled data collection:

The study implemented a standard survey to collect quantitative information regarding the acceptance and usage of AI technologies, along with the challenges and possibilities related to the adoption of AI in clinical trials.

The main findings of the study are as follows:

4.1.1 The use of AI (AI) in phase III clinical trials:

According to the survey findings, an important percentage of respondents, specifically 78.3%, reported the adoption of machine learning algorithms in Phase III trials, indicating broad acceptance of this technology. The importance of robotic process automation (RPA), which was mentioned by 56.5% of participants, was also a significant factor as shown in figure 7.

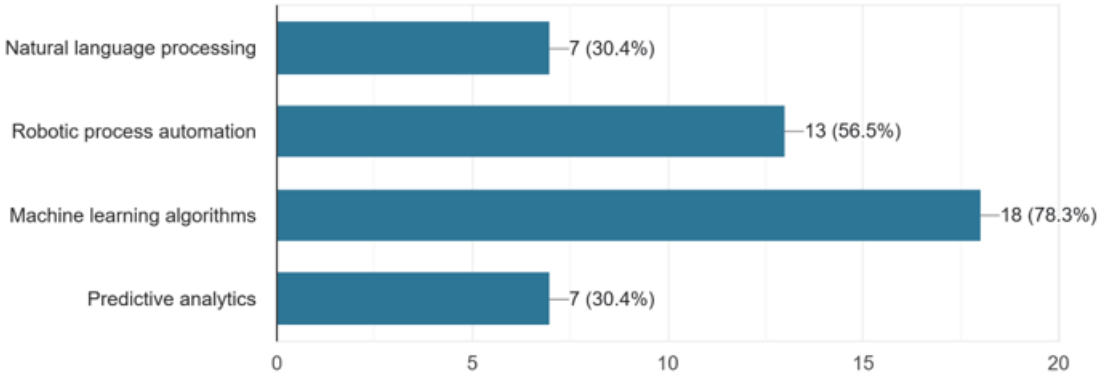

Figure 7: Most used Algorithm in CT

4.1.2 Difficulties with AI Application

Four key issues were identified based on the experiences of the respondents. The challenges identified in the study encompassed various aspects. These included problems with standardization and data quality (47.8%), regulations and compliance (52.2%), a lack of qualified workers (30.4%), and the difficulty of combining AI technology with current systems and processes (39.1%).

The study provided information on four major ethical dimensions that require concern while implementing AI technology. The factors mentioned earlier included the aspects of transparency of AI algorithms, informed consent and patient privacy, fairness and bias in AI decision-making, and accountability and responsibility for AI outcomes.

The survey findings indicate that AI played an important role in patient management throughout Phase III clinical trials, as reported by 30.4% of the respondents. In addition, figure 8, bar chart depicts 47.8% of respondents said they had seen some impact, while 13% said they had seen none at all.

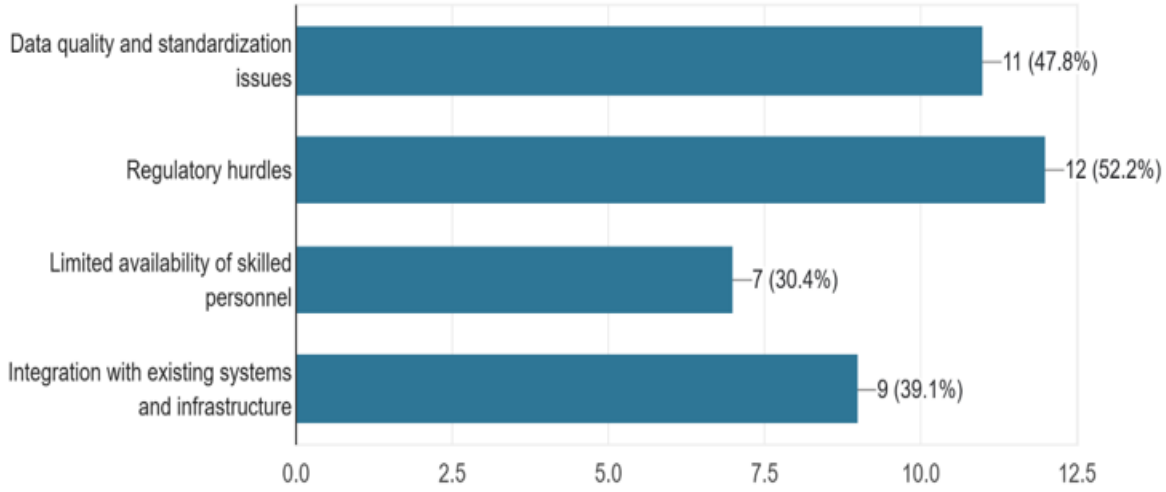

Figure 8: Challenges faced while implementing AI in CT in India

Objective 5: This study also aims to investigate the possibilities of future developments and prospects for AI (machine learning and robotic process automation) in Phase III clinical trials in India.

4.1.3 Future Opportunities for AI:

A large proportion of participants (78.3%) gave a positive attitude towards the possible chances for AI in Phase III clinical trials conducted in India. This observation suggests that there is an accepted belief in the considerable capacity of AI-powered developments to bring about major improvements in the field of healthcare research.

According to the respondents, the areas that are expected to receive the most benefits from future breakthroughs in AI are real-time safety monitoring (60.9%) and data evaluation and knowledge development (65.2%). The results mentioned above highlight the capacity of AI to improve safety protocols and offer timely analysis for decision-making based on actual data.

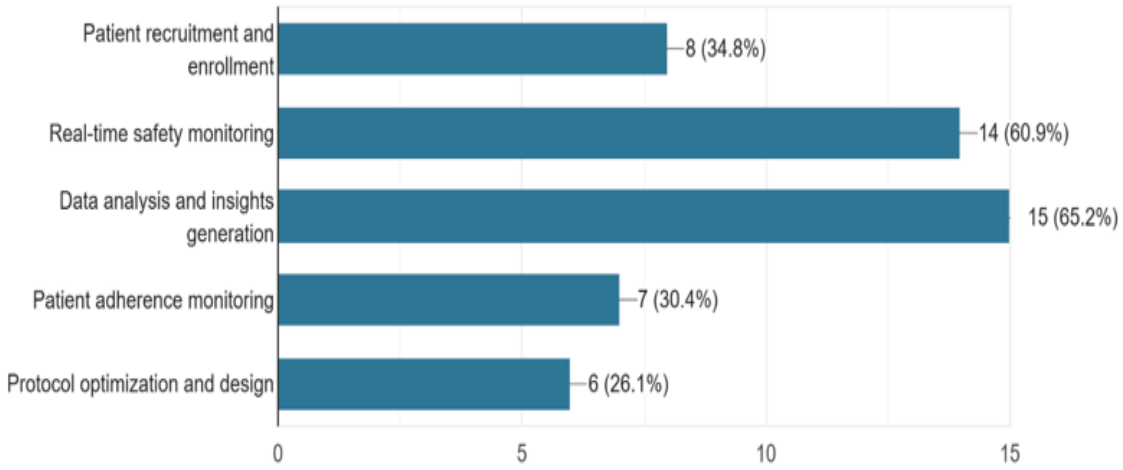

Figure 9: Future Advancement in CT

Research objective 3: The purpose of this study is to investigate how AI (including machine learning and robotic process automation) can help with patient care and adherence monitoring during Phase III clinical trials in India.

4.1.4 Factors to Consider in Assessing the Feasibility of AI Implementation:

Essential factors are taken into consideration during the evaluation of the feasibility of AI implementation in Phase III clinical trials involving cost-effectiveness and return on investment (69.6%), compatibility with existing systems (56.5%), access to dependable and comprehensive data (52.2%), respect to regulatory compliance and guidelines (26.1%), and ethical

considerations and safeguarding patient privacy (17.4%).

The areas in which AI is believed to have the most impact in Phase III clinical trials and healthcare are drug safety monitoring (43.5%) and precision medicine (30.4%). These results show the potential of AI to significantly transform drug safety protocols and personalize medical treatments according to the specific characteristics and requirements of individual patients. According to the survey findings, more than half of respondents (47.6%) identified Phase III clinical trials as the stage the chances to gain the greatest advantage from the application of AI . This acceptance indicates the potential impact that AI might have on this important stage of healthcare research.

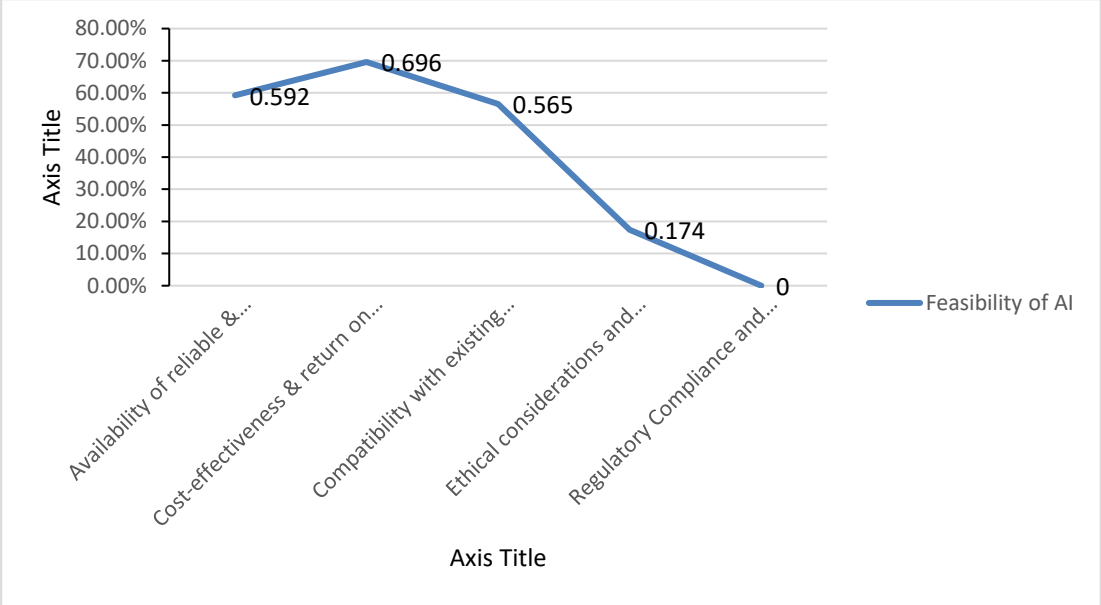

Figure 10: Feasibility of AI in CT

In conclusion, the survey results provide valuable information into the wide development and usage of AI technologies, including machine learning algorithms and robotic process automation (RPA), in Phase III clinical trials conducted in India. The successful implementation of AI requires the careful study and resolution of various difficulties, including those associated with data quality, regulatory compliance, specialized expertise, and ethical considerations. The positive opinions expressed by healthcare professionals and the acceptance of specific fields that are prepared to benefit from future breakthroughs in AI show the potential of AI in enhancing patient care, streamlining research efficacy, and improving drug development procedures. The results of the survey provide a strong basis for further investigation and implementation of AI technology in clinical trials, supporting progress based on AI healthcare improvements and personalized therapies for patients in India

4.1.5 Descriptive Statistical Analysis:

A statistical test that was used to acquire a deeper understanding of the correlations and patterns present in the collected data. The purpose of this method was to understand the accuracy of the findings. With the above data the following analysis came with the help of SPSS software. Basically, SPSS is an open source analyzing software provided by IBM. Once the data was imported to software in excel format, there are lots of tools available to analyze the data and represent it our required format. There is a representation of only those data which is more appropriate and suitable for the research topic. Here the data representation by bar chart and frequency table as follows:

Frequency table of graphical representation of enlisted questions:

Statistics

		Disadvantages in the adoption of AI when monitoring and safety analysis.	Advantages of using AI when monitoring and safety analysis.	Ethical considerations when integrating AI.	Benefited segments from future advancements in AI.	ML & RPA contribution to personalized treatments.
N	Valid	25	25	25	25	25
	Missing	0	0	0	0	0

Bar Charts:

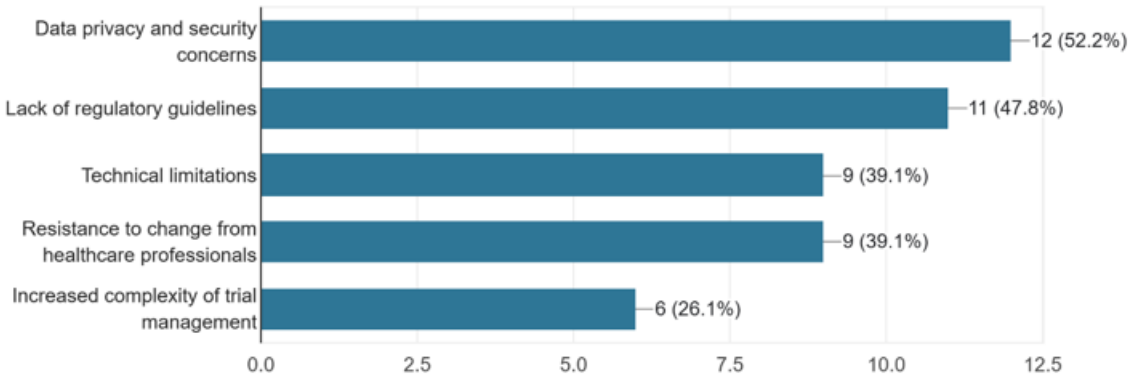

Figure 11: Disadvantages of AI for monitoring and safety analysis

Figure 11 methodically lists the drawbacks of using AI for clinical trial monitoring and safety analysis. This figure examines algorithmic bias, interpretability issues, data privacy problems, and expert validation. This also shows the challenges of using AI for monitoring and safety analysis by categorizing and explaining these drawbacks.

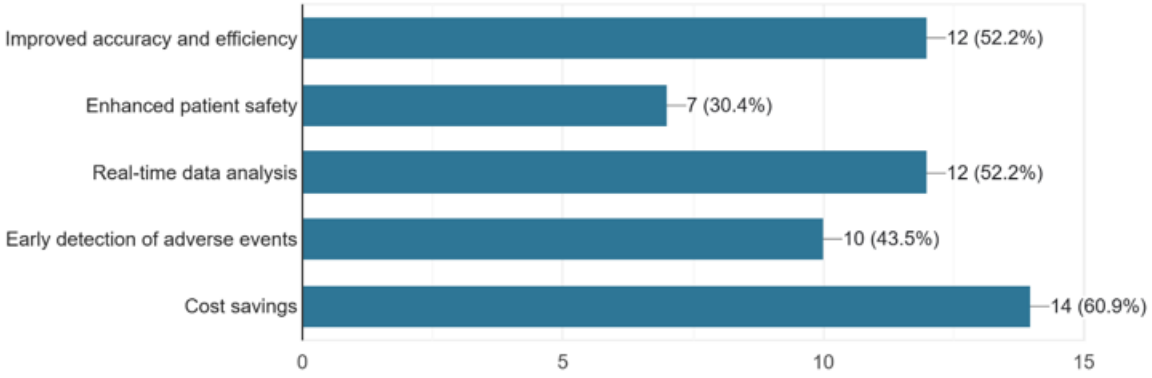

Figure 12: Advantages of AI for monitoring and safety analysis

Figure 12 highlights the benefits of using AI for clinical trial monitoring and safety analyses. This figure lists real-time data insights, early adverse event identification, better signal detection accuracy, and patient safety through a detailed descriptive analysis. This shows how AI improves monitoring and safety analysis by breaking down these benefits.

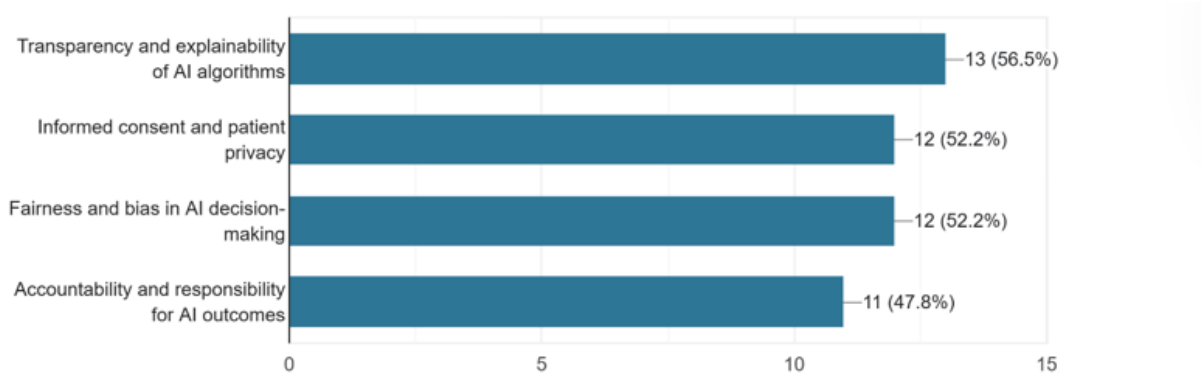

Figure 13: Ethical considerations in integrating AI

Figure 13 carefully examines the ethical issues of clinical trial AI integration. The figure tackles data privacy, informed consent, algorithmic decision-making openness, bias, and patient autonomy. The following figure provides an organized summary of these factors, revealing the ethical issues that must be considered while integrating AI.

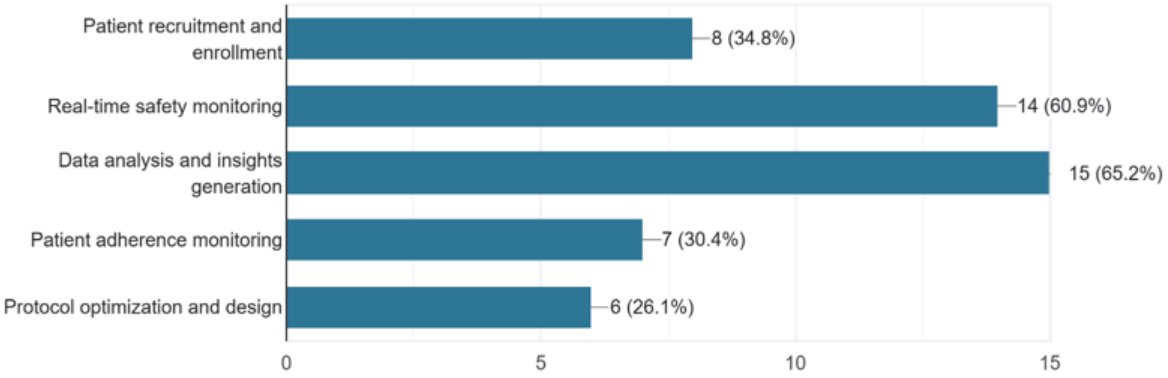

Figure 14: Benefited segments from future advancements in AI

A full review of clinical trial segments that will benefit from AI improvements is shown in Figure 14. The table lists patient recruiting, real-time monitoring, adverse event prediction, and physician data-driven decision assistance as potential beneficiaries. Figure 14 shows where AI's developing capabilities can improve clinical trial techniques.

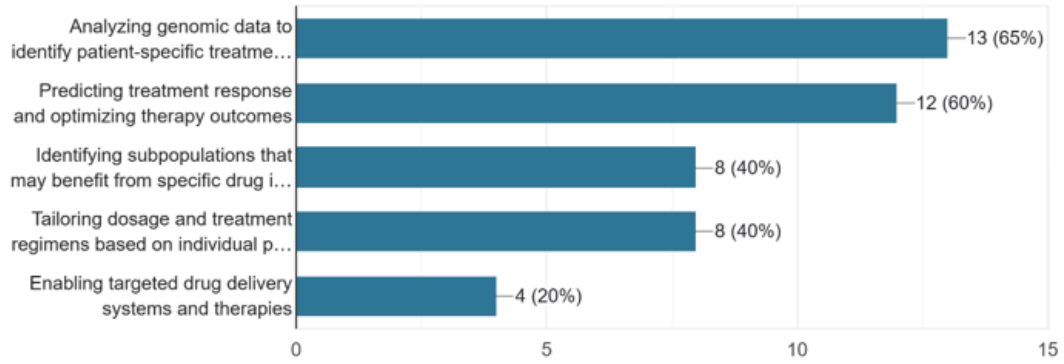

Figure 15: ML & RPA contribution in personalized treatment

Figure 15 details how machine learning (ML) and robotic process automation (RPA) contribute to tailored clinical trial treatments. The figure shows how ML helps with patient stratification, treatment response prediction, and dose optimization, while RPA accelerates administrative processes for personalized treatments. Figure 15 shows how ML and RPA synergistically improve clinical trial customized medicines by breaking out their contributions.

Frequency table of tabular representation of enlisted questions:

Statistics

		Challenges in implementing AI.	ML or RPA in clinical trials.	Healthcare professional's adoption of AI.
N	Valid	25	25	25
	Missing	0	0	0

Challenges in implementing AI:

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Data quality and standardization issues	4	16.0	16.0	16.0
	Data quality and	3	12.0	12.0	28.0

	standardization issues, Regulatory hurdles				
	Data quality and standardization issues, Regulatory hurdles, Integration with existing systems and infrastructure	2	8.0	8.0	36.0
	Data quality and standardization issues, Regulatory hurdles, Limited availability of skilled personnel, Integration with existing systems and infrastructure	2	8.0	8.0	44.0
	Integration with existing systems and infrastructure	2	8.0	8.0	52.0
	Limited availability of skilled personnel	3	12.0	12.0	64.0
	Limited availability of skilled personnel, Integration with existing systems and infrastructure	2	8.0	8.0	72.0
	None	1	4.0	4.0	76.0
	Regulatory hurdles	4	16.0	16.0	92.0
	Regulatory hurdles, Integration with existing systems and infrastructure	2	8.0	8.0	100.0
	Total	25	100.0	100.0	

Table 5: Challenge in implementing AI

Table 5 illustrates the challenges of implementing AI, ML, or RPA in clinical trials. The table carefully describes data privacy risks, algorithmic bias, integration challenges, regulatory compliance issues, and the need for interdisciplinary collaboration. Table 5 categorizes these problems to provide a structured understanding of the complex constraints to integrating AI-based technology into clinical trial operations.

ML or RPA in clinical trials

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Machine learning algorithms	6	24.0	24.0	24.0
	Machine learning algorithms, Predictive analytics	1	4.0	4.0	28.0
	Natural language processing	1	4.0	4.0	32.0
	Natural language processing, Machine learning algorithms	2	8.0	8.0	40.0
	Natural language processing, Robotic process automation, Machine learning algorithms	1	4.0	4.0	44.0
	Natural language processing, Robotic process automation, Machine learning algorithms, Predictive analytics	3	12.0	12.0	56.0
	Predictive analytics	2	8.0	8.0	64.0
	Robotic process automation	2	8.0	8.0	72.0
	Robotic process automation, Machine learning algorithms	4	16.0	16.0	88.0
	Robotic process automation, Machine learning algorithms, Predictive analytics	2	8.0	8.0	96.0
	Robotic process automation, Predictive analytics	1	4.0	4.0	100.0
	Total	25	100.0	100.0	

Table 6: ML & RPA in CT

A full descriptive analysis of healthcare professionals' AI technology adoption variables is shown in Table 6. Accessibility assessments, perceived benefits, training requirements, and job displacement issues are examined in the table to determine adoption. Table 6 gives an in-depth analysis of attitudes and beliefs that impact AI integration in healthcare by examining these elements.

Healthcare professional's adoption of AI

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid		4	16.0	16.0	16.0
	Embrace and support AI integration in clinical trials	8	32.0	32.0	48.0
	Have concerns but willing to explore AI's potential benefits	7	28.0	28.0	76.0
	Lack awareness and understanding of AI's role in clinical trials	3	12.0	12.0	88.0
	Show resistance and scepticism towards AI-driven approaches	2	8.0	8.0	96.0
	Unsure/not applicable	1	4.0	4.0	100.0
	Total	25	100.0	100.0	

Table 7: Healthcare professional's adoption of AI

Table 7 systematically describes the issues healthcare workers face while using AI technologies. The table describes these issues, which include resistance to change, AI unfamiliarity, data security concerns, and AI-assisted diagnostics accuracy concerns. Table 7 breaks down these issues to explain the complicated dynamics of encouraging healthcare professionals' AI adoption.

4.2 Interview-enabled data collection:

The interviews conducted with Clinical Research Organizations (CROs), stakeholders, and master's students have revealed significant changes in opinions regarding the advantages of AI, machine learning, and robotic process automation (RPA) in Phase III clinical trials. The participants agreed that these technologies have the capacity to transform the management of clinical trial data by improving efficiency, data quality, and overall trial efficacy.

Participants	Job Profile	Discussion topics
Participants 1: Manu Somanath	Clinical Data Manager (CDM)	Discussed about benefits of AI in future clinical trials for example: patient recruitment, data accuracy process and also about cost efficiency
Participants 2: Anonymous	Clinical Data Manager	Focus was on the benefits of RPA in repetitive tasks in clinical trials and efficiency of automation
Participants 3: Anonymous	Working under CDM	Analyze why India regarded as Clinical trial hub
Participants 4: Prakhar Tarun	Ex senior software engineer currently MS student	Exploration about Machine learning to prevent clinical trials failure rates and data collection
Participants 5: Rashi	Data co-ordinator	Consideration of EMR (Electronic medical record) & to capture data securely
Participants 6: Nitesh	Research co-ordinator	Discussion about reducing cost of productivity in Clinical trials &

		developing personalized treatment
Participants 7: Ankush Mittal	Clinical data project manager	Disadvantages of AI as it will decrease the interaction between patient and investigators

Table 8: Participants profile and discussion (source: developed by author)

The interviews were conducted about the potential applications of robotic process automation (RPA), artificial intelligence (AI), and machine learning (ML) in Phase III clinical trials in India with seven different people. The implementation of emerging technologies has the promise of facilitating beneficial transformations in various aspects of the trial process, including data management, patient recruitment, and cost effectiveness. Table 8 shows the designation of the recruited participants and the topic of discussion in zoom interviews and by Q/A format.

During all of interactions, an individual, Participant 2, provided a detailed description on how it works of Robotic Process Automation (RPA) within the field of clinical trials. They revealed the efficacy of Robotic Process Automation (RPA) in rapidly and accurately handling repeated activities, hence enhancing the overall efficiency of trial management processes. Hence participant discussed about the "In, streamlining the data. Because it has to maintain accuracy and reduce manual human errors that happens it can be So another thing that We're talking about would be like based on a first point Could be automating data cleaning, because data cleaning is a previous process when it comes to data management and this task takes a lot of effort within my company. So, we have started implementing RPA so it can be programmed to identify".

Participant 4 offered valuable insights regarding the field of Machine Learning (ML). It stressed the importance of machine learning (ML) in the analysis of vast quantities of data, enabling the identification of patterns that may avoid human perception. Participant quoted "We have an abundance of data, but sorting through this sea of data to locate the specific relevant information is difficult—it's similar to searching for a needle in a stack." This comparison captures the difficulty of data analysis in the current research environment, where the capacity to generate valuable conclusions from an abundance of data is of paramount significance. Implementing this approach can contribute to maintaining data accuracy and minimizing the chance of errors

during Clinical trials. More discussion was about data analysis and security purpose.

Even so, there were others with whom interviews were who expressed concerns regarding these emerging technologies. Issues were expressed by participants 1 and 7 over the potential dependency on artificial intelligence (AI). They noticed that if AI took control, there may be less human involvement with patients, which could be an issue. Particularly participant 1 addressed "The cost is less. So, when you when you plan to connect a trial in India. If you are spending $100 in out-of-India countries but within space spending $50 or $700, you can get that trial done, perspective, because of the cost, where the cost effect is very cost-effective". Additionally, it was predicted that the investigators, who assume the role of trial leaders, may encounter challenges in collaborating with artificial intelligence. Additionally, the individuals also expressed an opinion that artificial intelligence (AI) has the potential to reduce their stress levels. This opinion is particularly strong due to their years of working in the industry, which has exposed them to the various difficulties associated with AI. While participant 7 explored the idea of "reducing stress and burden on them and also about the disadvantage of AI as it will minimize the patient investigator interaction process".

The remaining Participant 5 and 6 provided the information through Q/A format and mentioned about the EMR (Electronic medical record), reducing cost of productivity, developing personalized treatments and about capturing data safely and swiftly. While participant 3 expressed different points of view. Participant 3 mentioned "I think it's now in India is considered as a crucial clinical trial market because it has a vast population as you also and the thing is that, the patient, you like, or diverse, there's also diverse patient pool because they have a patient from a lot of background, a lot of different lifestyles,". It was considered that the considerable population of India provides it an ideal place for conducting trials and that the use of artificial intelligence (AI), machine learning (ML), and robotic process automation (RPA) may enhance the precision and efficiency of the procedure. Participant 5 revealed about "Predict outcomes in clinical trials, leading to faster drug approval times, lower costs, and more funding to develop new treatments. The researchers believed that the implementation of these technologies has the potential to speed up the identification of appropriate candidates for clinical trials and enhance the precision with which these studies are conducted." When considering the broader perspective, there was absolute acceptance regarding the significance of employing these new innovations in a responsible manner. The necessity for well-defined rules and regulations to ensure the ethical execution of tasks was highlighted. While participant 6 provided an insight on

“This huge dataset, which includes genetic information and electronic health records like medical history and allergies, has allowed clinicians to look more closely at individual patients and their conditions, in ways that they couldn’t have done before.” The significance of safeguarding patient data and ensuring adequate training for anyone involved in the use of these technologies was also highlighted.

In summary, it was collectively agreed that the strategic use of AI and RPA has the potential to improve the methodologies employed in clinical trials in India. This has the potential to result in improved healthcare outcomes and improved patient access to innovative therapies. Still, it is crucial to consider the prospective obstacles and ethical dimensions in order to ensure that new technologies genuinely provide benefits for all those concerned.

Research objective 1: The purpose of this research is to investigate the particular applications of AI (machine learning and robotic process automation) in Phase III clinical trials in India.

4.2.1 Emergence of acknowledgment for AI, ML & RPA benefits:

Benefits were acknowledged in many areas, including medication discovery, protocol optimization, patient recruiting, and data analysis. AI (AI) and machine learning (ML) have been recognized as highly effective instruments for using large quantities of clinical data produced during trials. These technologies enable researchers to detect patterns, correlations, and potential dangers that may otherwise remain undetected. The application of Robotic Process Automation (RPA) has been recognized as highly valuable in the automation of repetitive and boring operations, leading to enhanced efficiency in data processing, diminished occurrence of human errors, and the allocation of resources towards more crucial responsibilities.

4.2.2 Enhancing Clinical Trials with AI and ML development:

The interviewees highlighted the wide range of applications for AI (AI) and machine learning (ML) in optimizing every aspect of clinical trials. AI algorithms that evaluate patient data, medical records, and demographic data to find interested candidates could greatly help patient recruiting, which has historically been a time-consuming and expensive procedure. Machine learning models have the potential to be provided in order to provide predictions on the eligibility of patients for certain clinical trials, hence enhancing the rates of success in recruitment.

4.2.3 Harnessing RPA’s potential in managing Clinical Trial Data:

The optimization of the trial design was also acknowledged as a significant area of influence. The use of AI (AI)-powered models and predictive modelling techniques have the potential to enhance the design of clinical trials, making them more efficient and adaptable. This, in turn, can lead to a reduction in the necessity for significant and expensive protocol changes. Moreover, the use of risk prediction models empowered by AI can contribute to the early detection of potential safety issues during clinical trials, resulting in improved safety measures and expedited identification of adverse events.

The participants collectively highlighted the significant importance of Robotic Process Automation (RPA) in the administration of clinical trial data. The utilization of Robotic Process Automation (RPA) has played a crucial role in enhancing the efficiency of the data management process by automating processes that are repetitive and consume significant amounts of time. For example, the automation of data gathering from many sources, including electronic health records, laboratory information systems, and patient-reported outcomes, can guarantee rapid availability of accurate information for analysis.

Data transformation and cleaning were also impacted by RPA. Through the implementation of automated procedures for data validation and cleansing, researchers are able to guarantee the collection of data of superior quality, hence diminishing the probability of detecting mistakes and inconsistencies. Moreover, the introduction of Robotic Process Automation (RPA) facilitated the generation of real-time reports and the monitoring of adverse occurrences, resulting in enhanced response times and improved safety oversight throughout the trial.

4.2.4 India's Strategic Significance as a Clinical Trial Market:

The relevance of India as a prominent clinical trial market was highlighted during the interviews. The large and diversified population facilitated the collection of a broad spectrum of patient profiles, hence enabling researchers to effectively enlist patients for trials that demand certain demographic criteria. In addition, the comparatively reduced expenses associated with conducting clinical trials in India in comparison to other geographical areas provided a financially efficient alternative for pharmaceutical corporations and researchers.

AI, machine learning, and robotic process automation (RPA) possess the capability to take advantage of these benefits in order to accelerate the process of patient recruitment and enhance the processing and analysis of data. AI (AI) algorithms have the capability to effectively identify

suitable trial participants from a large pool of patients. Additionally, robotic process automation (RPA) can automate the data management process, resulting in a reduction of human error and the time required for trial completion.

Research objective 2: This study aims to determine the benefits and drawbacks of using AI (machine learning and robotic process automation) for real-time monitoring and safety analysis in Phase III clinical trials in India.

4.2.5 Tackling Challenges in implementing AI:

Challenge 1: Regulatory & Ethical compliance

Interviewees identified several challenges that must be solved for AI and RPA to be successfully used in clinical trial data management, despite the enthusiasm for their adoption. One of the major hurdles observed included effectively dealing the regulatory framework and ensuring adherence to ethical principles. As improvements in AI and ML technologies continue, regulatory authorities encounter emerging ethical and privacy concerns.

Challenge 2: Collaborations with regulatory compliance

In order to address these problems, it is necessary for researchers and stakeholders to engage in close collaboration with regulatory authorities in order to develop specific requirements related to the use of AI and RPA in clinical trials. Also, it is important to promote collaboration in order to enhance the establishment of complete data privacy and security procedures, thereby ensuring the protection of patient information throughout the duration of the research.

Challenge 3: Skilled Workforce

Another difficulty that was found linked to the requirement for professional staff with the ability to create, implement, and sustain AI systems. The technology industry in India, which is experiencing rapid growth, has the potential to significantly contribute to tackling this problem through strategic investments in specialized training and educational initiatives that prioritize the integration of healthcare and AI.

Research objective 4: In terms of India's healthcare system, investigate the ethical considerations and challenges connected with the use of AI (machine learning and robotic

process automation) in Phase III clinical trials.

4.2.6 Ethical Considerations in AI and ML Usage:

The interviews provided details about the important role of ethical considerations in the integration of AI and ML technologies within the context of clinical trials. The discussions continually highlighted the need of upholding patient privacy and obtaining informed permission. The use of AI algorithms in the processing of extensive patient data introduces greater potential for accidental release of sensitive information or breaches of patient privacy. The interviewees highlighted the importance of using thorough data encryption methods and implementing strong security measures in order to safeguard patient identities and medical records.

The ethical need for transparency and interpretability in AI models was also addressed. It is imperative for researchers and stakeholders to exert efforts toward the advancement of AI models that possess the capacity to be understood and verified. This is crucial in order to guarantee that the decisions provided by AI algorithms are both clear and justifiable.

4.2.7 Collaborative Efforts for Responsible Integration:

The results of the study highlight the significance of working together among different organizations involved in the industry, including stakeholders from the private sector, regulatory bodies, and academic researchers. These collaborations are crucial in order to guarantee the responsible and effective incorporation of AI and robotic process automation (RPA) within the framework of clinical trials. The scope of this partnership must expand the initial installation phase, encompassing the ongoing validation and monitoring of AI models during the trial.

The establishment of transparency and effective communication among all relevant parties is considered crucial in fostering confidence and effectively addressing concerns associated with the implementation of AI and Robotic Process Automation (RPA). Industry forums, workshops, and conferences that center around the topic of AI in the healthcare sector have the potential to function as effective platforms for facilitating open discussions and facilitating the exchange of knowledge.

In summary, the interviews showed an increasing acknowledgment of the potential advantages

of AI, machine learning, and robotic process automation (RPA) in the handling of Phase III clinical trial data in India. The integration of these technologies has the potential to significantly improve the efficiency, data quality, patient recruitment, and overall success of clinical trials. To ensure responsible and effective implementation, it is essential to address issues with regulation, data protection, the availability of qualified workers, and ethical considerations. By maintaining ethical principles and promoting cooperation among many parties involved, the clinical trial market in India has the potential to adopt AI and robotic process automation (RPA) technologies. This adoption can lead to enhanced healthcare results and quicker delivery of innovative therapies to patients.

4.2.8 Conceptual framework:

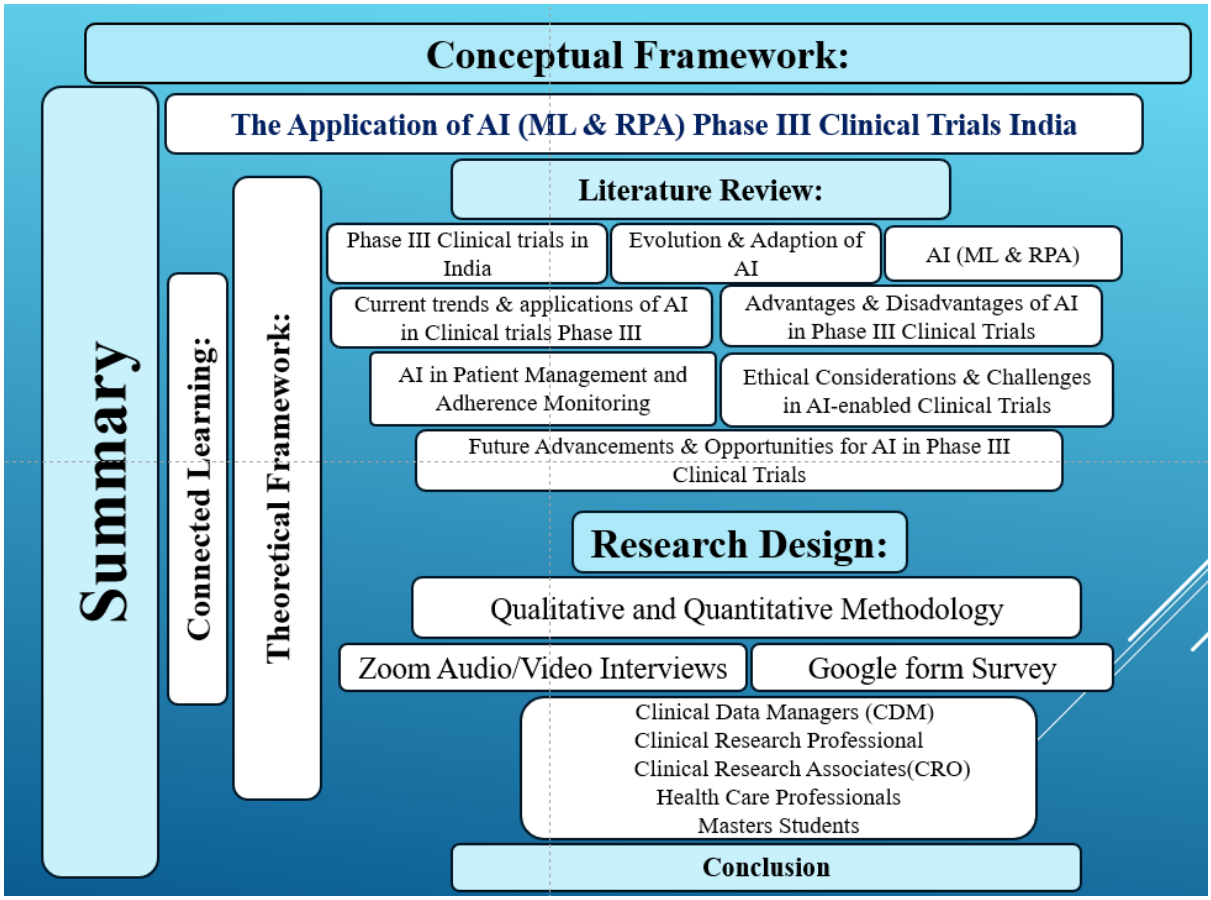

Figure 16: Conceptual Framework

Figure 16 illustrates the conceptual framework provides a structured and comprehensive overview of the role of AI, ML, and RPA in Phase III clinical trials, highlighting their potential to revolutionize clinical research in India while acknowledging the importance of addressing ethical concerns and technological advancements for effective implementation.

By combining quantitative and qualitative data, its discovered how AI is changing medicine development. The quantitative study showed statistically significant patterns showing AI's impact on Phase III studies. These empirical findings supported AI's ability to optimize operations and improve efficiency and identified areas of challenge and inconsistency. The investigation was enhanced by qualitative perspectives from clinical research participants. It understood the real-life experiences and perceptions of those at the forefront of AI integration by exploring its complexities, obstacles, and ethical issues.

In the next chapter, "Further Recommendations and Conclusion," the results of investigation help to develop conclusions and provide recommendations. Empirical evidence and knowledge of context are going to clarify AI's function in Phase III clinical trials. The findings from the study will inform the next chapter, which will provide the framework for future research and conclude the exploration.

Chapter 5: Conclusions & Further Recommendations

This chapter discuss the exploration revealed AI's transformative potential and significant gaps and obstacles. Algorithmic bias, data privacy, and seamless integration raised ethical issues about combining technology with clinical practices. The recommendations include transparent algorithm design, strong data privacy measures, the involvement of stakeholders, and interdisciplinary collaboration to close these gaps. These solutions demonstrate appropriate and effective use of AI in clinical trials for future research in this dynamic sector.

By evaluating our findings and recommendations, that acknowledge AI's significant impact on medication development and emphasize patient well-being and scientific integrity. This chapter concludes the research and highlights the current healthcare technology issue. The resulting analysis contributes to the developing picture by effectively integrating AI in Phase III clinical studies in India.

5.1 Gap 1: Ethical Principles and the Regulatory Framework

1. Improving the Regulatory Framework and Ethical Principles:
Regulation compliance and ethical issues are made more difficult by the implementation of AI in clinical studies. To fix this, it recommended that complete instructions should developed together that are specially targeted to AI integration in Phase III clinical studies. Stakeholders, researchers, and regulatory authorities should all contribute to the development of these guidelines. Patient safety, data privacy, and adherence to ethical standards will be given priority within the regulatory framework due to this cooperative effort.

Guideline Development and Collaboration: This initiative is to encourage collaborative efforts in the development of comprehensive guidelines related to the implementation of AI in Phase III clinical research. It is imperative to include several stakeholders, including researchers, experts in artificial intelligence, healthcare practitioners, and regulatory agencies, throughout every step of the process. The essential considerations are the safety of patients, the protection of data privacy, and adherence to ethical norms. These criteria must include ethical considerations, algorithm transparency, and patient permission, hence promoting collaboration among all relevant stakeholders.

The implementation and monitoring phase: It involves strict compliance to rules through detailed testing and validation of AI algorithms before implementing them. It is necessary to

place a high level of importance on ensuring patient safety and safeguarding data privacy throughout the duration of the research. It is important to establish and sustain transparent channels of communication with regulatory authorities in order to guarantee compliance with existing regulations. The research should be monitored consistently, with regular modifications made depending on feedback received. Additionally, stakeholders should be provided with education and training opportunities. By implementing this dual strategy, the ethical and compliant integration of AI in Phase III clinical trials can be accomplished, thereby promoting the progress of medical research while ensuring the protection of patient well-being and accordance to regulatory standards.

2. Development of a broad ethical framework:

It is necessary to develop an ethical framework that particularly directs the implementation of AI, machine learning, and robotic process automation (RPA) in Phase III clinical trials, based on the idea of broad guidelines. The system should take into consideration ideals including patient confidentiality, data security, openness, responsibility, and justice. For this, teamwork among ethics members, legal experts, and regulatory bodies is required to develop an overall set of ethical guidelines that effectively address newly developed ethical challenges as AI technologies evolve.

Collaborative Ethical Framework Development: The proposed approach involves the initiation of an agreement that brings together professionals in the fields of ethics, law, and regulation. The objective of this collaborative effort is to develop a complete ethical framework that is specifically designed for the use of artificial intelligence (AI), machine learning, and robotic process automation (RPA) in Phase III clinical trials. The proposed framework must to incorporate basic principles related to patient confidentiality, data security, openness, accountability, and justice. By using the combined knowledge and experience of various individuals, it is possible to develop a comprehensive ethical framework that effectively directs the responsible and ethical application of artificial intelligence (AI) technology.

Continuous Evolution and Application: Develop an ethical framework that is flexible enough to adapt as AI and medical research develop. It is essential to consistently evaluate and revise the framework in response to emerging ethical issues due to technological progress. It is essential to ensure the adoption of ethical standards throughout every phase of AI-enabled clinical trials, including the stages of design, execution, and analysis. This methodology, characterized by

collaboration, flexibility, and continuous concentration, will facilitate the easy adoption of artificial intelligence (AI) technologies while maintaining the highest ethical principles and safeguarding the welfare of patients and the credibility of research results.

3. Interdisciplinary AI Governance Committees:

It is advised that interdisciplinary governance committees be established in order to guarantee constant conformity to growing ethical standards and legal limitations. Experts from areas of study, such as medical, computer science, ethics, law, and policy, should be represented on these committees. Their job would be to continuously supervise, evaluate, and advise on the best ways to integrate AI in clinical trials. These committees can support preserving ethical consistency and legal compliance by bringing together a variety of skills.

The development of interdisciplinary AI governance committees is recommended, with the objective of combining specialists from a range of areas like as medical, computer science, ethics, law, and policy. It is essential that every committee member contributes their own perspective, so facilitating an integrated approach to ethical and legal discussions. This collective effort will facilitate the identification of possible challenges and solutions from many perspectives.

Continuous Oversight and Guidance: Assign the AI governance committees with the duty of providing continual supervision, evaluation, and guidance regarding the use of artificial intelligence in clinical trials. It is crucial to establish a consistent schedule of meetings and discussions in order to evaluate the progress of ongoing initiatives, discuss on issues of ethics, and evaluate potential legal consequences. These committees possess the capacity to offer essential perspectives in order to guarantee that the adoption of artificial intelligence (AI) technology is in accordance with legal requirements, the well-being of patients, and regulatory frameworks.

5.2 Gap 2: Collaboration and the Development of Skills

4. Workforce Training Investment:

Strategic training initiatives are needed to address the lack of qualified people capable of

developing and maintaining AI systems. The technology and healthcare industries can work together to develop specific training programs that give professionals the knowledge and abilities needed for successful implementation of AI in clinical trials. These initiatives can close the knowledge gap that exists between technology developments and successful application.

The objective is to determine the skill requirements necessary for successful implementation of artificial intelligence (AI) in clinical trials by promoting collaboration between the technology and healthcare industries. Roles such as AI developers, data scientists, healthcare experts, and ethics professionals are crucial to many aspects of AI-driven clinical research.

Develop Customized Training Programs: Establish and execute customized training programs that address the specific skill needs that have been identified. It is important that these programs provide a comprehensive combination of technical expertise and specialized knowledge of clinical research procedures within certain domains. The proposal suggests establishing partnerships with universities, training institutions, and industry associations in order to provide broad educational programs that include many aspects of artificial intelligence (AI) technologies, ethical considerations, regulatory compliance, and the complexities of medical research.

Integrating Experiential Learning: Introduce experiential learning opportunities as a key element of the training programs. Possible examples of activities that could be included in the classroom include the utilization of real-world case studies, simulated clinical trial cases, and collaborative projects that replicate the complexities associated with the integration of artificial intelligence (AI) in clinical trials.

Continuous Learning and Updates: In consideration of the rapid progression of technical developments, it is vital to establish mechanisms that facilitate ongoing learning and the acquisition of new skills. Provide refresher courses and workshops aimed at facilitating the continuous professional development of individuals in the field, enabling them to stay informed of the most recent advancements in artificial intelligence (AI) technology and its application in the field of clinical research.

Promotion of Cross-Disciplinary Collaboration: Promote the engagement of experts belonging from various fields, including but not limited to technology, healthcare, ethics, and law, in collaborative initiatives. The interdisciplinary collaboration will facilitate an in-depth

knowledge of the integration of artificial intelligence (AI), facilitate efficient communication, and improve the overall quality of clinical trials.

Industry Partnerships: The idea aims to establish collaborative alliances among healthcare organizations, technology businesses, and educational institutions, with the objective of establishing an appropriate environment for the purpose of workforce training. Furthermore, these collaborations have the potential to provide valuable internship opportunities, mentorship programs, and on-the-job training, thereby facilitating the integration of theoretical knowledge with practical experience.

Figure 17: Gap 2: Collaboration and the Development of Skills

5. Interprofessional Cooperation:

To ensure a balanced use of AI in clinical trials, collaboration amongst specialists in healthcare,

technology, law, and ethics is important. This partnership will make it easier to create complete approaches that include both technology and ethical innovations. This cooperation can promote innovation while protecting patient safety, data integrity, and ethical principles by cooperatively dealing with obstacles and possibilities.

Integrated Project Planning: The practice of integrated project planning involves the inclusion of specialists from many disciplines at the initial phases of project planning for clinical trials that incorporate artificial intelligence. The objective is to collectively evaluate any ethical and legal obstacles, recognize issues related to patient safety, and develop strategies to minimize risks.

Regular Communication Channels: Establishing and maintaining consistent and transparent channels of communication among professionals from diverse disciplines. This practice guarantees that emergent difficulties and possibilities are rapidly acknowledged and that the integration process remains in accordance with ethical values and regulatory requirements.

Problem-Solving and Innovation: The promotion of collaboration within interprofessional teams is crucial in promoting problem-solving and innovation, since it enables the collective effort of diverse expertise to tackle complex difficulties and develop new approaches. The inclusion of a wide range of perspectives has the potential for developing innovative problem-solving strategies that place emphasis on ensuring patient safety, maintaining data integrity, and upholding ethical norms.

6. Algorithmic Bias Mitigation:

As AI systems have the potential to unintentionally promote biases, it is essential to fund research and development targeted at identifying and eliminating algorithmic biases. The development of advanced methods and algorithms that actively identify and correct biases will guarantee that the results of AI are equal across various patient groups. This method improves the fairness and dependability of AI's participation in clinical studies.

Bias Identification: The prioritization of research that focuses on identifying biases within AI systems used in clinical trials is supported. This study aims to examine various data sources, model outputs, and decision-making processes in order to identify potential dissimilarities that may exist among different demographic groups.

Algorithm Development: It is recommended to allocate resources towards the advancement of advanced algorithms that proactively address and reduce biases. This covers methodologies such as data re-sampling, competitive training, and fairness-aware learning, which will ensure that AI models produce consistent and impartial outcomes across all patient groups.

Dataset Diversity: It is important to guarantee that training datasets exhibit diversity, representativeness, and absence of essential biases. Engage in collaborative efforts with healthcare professionals to gather extensive data addressing underrepresented communities, thereby preventing the potential the growth of bias.

Continuous monitoring: It should be implemented to detect any growing biases in AI systems during their implementation. It is important to consistently evaluate the performance of models across various groups of patients and make necessary algorithmic adjustments upon identifying any biases

Transparency and explain ability: The improvement of transparency in AI models can be achieved by the implementation of clarity systems, which enable an understanding of their decision-making processes. This enables researchers to identify potential causes of bias and implement corrective actions.

Collaborations: Promote collaboration among experts in artificial intelligence, healthcare practitioners, and intellectuals to collectively identify and resolve algorithmic biases. The use of an interdisciplinary approach guarantees a broad perspective regarding the concepts of fairness and equity.

Ethical Considerations: Combine Measures for Bias Detection and Mitigation into the Ethical Review Process of Clinical Trials Incorporating Artificial Intelligence. It is essential for ethical review boards to thoroughly evaluate and resolve any potential biases prior to granting approval.

5.3 Gap 3: Data Quality and Long-Term Impact

Healthcare is one of several industries that has been transformed by the integration of AI (AI) and machine learning (ML) technology. The use of AI and ML in Phase III clinical trials in India offers a lot of potential to improve productivity, accuracy, and patient outcomes. However, it is essential to develop a thorough plan that includes long-term impact evaluation, data quality

improvement, and strong data security measures in order to assure the continued impact of AI integration.

7. Impact analysis of long-term AI:

Conducting ongoing research becomes essential to determine the long-term effects of AI integration in Phase III clinical trials in India. Even though immediate results are crucial, observing both advantages and possible problems develop over time offers a broader view. Others can discover areas for improvement, improve strategy, and quickly address growing problems by observing trends and patterns. The continued improvement of AI application in Indian clinical trials will be facilitated by this continuous assessment.

Establish Metrics and Indicators: Specify Key Performance Indicators (KPIs) that are Consistent with the Objectives of AI Integration in Clinical Trials. Potential factors to consider include patient outcomes, research efficiency, cost-effectiveness, data security, and ethical considerations.

Data Collection and Monitoring: The implementation of a complete information collecting and monitoring system is important in order to effectively track relevant metrics over a prolonged duration. This includes information related to patient reactions, outcomes of trials, occurrences of data privacy breaches, and any unexpected consequences that result from the use of artificial intelligence.

Regular Assessment: Periodic evaluation should be conducted to analyze the gathered data in order to discover trends, patterns, and alterations in outcomes. This paper aims to conduct an analysis of the effects of artificial intelligence (AI) on several aspects of healthcare, including patient safety, data integrity, research efficiency, and ethical considerations.

8. Standardization and Enhanced Data Quality:

The consistency and quality of the data used for analysis is important for the success of based on AI results. It is essential to promote standards throughout the data existence to overcome issues with data quality. Standardized data formats and strong quality assurance processes may be established through collaborative efforts within the healthcare sector of India Researchers as well as professionals can make sure that information produced by AI are dependable, accurate, and

repeatable by following to these principles.

9. Dependable infrastructure for data security & a patient-centered strategy

A strong data security design is needed to protect patient information and uphold data integrity when implementing AI and ML into clinical trials. The adoption of advanced security methods, safe data sharing protocols, and complex authentication procedures becomes essential in partnership with cybersecurity specialists. Stakeholders may promote patient trust, respect to regulatory regulations, and protect sensitive data throughout the AI-driven clinical trial process by anticipating data security concerns.

Maintaining a patient-centric approach is essential when using AI and ML in clinical trials. Researchers can accelerate decision-making, streamline data analysis, and personalize treatment strategies based on unique patient features using these technologies. This individualized strategy not only improves patient experiences but also helps clinical studies generally succeed in India.

5.4 Gap 4: Engagement and innovation in India

10. Public Awareness and Involvement:

It is critical to raise public awareness and involvement about AI's role in clinical trials. Develop open communication platforms for healthcare experts, patients, politicians, and the general public. These platforms encourage the exchange of ideas, concerns, and expectations, resulting in a more inclusive and transparent AI implementation process.

The significance of involving the public in issues related to the involvement of artificial intelligence (AI) in clinical studies.

It aims to highlight the significant role that openness and open communication play in enhancing the process of healthcare decision-making. It focuses on the prospective advantages of artificial intelligence (AI) implementation in clinical trials, encompassing enhanced efficiency, heightened precision, and quicker drug discovery.

Providing Inclusive Communication Platforms:

Establishing digital platforms that accommodate healthcare professionals, patients, policymakers, and the broader public. This aims to explore the significance of online forums, social media platforms, webinars, and workshops in developing open dialogues. The importance

of prioritizing accessibility cannot be overstated, since it is crucial for facilitating the inclusion and comprehension of a wide range of individuals.

Promoting Collaboration among Healthcare Professionals:

Facilitating the participation of clinicians, researchers, and AI experts in order to encourage the exchange of knowledge and perspectives about the incorporation of artificial intelligence (AI) in the context of clinical trials. Meeting expert panels to engage in discussion related to the technological terms, advantages, and challenges associated with the integration of artificial intelligence. This aims to address concerns regarding the impact of artificial intelligence (AI) on conventional research methodology and the provision of medical care.

Examining Strategies for Engaging Patients:

Investigating approaches to include patients as vital stakeholders in discussions concerning artificial intelligence and clinical trials. This clarifies the potential benefits of artificial intelligence (AI) in enhancing patient experiences, diagnostics, and treatment options.

In answer to patient concerns over data protection, informed permission, and the ethical utilization of artificial intelligence (AI) within the healthcare sector. The goal is to provide a forum that facilitates meaningful exchanges among professionals in the fields of artificial intelligence, healthcare, and policy-making, with the aim of promoting informed decision-making.

The importance of transparency in artificial intelligence (AI) algorithms and decision-making processes will be examined, with a focus on ethical considerations. This aims to examine the ethical considerations related to bias, fairness, and responsibility within the context of AI-driven clinical trials and to discuss the distribution of effective methodologies for the examination and verification of artificial intelligence (AI) algorithms used in healthcare research.

The objective is to develop instructional resources that effectively explain complex topics related to artificial intelligence (AI) in a manner that is understandable and easily approachable.

supplying information so that people can learn about clinical trial fundamentals, AI's function, and prospective effects. The objective is to help with informed decision-making by providing unbiased data regarding the advantages and restrictions of artificial intelligence (AI).

11. Future Research and Development:

Allow continuing AI research and innovation for clinical trials. Support projects that investigate unique applications such as real-time safety monitoring along with personalized treatment. Evaluate the practicality, efficacy, and significant potential of these applications to keep healthcare research and patient care into the future.

Steps need to be taken for future reference:

Step 1: Establish Collaborative Partnerships

Promote partnerships among research institutes, artificial intelligence (AI) developers, pharmaceutical corporations, and healthcare providers. The use of a broad strategy allows for the combination of many areas of expertise and available resources in order to promote the development of innovative ideas.

Step 2: Fund Research Initiatives

Propose the distribution of financial resources towards investigations that specifically concentrate on the use of artificial intelligence in the field of clinical trials. Provide funding along with resources to facilitate research initiatives focused on the development of real-time safety monitoring and personalized therapy methods.

Step 3: Prioritize ethical considerations

It is essential to ensure that artificial intelligence (AI) applications follow to established ethical standards and uphold data privacy regulations. Propose the establishment of an ethical review board to provide oversight for the advancement and implementation of artificial intelligence (AI) technologies within the parameters of clinical trials.

Step 4: Develop Proof of Concept

It is required to motivate researchers to engage in the development of prototypes and proof of concept for artificial intelligence (AI)-based real-time safety monitoring and individualized treatment techniques. This leads to preliminary data regarding the possible advantages and viability of various applications.

Step 5: Perform Feasibility Studies

Perform thorough feasibility analyses to assess the technical, operational, and economic feasibility of adopting artificial intelligence (AI) technologies within clinical trial areas. This task involves the identification of prospective issues and the development of methods to effectively

address and overcome them.

Step 6: collaborative efforts with regulatory authorities

It is important to actively collaborate with regulatory authorities in order to guarantee that artificial intelligence (AI) applications follow to current laws and standards. Collaborate together with relevant agencies to produce clear regulations relevant to the use of artificial intelligence (AI) within the scope of clinical studies.

Step 7: Establishment of a robust data infrastructure

Develop an efficient data structure that facilitates the acquisition, retention, and examination of patient data in real-time. This will establish the basis for safety monitoring and personalized treatment through the use of artificial intelligence.

Step 8: Tests in controlled environments

Perform trials to evaluate the efficacy of artificial intelligence (AI) solutions inside tightly regulated clinical trial conditions. Collect comments from healthcare professionals, researchers, and patients in order to enhance and optimize the technology.

Step 9: The monitoring and evaluation of the task at hand

It is essential to maintain a continuous monitoring of the performance and impact of artificial intelligence (AI) applications throughout the duration of clinical trials. Collecting data on safety outcomes, treatment efficacy, and patient experiences is crucial in order to provide useful information that can guide future enhancements.

Step 10: Iterating and enhancing the existing work

The AI applications should be repeated and improved based on the feedback and data that has been acquired. Execute essential updates and improvements to guarantee that the technology progresses similarly with developing insights and innovations.

Step 11: The transfer of knowledge

Provide research findings, exemplify best practices, and showcase success stories using conferences, journals, and collaborative platforms. Promote the exchange of knowledge in order to speed up the use of artificial intelligence (AI) advancements within the scope of clinical trials.

Step 12: Cultivating a sustained dedication

It is necessary to sustain a prolonged dedication to artificial intelligence (AI) research within the context of clinical trials. Promote a constant urge for innovation, embrace the dynamic nature of evolving technology, and cultivate a climate of knowledge acquisition and advancement within the healthcare and research sectors.

Figure 18 provides a visual roadmap of prospective research and development options for the study. This dynamic figure depicts prospects as well as unexplored limits. It suggests refining AI algorithms for clinical decision support, addressing ethical concerns about AI integration, exploring personalized treatment strategies through precision medicine, and improving data security in AI-powered clinical trials. This visual a description shows the changing picture of AI in healthcare research and the tremendous potential for innovation, patient care, and scientific discovery in clinical trials.

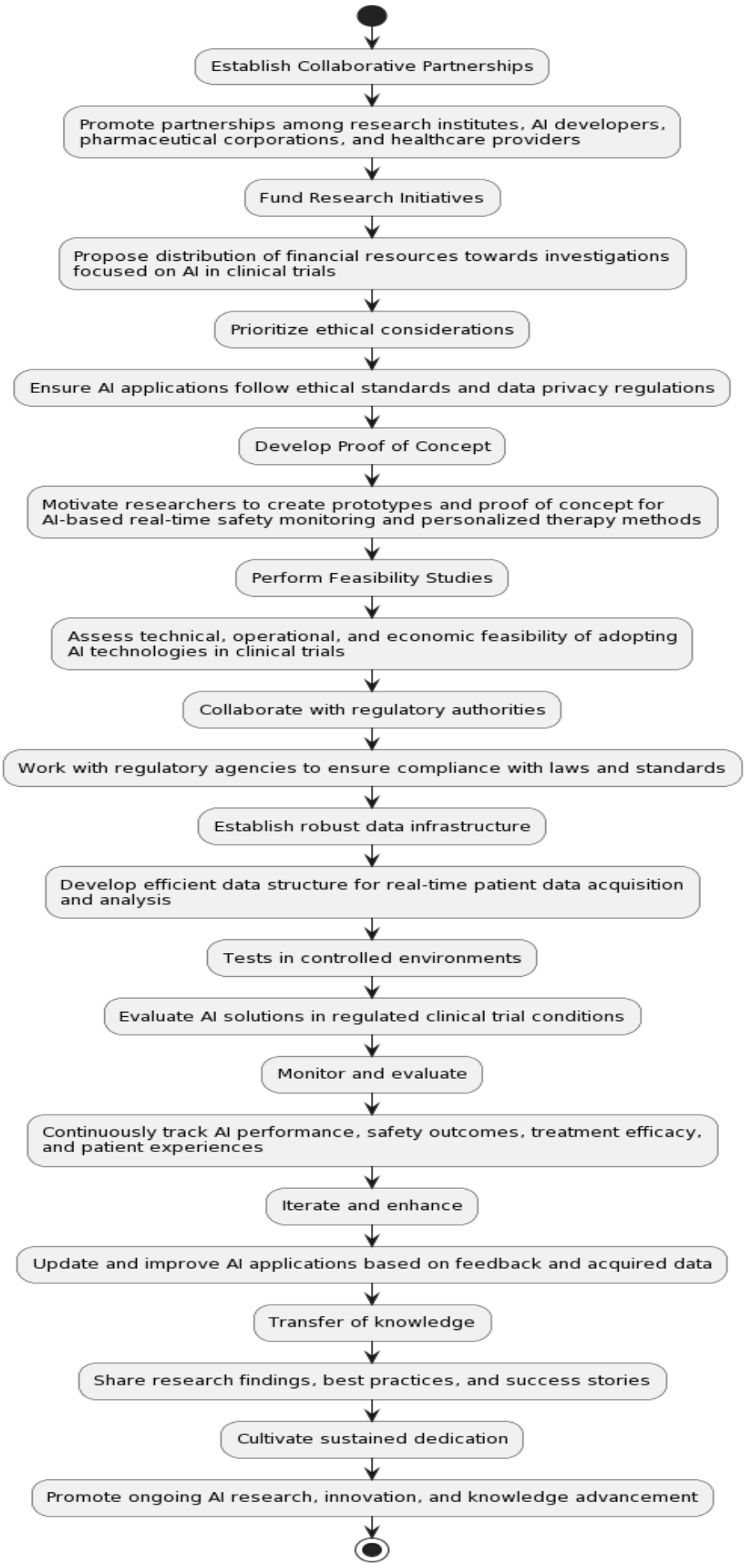
Establish Collaborative Partnerships
Promote partnerships among research institutes, AI developers, pharmaceutical corporations, and healthcare providers
Fund Research Initiatives
Propose distribution of financial resources towards investigations focused on AI in clinical trials
Prioritize ethical considerations
Ensure AI applications follow ethical standards and data privacy regulations
Develop Proof of Concept
Motivate researchers to create prototypes and proof of concept for AI-based real-time safety monitoring and personalized therapy methods
Perform Feasibility Studies
Assess technical, operational, and economic feasibility of adopting AI technologies in clinical trials
Collaborate with regulatory authorities
Work with regulatory agencies to ensure compliance with laws and standards
Establish robust data infrastructure
Develop efficient data structure for real-time patient data acquisition and analysis
Tests in controlled environments
Evaluate AI solutions in regulated clinical trial conditions
Monitor and evaluate
Continuously track AI performance, safety outcomes, treatment efficacy, and patient experiences
Iterate and enhance
Update and improve AI applications based on feedback and acquired data
Transfer of knowledge
Share research findings, best practices, and success stories
Cultivate sustained dedication
Promote ongoing AI research, innovation, and knowledge advancement

Figure 18: Steps need to be taken for future reference

12. Acceleration of AI-Driven medication Development:

Collaborative efforts between pharmaceutical corporations, academic institutions, and AI technology providers can result in faster medication development. Develop AI algorithms that optimize the pre-clinical and clinical trial phases, allowing for more efficient identification of potential treatment concepts. This partnership has the potential to change the drug development system forever.

Step 1: Establish Cross-Sector Consortia

Facilitate collaborations among pharmaceutical businesses, academic researchers, and professionals in the field of artificial intelligence (AI). Promote a collaborative atmosphere wherein common objectives, specialized knowledge, and available resources are leveraged to expedite the process of pharmaceutical innovation.

Step 2: The identification of developmental limitations

Identify and analyze issues and obstacles encountered with current pharmaceutical development procedures. This analysis focuses on identifying key areas where the integration of artificial intelligence (AI) will provide significant benefit. Specifically, the areas of interest include target selection, compound screening, and patient recruiting for clinical trials.

Step 3: The development of algorithms

It is recommended to allocate resources toward the investment in research and development efforts focused on the advancement of artificial intelligence algorithms that are ideal to address the unique requirements associated with the production of medications. The primary areas of interest include to algorithms that aim to enhance the efficiency of trial design, predict drug interactions, and promptly detect potential adverse effects during the first stages of drug development.

Step 4: Assemble Sufficient Datasets

Aggregate broad and diverse datasets, including molecular data, clinical information, and details about patients. These datasets will be used as the fundamental basis for the training of artificial intelligence models and the subsequent validation of their predictive capabilities.

Step 5: Collaborative model training

The collaborative training of AI models involves a collection of expertise and data from several sources, including pharmaceutical corporations, academic research institutions, and AI technology suppliers. The collaborative attempt serves to improve the precision and applicability of the formulated algorithms.

Step 6: Implement in Pre-Clinical Trials

The integration of artificial intelligence (AI) algorithms into the pre-clinical trial phases has the potential to enhance various aspects of the process, including target validation, chemical screening, and toxicity prediction. Use artificial intelligence (AI) insights to effectively prioritize candidates with the highest potential and minimize the occurrence of failure pathways.

Step 7: Enhance Clinical Trial Design

The application of artificial intelligence (AI) can be employed to enhance the efficiency of clinical trial design through the identification of appropriate patient populations, anticipation of response variability, and recommendation of adaptive trial designs. By minimizing the time of trials, there is an increased probability of achieving good outcomes.

Step 8: The analysis of real-time data

Apply artificial intelligence algorithms to facilitate real-time analysis of data obtained from clinical trials. The monitoring of patient responses, identification of patterns, and timely addressing of safety concerns might facilitate improved decision-making and perhaps accelerate the conclusion of clinical trials.

Step 9: Iterative Feedback Loop

Implement a continuous feedback loop that consistently enhances artificial intelligence (AI) models using data acquired throughout the process of pharmaceutical development. It is imperative to consistently revise algorithms in order to enhance their precision and accommodate the ever-changing understanding of the subject matter.

Step 10: Regulatory collaboration

It is essential to involve regulatory agencies at an early stage in order to ensure that AI-driven methodologies are in accordance with regulatory obligations. The objective is to engage in a collaborative effort aimed at formulating a set of standards that will govern the process of

validating and accepting ideas given by artificial intelligence in the field of drug development.

Step 11: knowledge sharing

Promote the spread of knowledge and promote collaborative efforts among collaboration members and the wider scientific community. It aims to together progress the development of AI-driven medication by sharing significant achievements, encountered obstacles, and valuable insights gained throughout the process.

Step 12: Long-term commitment

Develop a constant commitment to lifelong collaboration and creativity. Promote the establishment of an ecosystem that places emphasis on the continuous improvement of AI algorithms and techniques, with the aim of enhancing drug development procedures.

Figure 19 shows how artificial intelligence has accelerated pharmaceutical development. The image shows how AI speeds up target selection, compound screening, pre-clinical testing, and Phase III trials in drug research and development. The graphic shows the steps how AI streamlines the time-consuming drug development process, making pharmaceutical development more efficient and effective in clinical trials.

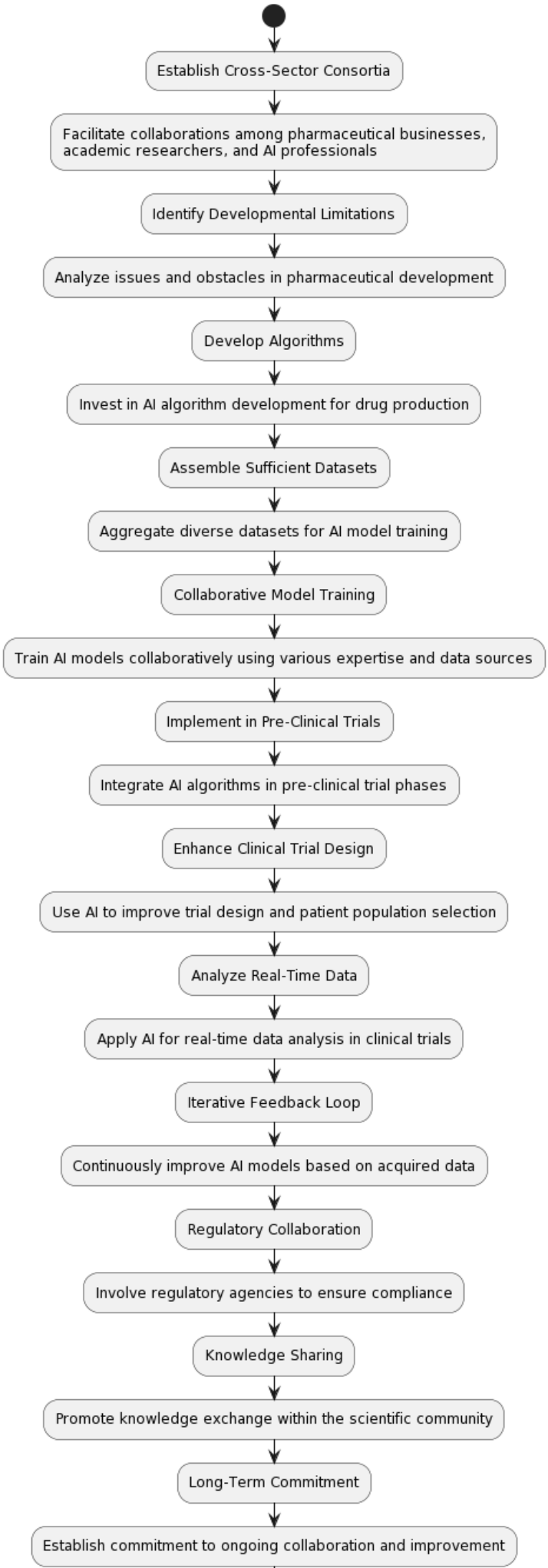
Establish Cross-Sector Consortia
Facilitate collaborations among pharmaceutical businesses, academic researchers, and AI professionals
Identify Developmental Limitations
Analyze issues and obstacles in pharmaceutical development
Develop Algorithms
Invest in AI algorithm development for drug production
Assemble Sufficient Datasets
Aggregate diverse datasets for AI model training
Collaborative Model Training
Train AI models collaboratively using various expertise and data sources
Implement in Pre-Clinical Trials
Integrate AI algorithms in pre-clinical trial phases
Enhance Clinical Trial Design
Use AI to improve trial design and patient population selection
Analyze Real-Time Data
Apply AI for real-time data analysis in clinical trials
Iterative Feedback Loop
Continuously improve AI models based on acquired data
Regulatory Collaboration
Involve regulatory agencies to ensure compliance
Knowledge Sharing
Promote knowledge exchange within the scientific community
Long-Term Commitment
Establish commitment to ongoing collaboration and improvement

Figure 19: Steps for Acceleration of AI-Driven medication Development

5.5 Gap 5: Collaboration and adaptation

13. Collaborative Initiatives and Pilot Projects:

Pilot initiatives demonstrating the practical benefits of AI integration in Phase III clinical trials should be supported. Develop successful case studies in collaboration with clinical research institutions, academia, and industry partners. Sharing case studies and lessons gained might help to create a database of best practices for wider implementation.

14. Cross-Continental AI Collaboration Networks:

Develop international collaboration networks that focus on AI in healthcare and clinical trials. Conferences, workshops, and forums can provide information about global trends, issues, and guidelines. This international collaboration makes it easier to adapt successful approaches to specific conditions.

15. Dynamic Regulatory Adaptation Mechanism:

Work collaboratively with regulatory agencies to develop an adaptive regulatory framework for AI technologies. This system should be able to respond quickly to changing AI landscapes while conforming to ethical considerations and regulatory frameworks. In advance addressing regulatory changes guarantees that AI developments be implemented on schedule.

The sixth theme is a patient-centered approach.

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16. AI-Enhanced Patient-Centric Trials:

Include AI in patient-centric trial designs to improve patient experiences and engagement. Design algorithms that customize trial protocols based on individual patient profiles, preferences, and medical histories. This method increases recruitment rates, decreases dropouts, and produces more customized and strong therapeutic outcomes.

17. AI-Powered Patient Adherence Enhancement:

Apply AI technologies to improve patient adherence throughout the clinical trial process. Design based on AI treatments that offer customized reminders, assistance, and motivational techniques. These strategies increase participant involvement and help to produce higher-quality clinical data.

18. Ethical AI Education for Healthcare Workers:

Develop broad educational programs to help healthcare workers know the ethical implications of AI. By offering focused training and raising awareness of ethical implications, these programs help build a culture of responsible AI adoption.

Figure 20 shows a key gap that emphasizes the need for better collaboration and AI integration. This gap illustrates the difficulty of integrating AI technologies with clinical practises, underlining the need for collaboration. The image shows how collaborative and adaptable tactics are crucial to adopting AI in Phase III clinical trials. The figure emphasizes the importance of tackling this gap as we navigate the revolutionary future of AI-powered healthcare developments.

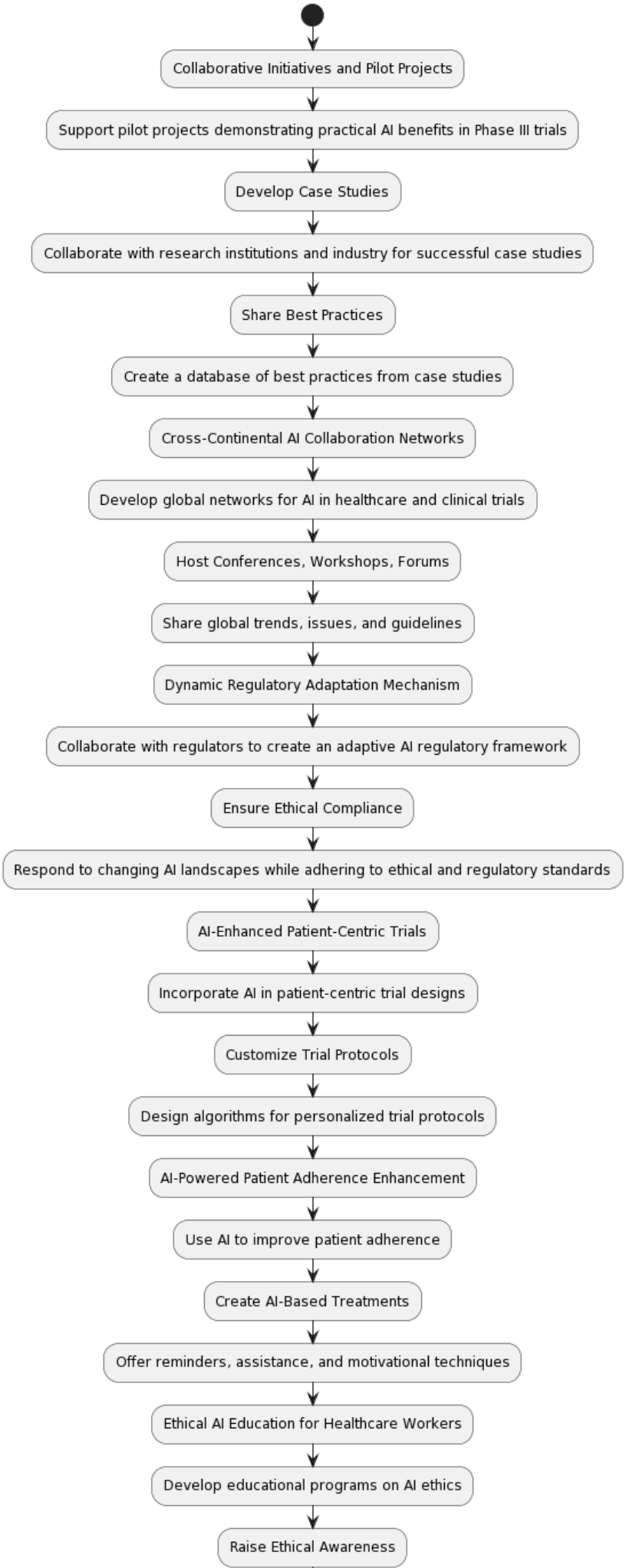
Collaborative Initiatives and Pilot Projects
Support pilot projects demonstrating practical AI benefits in Phase III trials
Develop Case Studies
Collaborate with research institutions and industry for successful case studies
Share Best Practices
Create a database of best practices from case studies
Cross-Continental AI Collaboration Networks
Develop global networks for AI in healthcare and clinical trials
Host Conferences, Workshops, Forums
Share global trends, issues, and guidelines
Dynamic Regulatory Adaptation Mechanism
Collaborate with regulators to create an adaptive AI regulatory framework
Ensure Ethical Compliance
Respond to changing AI landscapes while adhering to ethical and regulatory standards
AI-Enhanced Patient-Centric Trials
Incorporate AI in patient-centric trial designs
Customize Trial Protocols
Design algorithms for personalized trial protocols
AI-Powered Patient Adherence Enhancement
Use AI to improve patient adherence
Create AI-Based Treatments
Offer reminders, assistance, and motivational techniques
Ethical AI Education for Healthcare Workers
Develop educational programs on AI ethics
Raise Ethical Awareness

Figure 20: Gap 5: Collaboration and adaptation

Table 9 illustrates the summarize format of gaps and solutions investigated for the recommendations

GAPS	SOLUTIONS
Gap 1: Ethical principle & regulatory framework	• Improving regulatory framework • Development of a broad ethical framework • Interdisciplinary AI governance committees
Gap 2: Collaboration and the development of skills	• Workforce training investment • Interprofessional co-operation • Algorithm bias mitigation
Gap 3: Data quality and long-term impact	• Impact analysis of long-term AI • Standardization and enhanced data quality • Dependable infrastructure for data security
Gap 4: Engagement and innovation in India	• Public awareness and involvement • Future research and development • Acceleration of AI driven medication & development
Gap 5: Collaboration and adaption	• Collaborative initiatives • Dynamic regulatory adaption mechanism • AI enhanced patient centric trials • Ethical AI education for healthcare workers • AI powered patient adherence enhancement

Table 9: Gaps and solutions (source: developed by author)

Conclusion:

The use of AI, machine learning (ML), and robotic process automation (RPA) in Phase III clinical trials in India indicates a dynamic transition that needs an in-depth and cooperative approach. By making sure that AI, ML, and RPA are used responsibly, prioritizing patient safety, data protection, and adherence to legal regulations, by strengthening the regulatory framework and ethical principles. Patient confidentiality, data security, transparency, and fairness are protected in the implementation of these technologies because a strong ethical framework has been developed, guided by stakeholders from diverse disciplines.

The continuous balancing of changing ethical standards with legal restrictions will be accomplished through broad governance bodies. Experts from the areas of medicine, computer science, ethics, law, and policy will be involved, which will promote consistent and legal integration. Investing in workforce development initiatives that close the gap between technological breakthroughs and actual use in clinical trials is also important. A skilled workforce capable of exploiting the potential advantages of AI, ML, and RPA will be developed as a result of collaboration between the healthcare and technology industries.

The landscape of medical research and patient care may change as a result of the inclusion of AI and ML in Phase III clinical trials in India. A combined strategy comprising effect evaluation, data quality improvement, and data security measures is essential to guarantee the long-term viability and impact of AI-driven insights. India can take the lead in harnessing AI's obstructive potential while protecting patient safety, data integrity, and research quality through cooperative efforts and innovative approaches

In order to guarantee equal and reliable results across various patient groups, algorithmic bias must be addressed. The value of AI-driven results will be increased by research and development aimed at identifying and eliminating biases. Data integrity will be maintained throughout the AI-driven clinical trial process due to the standardization of data formats, stringent data quality assurance methods, and strong data security standards.

Initiatives for engagement and openness, such as public awareness campaigns and cooperative forums, will encourage open discussion among stakeholders. This open strategy will promote an

inclusive atmosphere and enable the discussion of ideas, issues, and expectations around the use of AI, ML, and RPA in clinical trials. Cross-continental cooperation networks will make it easier for people to share their ideas and best practices, promoting the responsible and efficient use of modern technologies.

In the end, the effectiveness of involving AI, ML, and RPA into Phase III clinical trials is supported by a patient-centric methodology. Customizing trial protocols, improving patient compliance, and making sure healthcare professionals receive ethical training all help achieve conditions where patients actively participate in their own care. This broad strategy not only advances clinical research but also represents the moral and innovative values needed to guide the development of healthcare in India and beyond.

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APPENDICES

A1. Ethical procedure

Sample participant consent form

Consent Form

THE APPLICATION OF AI (MACHINE LEARNING & ROBOTIC PROCESS AUTOMATION) PHASE III CLINICAL TRIALS IN INDIA

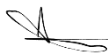
- I voluntarily agree to participate in this research study.
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind.
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- I understand that participation involves conducting interviews on the Zoom platform.
- I understand that I will not benefit directly from participating in this research
- I understand that all information I provide for this study will be treated confidentially
- I understand that in any report on the results of this research, my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of the people I speak about.
- I agree to my interview being audio-recorded.
- I understand that disguised extracts from my interview may be quoted in the dissertation, viva, and in future conference presentations, published papers, journals, and libraries.
- If data is coming from within one company or specifically about one company the researcher will adhere to all of the codes of conduct and employee confidentiality requirements of the company and there is no expectation to breach these in this research. A signed confidentiality statement between the researcher and the company can be agreed upon and signed if deemed necessary.
- I understand that if I inform the researcher that I or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission

- I understand that signed consent forms and original audio recordings will be retained on a password-protected laptop until two years of the interview.
- I understand that a transcript of my interview in which all identifying information has been removed will be retained till September 2025.
- I understand that under freedom of information legalization, I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher details:
Griffith College, Dublin, Ireland
Contact number -
Contact mail –

Signature of participant

Signature of research participant



---------- Date 25/07/2023

Signature of researcher

I believe the participant is giving informed consent to participate in this study

Signature of researcher

Date: 22-07-2023

Sample participant information letter (PIL)

INFORMATION LETTER FOR PARTICIPANT

THE APPLICATION OF AI (MACHINE LEARNING & ROBOTIC PROCESS AUTOMATION) PHASE III CLINICAL TRIALS IN INDIA

Participant Information Letter

I would like to invite you to take part in a research study. Before you decide if you agree to take part you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is---------. I am pursuing my MSc in Pharmaceutical Business and Technology at Griffith College Dublin, Ireland. I am conducting this study as part of my research project during my final postgraduate term. I am undertaking this study to evaluate "The Application of AI (Machine Learning & Robotic process automation) Phase III Clinical Trials in India"**.** The study will collect some data through interviews and surveys with people in the pharmaceuticals sector and will be conducted through the online Zoom platform. A set of questions will be asked during the interview regarding the use of AI (machine learning & RPA) clinical trials in Phase III India. The interview will be recorded for the further analysis of data.

WHAT WOULD TAKE PART INVOLVE?

The study will be carried out as an interview conducted through the Zoom platform. If you agree to take part in the interview, the timing will be according to your availability. During the interview questions will be asked regarding the impact of AI/ML in the pharmaceutical sector. It will take circa 30 minutes to complete. The interview will be recorded for further analysis. The recordings will be highly confidential and only accessible to the authorized person.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

I have requested you take part in this study because you are working in the field of Clinical Trials. You have good knowledge and be well-informed about the impact of implementation of the recent technologies in clinical trials.

DO YOU HAVE TO TAKE PART?

Your participation in this study is completely voluntary and you have the right to refuse to participate and refuse to answer any question. You can withdraw at any time without any consequence whatsoever. If you need to withdraw from the study at any stage, please contact the researcher's phone number

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

There will be no significant risks of harm, risks to confidentiality or psychological risk. The benefit will be that you will contribute to research on this important topic.

WILL TAKING PART BE CONFIDENTIAL?

The confidentiality and anonymity of all participants and any individuals mentioned will be upheld. The name and whereabouts of participants will not be disclosed. The data can only be accessed by the researcher. During the course of conducting the research, non-anonymized information, such as consent forms and audio recordings, will be collected and retained.

HOW WILL THE INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

Signed consent forms and original audio recordings or transcripts of them will be retained in Griffith College Dublin, Ireland until after my degree has been conferred. A transcript of interviews in which all identifying information has been removed will be retained for a further two years after this. Under freedom of information legalization, you are entitled to access the information you have provided at any time.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

Research in this area is limited to the dissertation only. All dissertation research projects and their content will be made accessible in the Griffith College Library. It could be published in e-journals or repositories online, but, the details of participants will be kept anonymous.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Researcher details:
Griffith College, Dublin, Ireland
Contact number -

THANK YOU

Submitted ethics application & declaration form

Ethics Application & Declaration Form

SECTION 1: ETHICS APPLICATION DETAILS

1.1 PROJECT TITLE:	The Application of AI (Machine Learning & Robotic process automation) Phase III Clinical Trials in India
1.2 RESEARCHERS NAME:	Shubhangi Chaurasia
1.3 PROGRAMME OF STUDY:	MSc Pharmaceutical Business Technology.
1.4 SUPERVISOR'S NAME:	Dr. Sue Mulhall
1.5 DECLARATION:	The information in this application form is accurate to the best of my knowledge. I undertake to abide by the ethical principles outlined by the Innopharma and Griffith College ethics policy. If this proposal is approved by the Griffith College Ethics Committee, I undertake to comply with any conditions required by the Committee. I confirm that this application is complete with all required documentation and signatures and that these are attached as appendices.
	Yes

For Student:

STUDENT SIGNATURE: Shubhangi Chaurasia

DATE: 21-06-2023

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

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ☐

SUPERVISOR SIGNATURE: Sue Mulhall

DATE: 23-06-2023

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

SECTION 2: DESCRIPTION OF RESEARCH STUDY

2.1 PURPOSE OF THE RESEARCH

Topic:

The topic "The Application of AI (Machine Learning & Robotic process automation) in Phase III Clinical Trials in India" depends on the use of advanced technologies such as AI, machine learning, and robotic process automation with regard to Phase III clinical trials conducted in India. This research evaluates the potential benefits and drawbacks of the specific applications of AI and robotic process automation at this important phase of clinical trials. Also, it examines how these technologies can improve patient management, adherence monitoring, real-time monitoring, and safety analysis, and identifies the ethical considerations and challenges caused by their implementation. Similarly, it needs to identify potential future developments and opportunities for AI in Phase III clinical trials in India.

Title: The Application of AI (Machine Learning & Robotic process automation) Phase III Clinical Trials in India

Hypothesis: The use of AI (Machine Learning & robotic process automation) in Phase III Clinical Trials in India will improve trial efficiency, accuracy, and efficacy, resulting in better patient outcomes and faster treatment.

This hypothesis proposes that using AI (Machine Learning & robotic process automation) technology in Phase III clinical trials in India will have an advantageous effect on several parts of the trial procedure. It indicates that using AI algorithms and models for data analysis, patient recruitment, adverse event monitoring, treatment response prediction, and overall trial management will result in better outcomes.

Modules the topic is linked to:

- Clinical research management (CRM)
- 21st-century dynamics in emerging trends (CDET)

Overall Aim:

The primary objective of this research is to evaluate the possibility and effectiveness of applying artificial intelligence, more especially machine learning and robotic process automation, in phase III clinical trials in India. The specific areas of focus for this research are located in India. The results of the study will be beneficial to researchers as well as pharmaceutical companies, regulatory authorities, and healthcare professionals who are involved in the design, administration, and monitoring of clinical trials. The aim is to give scientific advice and guidelines for harnessing AI technology to improve clinical trial procedures, which will lead to greater efficiency, lower costs, and enhanced patient outcomes.

Objectives:

- The purpose of this research is to look into the particular applications of artificial intelligence (machine learning and robotic process automation) in Phase III clinical trials in India.
- This study aims to determine the benefits and drawbacks of using artificial intelligence (machine learning and robotic process automation) for real-time monitoring and safety analysis in Phase III clinical trials in India.
- The purpose of this study is to investigate how artificial intelligence (including machine learning and robotic process automation) can help with patient care and adherence monitoring during Phase III clinical trials in India.
- In terms of India's healthcare system, investigate the ethical considerations and challenges connected with the use of AI (machine learning and robotic process automation) in Phase III clinical trials.
- This study also aims to investigate the possibilities of future developments and prospects for AI (machine learning and robotic process automation) in Phase III clinical trials in India.

2.2 RESEARCH METHODOLOGY:

Philosophical approach:

The "Use of AI (Machine Learning & RPA) in Phase III Clinical Trials in India" study will mainly use a qualitative research method. A comprehensive review of the literature will be part of the research to collect the amount of knowledge already available on the topic. Key stakeholders, including researchers, clinical data managers, regulators, and industry experts, will be interviewed and would be a part of surveys and part of informal discussions in order to learn more about their attitudes, experiences, and difficulties with the application of AI and RPA in Phase III clinical trials. The interviews and surveys will be recorded on audio and then transcribed for evaluation. To find common themes and trends in the data, thematic analysis will be used. This will make it possible to investigate the major variables affecting the acceptance, use, and results of AI and RPA in clinical trials. The research will give participants a complete understanding of the challenges,

possibilities, and moral issues regarding the use of AI and RPA in Phase III clinical trials in India. It will help to move forward the discussion about the ethical, scientific, and social aspects of using artificial intelligence in healthcare research, and for more informed decision-making and promoting responsible and fair use of AI technology & RPA in clinical trial methods.

Primary research strategy: Mixed methodology approach

Type of Data to be collected: Quantitative and qualitative (both)

Methodology: Abductive approach (Surveys and interviews)

Type of data: Data will be collected by mixed method approach so surveys and interviews both will be conducted. For surveys, I have already prepared a Google form survey with multiple-choice questions. Here is the link for that

https://docs.google.com/forms/d/e/1FAIpQLSeu687JVPIQwYfH0I54Ah4so4oMydjhcQ6uAbEdG7QnJqnYCw/viewform

For interviews the questionnaire that I prepared:

Theme: Adoption and Growth of AI in Clinical Trials

1. How has the adoption of AI and machine learning (ML) & RPA in clinical trials grown in recent years?
2. Why is India regarded as one of the most important clinical trial markets, particularly in the context of AI/ML applications?

Theme: Benefits and Efficiency of AI in Clinical Trials

3. What influence does AI machine learning & RPA have on Phase III clinical trials' effectiveness and efficiency in India?
4. What are the possible benefits of using AI and machine learning in clinical trial preparation, execution, and analysis?
5. How can AI and machine learning increase clinical study efficiency and cost-effectiveness?

6. How can machine learning-based predictive models help in the early detection and prevention of drug-drug interactions (DDIs) in Phase III clinical trials?
7. What are the possible benefits of employing AI and RPA for developing personalized therapy plans?
8. How can AI and RPA help to reduce clinical trial failure rates in India?

Theme: Challenges and Obstacles in Implementing AI in Clinical Trials

9. What are the challenges and obstacles to applying AI machine learning in India's Phase III clinical trials?

Theme: Insights from Clinical Trial Professionals

10. What insights can be gained from individuals with experience in clinical trials, particularly those who have worked or are currently working in Phase III clinical trials in India, regarding the use of AI machine learning & RPA in these trials?

Collection method:

The research plan implements a mixed-methods approach for data collection, encompassing both Google surveys and interviews. Google surveys will be used to conduct online questionnaires, enabling participants to conveniently respond at their own pace. These surveys will consist of structured questions with multiple-choice, or open-ended response options, facilitating efficient data collection from a larger number of participants. Additionally, remote interviews, lasting 15 to 20 minutes each, will be conducted in a semi-structured format. Remote interviews will be conducted through Zoom video conferencing platforms or on a phone screening. The interviews will incorporate a mix of open-ended and closed-ended questions, allowing for an in-depth exploration of topics while gathering specific information. This combined approach of surveys and interviews aims to provide comprehensive knowledge of the research topic, capturing both quantitative trends and qualitative perspectives.

Data analysis method:

The audio-visual recordings will be initially stored on a digital device, such as a smartphone, during the interview sessions. Once the recordings are transferred to my personal PC, they will be deleted from the phone to ensure data security and privacy. Additionally, to ensure data backup, a copy of the recordings will be saved on Griffith's

One Drive, a secure cloud storage platform. For data analysis, transcripts of the interview conversations will be prepared in Microsoft Word. These transcripts will capture the interviews and provide a textual representation of the data. Similar to the audio-visual recordings, the transcripts will be stored on my personal PC and backed up on Griffith's One Drive.

Quantitative data will be collected through Google form surveys distributed to participants. The survey data will be collected and stored directly within Google Forms, ensuring data confidentiality and ease of analysis. Google Forms provides a secure and convenient platform for gathering quantitative data.

Overall, these data collection and storage measures aim to ensure the privacy, security, and organization of both qualitative and quantitative data throughout the research process.

Participants:

The participants I am planning to include will be the researchers, physicians, clinical trial coordinators or managers, university students, and AI experts. By engaging in interviews and surveys with these experienced professionals, the aim is to obtain in-depth information about their first-hand experiences and perspectives regarding the use of AI machine learning & RPA in Phase III clinical trials. I planned for both interviews and surveys so that I can get more data and at least a response rate of 50-60%. For getting a better response rate I am thinking of keeping the surveys anonymous for participants so they will feel free to answer the surveys.

Recruitment plan for participants:

For recruiting participants for surveys, I will conduct Google forms and send them with the help of emails, LinkedIn, and through WhatsApp. It will not take so much time so participants will fill in the answers according to their pace. While for interviews I need to reach participants first through LinkedIn and emails to discuss my idea and to get their consent only then I can schedule an interview with them.

2.3 PROPOSED QUESTIONS

Theme: Influence and Benefits of AI in Clinical Trials

1. What influence does AI machine learning & RPA have on Phase III clinical trials' effectiveness and efficiency in India?
2. How has the adoption of AI and machine learning (ML) & RPA in clinical trials grown in recent years?
3. Why is India regarded as one of the most important clinical trial markets, particularly in the context of AI/ML applications?
4. What are the possible benefits of using AI and machine learning in clinical trial preparation, execution, and analysis?

Theme: Challenges and Obstacles in Implementing AI in Clinical Trials

5. What are the challenges and obstacles to applying AI machine learning in India's Phase III clinical trials?

Theme: Insights from Clinical Trial Professionals

6. What insights can be gained from individuals with experience in clinical trials, particularly those who have worked or are currently working in Phase III clinical trials in India, regarding the use of AI machine learning & RPA in these trials?

Theme: AI and RPA for Improving Clinical Trial Efficiency

7. How can AI and RPA help to reduce clinical trial failure rates in India?
8. How should AI and machine learning increase clinical study efficiency and cost-effectiveness?
9. How can machine learning-based predictive models help in the early detection and prevention of drug-drug interactions (DDIs) in Phase III clinical trials?
10. What are the possible benefits of employing AI and RPA for developing personalized therapy plans?

SECTION 3: ETHICAL ISSUES

3.1 SUBJECT MATTER

Does the research proposal involve:

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

3.2 RESEARCH PROCEDURES

Does the research proposal involve:

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

3.3 PARTICIPANTS

Does the research proposal involve:

- People who are not competent and/or fluent in English? No
- Does your research group/sample include any of the following: (Adult participants; 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)? No

If you have answered NO to ALL questions, you do not need to complete Section 4. Please go to Section 5.

If you have answered YES to ANY question in SECTION 3, you must fill in SECTION 4.

SECTION 4: ETHICAL IMPLICATIONS

If you have answered YES to ANY question in SECTION 3, you must fill in SECTION 4 If you answered NO to ALL questions in SECTION 3 leave each box as 'N/A' or 'Not Applicable'.

4.1. SUBJECT MATTER

If your ethical issues related to ***Subject Matter***, outline your action plan to deal with such sensitive issues.

N/A

4.2. RESEARCH PROCEDURES

If your ethical issues related to ***Research Procedures***, outline your action plan to deal with sensitive research procedures.

N/A

4.3. RESEARCH PARTICIPANTS

If your ethical issues related to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

N/A

SECTION 5: PARTICIPANTS

5.1. PARTICIPANT PROFILE

The participants I am planning to include will be the researchers, physicians, clinical trial coordinators or managers, university students, and AI experts. I choose these participants because my topic is inclined toward the healthcare sector and getting information for healthcare, clinical trials is possible only if I have people who already work there or have worked there. Because the information that I need is not possible for the common man to answer without experience. By engaging in interviews and surveys with these experienced professionals, the aim is to obtain in-depth information about their first-hand experiences and perspectives regarding the use of AI machine learning & RPA in Phase III clinical trials. I planned for both interviews and surveys so that I can get more data and at least a response rate of 50-60%. For getting a better response rate I am thinking of keeping the surveys anonymous for participants so they will feel free to answer the surveys.

For recruiting participants for surveys, I will conduct Google forms and send them with the help of emails, LinkedIn, and through WhatsApp. It will not take so much time so participants will fill in the answers according to their pace. While for interviews I need to reach participants first through LinkedIn and emails to discuss my idea and to get their consent only then I can schedule an interview with them.

5.2 PARTICIPANT RECRUITMENT

As part of my participant recruitment strategy, I've decided to use Google Forms to conduct surveys. This procedure enables the design and distribution of the survey questionnaire to a large number of individuals. I plan to distribute the Google Form survey URLs via multiple channels, including emails, LinkedIn, and WhatsApp, in order to maximize the reach. I can directly contact potential participants who have expressed interest in the topic or who are experts in the field by using email. I will compose personal emails explaining the purpose of my research and requesting their participation in a survey. This strategy enables more communication and increases the possibility of receiving responses from individuals with expertise in AI in clinical trials.

LinkedIn can be used as a second source for participant recruitment. I will use my professional network and connections to posting or send direct messages containing the survey link. LinkedIn provides a platform where I can interact with the pharmaceutical industry, clinical research, and related professionals. This strategy will allow me to access a wide range of potential participants with useful information and opinions.

For interviews, a more personalized approach is necessary. After contacting potential participants through LinkedIn or email, I will initiate contact to discuss my research idea and request their permission to conduct an interview. I will describe the interview's purpose and scope, highlighting the value of their knowledge and contribution to the research. I will schedule interview sessions at mutually convenient times following their approval. I will guarantee accurate communication and respect participants' time and preferences throughout the recruitment process. I know that participants may have busy schedules, so I will make sure that their participation in surveys and interviews will be at their own time and convenience.

Using Google Forms, emails, LinkedIn, and WhatsApp, I expect to reach a wide variety of participants who can provide valuable points of view regarding the use of AI in Phase III clinical trials in India. I will personally approach those interested to guarantee a respectful and consent-based recruitment process.

SECTION 6: INFORMATION, CONSENT AND CONFIDENTIALITY

6.1 INFORMATION LETTER FOR PARTICIPANTS

Please confirm below that your information letter covers:

- Description of the research topic and method Yes
- Details of what participation will involve Yes
- Rights to anonymity Yes
- Confidentiality Yes
- Rights to withdraw from the research Yes
- The contact details of the researcher (and supervisor if necessary) Yes

6.2 CONSENT FORM FOR PARTICIPANTS

Yes: My research study involves interviews for which I need signed consent of participants but for my online Google form surveys, I do not need that

SECTION 7: STORAGE OF MATERIALS

7.1. DATA STORAGE AND MANAGEMENT PROTECTION ISSUES

Reflect on:

- Whose data you will collect.
- What data you will collect.
- Where you will collect it, store it and analyse it.
- How you propose to store the data.
- How long you will keep the data for.
- Reasons why you might need to maintain or keep it for longer.

State your plan in the box below:

For data collection, I have planned to use a mixed-method approach. Qualitative data will be collected through audio-visual recordings of interviews with participants, including clinical data managers, AI experts, university students, and employees with experience in clinical trials. These interviews will provide information about their perspectives and experiences related to the application of AI and robotic process automation in Phase III clinical trials in India. Particularly here I focused on the RPA part on clinical trials because I know a few of my colleagues who already worked in India in RPA regarding conducting clinical trials. So, it would be really interesting to know more about the implementation of ML as well in clinical trials in India. The audio-visual recordings will be initially stored on a digital device, such as a smartphone, during the interview sessions. Once the recordings are transferred to my personal PC, they will be deleted from the phone to ensure data security and privacy. Additionally, to ensure data backup, a copy of the recordings will be saved on Griffith's One Drive, a secure cloud storage platform.

For data analysis, transcripts of the interview conversations will be prepared in Microsoft Word. These transcripts will capture the interviews and provide a textual representation of the data. Similar to the audio-visual recordings, the transcripts will be stored on my PC and backed up on Griffith's One Drive.

Quantitative data will be collected through Google form surveys distributed to participants. The survey data will be collected and stored directly within Google Forms, ensuring data confidentiality and ease of analysis. Google Forms provides a secure and convenient platform for gathering quantitative data.

Overall, these data collection and storage measures aim to ensure the privacy, security, and organization of both qualitative and quantitative data throughout the research process.

In a mixed-methods approach, a sampling plan can use parts of both probability sampling and non-probability sampling. Sequential sampling is when you use probability sampling for one step (like random sampling for qualitative interviews) and non-probability sampling for the next step (like a survey). Triangulation uses different sample methods for qualitative and quantitative parts, such as purposive sampling for qualitative research and probability sampling (e.g., simple random sampling, stratified sampling) for quantitative research. With embedded sampling, one type of data collection is put inside another. One way uses probability sampling, and the other uses purposive sampling. Setting quotas for characteristics of interest and choosing participants on purpose to meet those quotas is how quota sampling ensures diversity and fair representation. The choice of strategy should be based on the study questions, the type of data, how easily it can be done, and how many resources are available. Validity and reliability should also be considered. Consulting with advisors or the dissertation committee can provide me with further guidance.

How will you manage data protection issues?

Information is to be collected and stored using password protection. The information is proposed to be stored for two years before being destroyed. Data will be handled using General Data Protection Regulation (GDPR) and national Data protection laws. Information provided by the participant will be stored adhering to Griffith College Dublin/ Innopharma Education policies

and in alignment with GDPR and Data Protection. Data retention is transparent and lawful in this research. All raw data obtained including signed consent forms and audio recordings will be stored confidentially until the end of the research and until the exam board confirms the results of the dissertation. This raw data will be stored in an appropriate folder on Moodle for archiving purposes. Limited personnel will have access to these files, but they can be reviewed by myself, my supervisor, a second reader, or an external examiner if required during the retention period.

Personal data will be anonymized at the earliest opportunity in this research study. Data will not be shared with anyone without the prior consent of the supervisor or the college authority. GDPR and national data protection guidelines will be followed for the protection of individual information. As this research is for a dissertation, all collected data, **including signed informed consent forms**, participant information letter, original audio recordings, and interview transcriptions will be kept in password-protected files on my laptop, which is locked with restricted access, and will be stored for a period of two years following the end of the research and post conferral of results of the dissertation by the exam board. Raw data including transcripts of interviews in which all personal identifying information has been removed will be uploaded to Moodle in a password-protected folder and will be accessible to the supervisor, the second reader, or an external examiner. The results of this study will be submitted in my final dissertation as part of my Master's degree.

SECTION 8: DOCUMENT CHECKLIST

Include Appendix A and B in this document. Please leave N/A if not applicable:

8.1 Information letter for the participant (Appendix A) Yes

8.2 Consent form for the participant (Appendix B) Yes

8.3 Questions (Appendix C) Yes

8.4 Other document(s) - please specify (Appendix D) N/A

APPENDIX D, etc.: OTHER DOCUMENTS

A2. Interview materials

Questionnaire protocol used for interviews

Interview Protocol

A. Opening Questions:

Personal Details:

- Name:
- Job Title:
- Department:
- Length of service:

1. What is your current role and area of expertise?
2. How long you have been working in Clinical Trials?

B. An overview of your Role:

1. Can you provide an overview of your role as a Clinical Data Manager in the context of phase III clinical trials?
2. How familiar are you with the concept of AI (machine learning & robotic process automation) and its application in clinical trial data management?

C. Views on implementation of AI (Machine learning & RPA) in clinical trials:

Influence and Benefits of AI in Clinical Trials

1. What influence does AI machine learning & RPA have on Phase III clinical trials' effectiveness and efficiency in India?
2. How has the adoption of AI and machine learning (ML) & RPA in clinical trials grown in recent years?
3. Why is India regarded as one of the most important clinical trial markets, particularly in the context of AI/ML applications?
4. What are the possible benefits of using AI and machine learning in clinical trial preparation, execution, and analysis?

Challenges and Obstacles in Implementing AI in Clinical Trials

5. What are the challenges and obstacles to applying AI machine learning in India's Phase III clinical trials?

Insights from Clinical Trial Professionals

6. As you have experience in clinical trials Phase III, what insights you can provide regarding the use of AI machine learning & RPA in these trials?

AI and RPA for Improving Clinical Trial Efficiency

7. How can AI and RPA help to reduce clinical trial failure rates in India?
8. How should AI and machine learning increase clinical study efficiency and cost-effectiveness?
9. How can machine learning-based predictive models help in the early detection and prevention of drug-drug interactions (DDIs) in Phase III clinical trials?
10. What are the possible benefits of employing AI and RPA for developing personalized therapy plans?

D. Closing Question:

15. Are there any other issues that you feel may be relevant to this discussion that you would like to explore?

Interview Invite:

Dear <recipient>,

Hope you are doing well.

As per our conversation. I have scheduled a Zoom meeting.
Shubhangi Chaurasia is inviting you to a scheduled Zoom meeting.

Topic: Shubhangi Chaurasia's Zoom Meeting
Time: Aug 6, 2023 05:00 PM Dublin

Join Zoom Meeting
https://griffith.zoom.us/j/7050355657
Meeting ID: 705 035 5657

The interview protocol consists of a list of questions for the interview.
The Participant Information Letter highlights the details of the thesis and how the information will be handled.
The Consent Form must be signed by you before I can use any of your information for my thesis.

Please find the attached documents.
Looking forward to hearing from you.

Thanks, and Regards
Shubhangi Chaurasia

Example of Interview transcript (Participant 1)

Hello Manu sir, please let us know about your current role and expertise right now.
Currently...Hi, this is Manu Somanath,
Okay, so, Just to inform you that this audio is going to be recorded, do you consent to that?
Yea…I consent to the recording.
16:23:39 Okay, and how long you have been working in the clinical trans?
16:23:44 Oh, 15 years?
16:23:46 Okay. And, if, I want to talk about your role, so can you provide me some overview of your role as a clinical data manager, in the context of phase 3 clinical trials?

16:24:04 Okay, yeah, yeah.

16:24:00 So I, I can't brief you in detail but I can just give a description descriptive, role which I'm working on.

16:24:09 Yeah.

16:24:16 Yeah.

16:24:09 So I mainly handle global studies where I manage my team here from India by reviewing their reports and by providing them details and required feedback.

16:24:23 To connect them and by giving them training and protocol and all.

16:24:31 Okay, so, like you are working already on clinical trials from the last 15 years. So like how familiar are you with the concept of AI machine learning, and robotic process automation in clinical trials?

16:24:44 In India.

16:24:46 In India, till now. It's not that familiar with AI technology.

16:24:53 Okay.

16:25:00 Okay.

16:24:55 I haven't come across any AI technologies. Recently in the last 15 years. It's been recently, that AI is coming out, approaching more in more covering of it more industries than in clinical trials.

16:25:07 I haven't seen much of that expertise. I am not an expert on AI in the clinical trial industry.

16:25:14 Okay, so like it's not that much familiar in India till now.

16:25:18 Not yet, not yet.

16:25:20 Okay. And, what do you think? What influence do AI machine learning and RPA have on clinical trials?

16:25:30 Like if it will come to India or if somewhere it's already working like.

16:25:36 It would be beneficial when it comes. It can reduce the time Gap, which has been.

16:25:44 Shown in this now current industry by or by identifying the exact correct Patients into the trial.

16:25:54 It can help in the recruitment process. Or it can work it can help in the analytical process. By giving exact results or parameters which has to be identified.

16:26:07 And that time can be the time of result which has been Now taking, now, now, we are observing and AI can reduce the time gap in comparison with the regular analytical methods.

16:26:21 Yeah.

16:26:24 Okay. During my research, I have seen Most of the paper or something like, like India

is regarded as one of the most important clinical trial markets.

16:26:38 So particularly in the context of AI or ML application, what do you think about that?

16:26:17 India is considered a good clinical trial market because of the cost when compared to other countries

16:26:51 Yeah.

16:26:52 The cost is less. So when you when you plan to connect a trial in India. If you're spending $100 in out-of-India countries but within space spending $50 or $700, you can get that trial done, PERSPECTIVE, because of the cost, where the cost effect is very cost-effective.

16:27:10 And, when, when it comes to AI also. The applications that are being used in the clinical industry.

16:27:17 That also would be costing less. So that's the reason, mostly. Most of the sponsors prefer Indian countries to be part of the Trials.

16:27:26 So that it is more effective for them. And they'll be also getting a large number of patient pools.

16:27:34 Yeah.

16:27:32 Patient population more here. So they get good results out of it. And with the cheaper quality that's a cheaper cost.

16:27:41 Okay, like, especially well, like if we, accept AI in India, so like it will cut the cost of the trials and consumes like consume less time.

16:27:54 Yes. Yes, yes.

16:27:53 So that's beneficial. So like the challenges and obstacles that we see in applying AI in India, what it would be like according to you?

16:28:04 These are the benefits that we were talking about this will cut the cost of the trials and save so much time but what will be the challenges?

16:28:15 What do you think about that about the challenges?

16:28:22 Yeah.

16:28:19 Challenges, I'm not sure about the challenges because we haven't seen any technologies here in India till now we haven't used come across any technologies using we've been using But when it comes it is beneficial for I just said that I'm, investing the time, which is invested in this.

16:28:40 Clinical trials on each, levels that can be reduced. But challenges. I'm not that sure about the challenges that can come across when A comes into clinical time industries.

16:28:54 Okay, so, The one question that I have in my mind I have like how can machine learning-based productive models help in the early detection and prevention of drug-drug interactions in phase III trials.

16:29:13 Yeah.
16:29:10 Can you brief me something about that? Like drug interactions with the help of AI or something. How can we?
16:29:17 Yeah, that's not that, you're using technology. You have the analytical part.
16:29:22 Will be a good opportunity for them to get good results out of it. By testing when you come when a company, Indian population or Indian.
16:29:31 Studies with large number of person has been tested on So, to analyze such kind of huge data. Yeah, and by giving a predictable result out of that huge data.
16:29:42 So AI would be a good, supportive method to be followed. Go to get good kind of results.
16:29:48 To analyze that's kind of data, huge data. And by that cutting out cutting on time and cost it can be it we can industry can move to the next phase of the trials also fast in faster phase instead of taking a long time say that for a, for taking a long time to get the analyst part done the next phase of the trials also, for taking a long time by saying that for a few feature
16:30:15 disadvantage, for taking a long time by say that for a few, and being taken longer times to get the analyst part to be done to review those data, to get the approvals, all those things.
16:30:18 You would be taking multiple, years. if AI comes into the picture then that can be in a slow, faster phase, in which that time cost would be reduced, the time would be reduced so that that, can be coming into the market in a more earliest.
16:30:32 Yeah, another way than which has been taken now. Now it has been taking more years. Do pass through many approvals, to analyze the data which is taking years.
16:30:42 And to the ones that are, that has to be given, giving an approval, a regulatory approval, has to be taken.
16:30:47 But when the analysis part is taken
16:30:51 In the through AI. It can cause the time can be lessened. And that can be first early approval be received.
16:31:00 The impact will be into the market beneficial for the patients who are suffering.
16:31:04 Okay, so like in the trials there are also personalized therapy plans that used to take place in the clinical trial thing so do you think AI will help in that also like?
16:31:17 Personalized medications that we provide to the patients.
16:31:21 Yeah, that will be helping. Yeah, I can help that kind of. Personal medication.
16:31:27 That's good. Yes. Yes, yes, that can help.
16:31:27 Okay, with the analytical part or, okay. Okay, so. Okay, so for the last question, is there any other issue that you feel may be relevant to the discussion that you would like to explore?

16:31:42 For my dissertation, it's like, so your insights will be really helpful for me.
16:31:47 So, like in a, The trial there are different kinds of trials like there are phase trials they are of this studies, there are RWA studies.
16:31:57 No.
16:31:59 So the AI can be implacable only in such few kinds of studies like it can be more implacable in RWA studies
16:32:08 Kind of studies where or up there some kind of studies where they are The studies are based on the data, which are we analyzed.
16:32:17 So this kind of AI technology, if we didn't, if it is implemented in our Kind of studies, that will be very helpful for research kind of studies where that analyst will be in faster phase and a greater number of studies can, come into the picture and they can come out with good results around outcomes.
16:32:36 Okay.
16:32:36 So PHASE plans, it is in phase, the A technologies can be used under. Statistical part, or research, and like, analytical part.
16:32:44 Yeah, and for recruiting patients, and yeah.
16:32:45 Or during the recruiting patient part or dispensing drug but on that and that category sending all the AI can be helpful.
16:32:55 Technology to be used so that it can be relevant in the phase trials also but It is more, it will be more helpful for the RW kind of studies where the data has been analyzed.
16:33:07 So it will be helpful for that kind of.
16:33:09 Like as I have selected particularly like research on the phase 3 clinical trial so like with the AI how it can be.
16:33:20 Helpful to me like for face especially.
16:33:21 Yeah, and if you are looking for phase 3 trials it will be helpful in the patient recruitment.
16:33:32 Yeah.
16:33:28 Where the patient can be recruited more and more. More an easier way and if there is if it is a randomized kind of trial The randomization process can be used through AI technologies or the drug dispense process or back to practice.
16:33:42 Just in that can be taken care of their technologies. Where Patients can be recruited in the easier way there is there we know. what you say is a matrix, which would happen in a normal general, randomization process, or this transition method, which has been, followed as a computerized method.

16:34:00 But if we need them, is AI technology kind of technology, we just use, well, expansion, the, or recruitment of the patients.
16:34:08 Yeah.
16:34:06 Or we run for randomization in the patients. This would be given minimal, mistakes would happen and that can be given.
16:34:13 Good results came out of it where the This is by minimal, but the benefit is more.
16:34:20 Okay.
16:34:28 Okay.
16:34:25 Thank you so much. I'll now stop the screen sharing. Yeah, thank you so much for your time.
16:34:37 Thanks.
16:34:37 I hope this will help me in my dissertation, so I'll go further with it. Yeah.
16:34:43 Sure, if you come across any other doubts you can just contact me I can give the feedback.

Question and answer format: sample (Participant 5)

Interview Protocol

A. Opening Questions:

Personal Details:

- Name: Rashi
- Job Title: I want to keep it anonyms.
- Department: Operations Department
- Length of service: 9 Months

1. What is your current role and area of expertise?
   Role- Data Coordinator
   Area of expertise - Clinical Data Manager
2. How long you have been working in Clinical Trials? 9 Months

B. An overview of your Role:

1. **Can you provide an overview of your role as a Clinical Data Manager in the context of phase III clinical trials?**
   - My role is to ensure the timely, reliable, and efficient compiling of any data or information gathered for the duration of the clinical trial also to record all data and coordinate with the investigators or research nurse regarding which pieces of data are to be collected and tracked.
2. **How familiar are you with the concept of AI (machine learning & robotic process automation) and its application in clinical trial data management?**
   - Concept of AI has been a boom from past few years, having many applications and electronic data capture systems are now standard, in comparison to data entry capabilities of the last twenty years, allowing for the automation of processes, storage, and electronic data display, improving patient care while reducing processing times and costs. With an average of more than 12 different data types from various sources being collected for a trial, it is imperative to have a good decentralized clinical trial (DCT) strategy to capitalize on learnings from the captured data.
   - Using artificial intelligence (AI) and machine learning capabilities, research teams can move more quickly in the review of their captured data. Moving to clean data capture with AI and machine learning vs the original manual review of data, it has been reported from larger trails to reduce manual data cleaning by more than 3000 hours.

C. Views on implementation of AI (Machine learning & RPA) in clinical trials:

Influence and Benefits of AI in Clinical Trials

1. **What influence does AI machine learning & RPA have on Phase III clinical trials' effectiveness and efficiency in India?**
   - Future of clinical development is on the verge of a major transformation due to convergence of large new digital data sources, computing power to identify clinically meaningful patterns in the data using efficient artificial intelligence and machine-learning algorithms, and regulators embracing this change through new collaborations.

2. **How has the adoption of AI and machine learning (ML) & RPA in clinical trials grown in recent years?**
    - We view AI/ML as knowing what to do, RPA is knowing how to do it- Machine learning and RPA has the potential to help improve the success, generalizability, patient-centeredness, and efficiency of clinical trials. Various ML approaches are available for managing large and heterogeneous sources of data, identifying intricate and occult patterns, and predicting complex outcomes
3. **Why is India regarded as one of the most important clinical trial markets, particularly in the context of AI/ML applications?**
    - India has rapidly become one of the preferred destinations for clinical trials owing to its large heterogeneous patient pool, rapidly transforming healthcare market, highly educated physicians and cost competitiveness propels the market growth. In addition, increased investment from foreign companies as well as local market players either individually or in collaboration is likely to boost the market growth during the forecast period. Further, emerging research areas such as diagnostic research are expected to fuel the Indian CRO market.
4. **What are the possible benefits of using AI and machine learning in clinical trial preparation, execution, and analysis?**
    - AI and machine learning can improve clinical trials in the following ways:
        - Reduce clinical trial cycle times.
        - Improve the costs of productivity and outcomes of clinical development.
        - Enable the continuous stream of clinical trial data to be cleaned, aggregated, coded, stored, and managed.
        - Help life sciences companies build trust with communities that have been historically underrepresented in clinical trials and improve health outcomes.
        - Predict outcomes in clinical trials, leading to faster drug approval times, lower costs, and more funding to develop new treatments.

Challenges and Obstacles in Implementing AI in Clinical Trials

5. **What are the challenges and obstacles to applying AI machine learning in India's Phase III clinical trials?**
    - The digitalization and accessibility of (**Electronic Medical Record)** EMR data in Phase III clinical trials that are used extensively by AI methods are not trivial. Both

tasks are challenging for contrary reasons: on the one hand a lack of regulatory frameworks on data collection causes EMR formats to differ widely, to be incompatible with each other or not digital at all, and to reside in a decentralized ecosystem without established data exchange or access gateways. On the other hand, a strongly regulated legal environment strictly limits third-party access to patient data and even makes it difficult for patients themselves to access their own data. This so-called 'EMR interoperability dilemma' is being recognized as major hurdle to making healthcare systems more efficient, and substantial investments are being made by governments and medical institutions towards overcoming this hurdle. In parallel, legal frameworks such as, for example, the US Health Insurance Portability and Accountability Act (HIPAA) and the EU General Data Protection Regulation (GDPR) continue to evolve as governing and protecting sensitive health data becomes an increasingly complex endeavor in the growing network of devices, data owners, and service providers. Further, exactly as with EMR mining, for clinical trial matching the legal aspects of data privacy and security as well as a sufficient degree of explainability of AI models need to be addressed to ensure that AI-based systems are operable and gain regulatory approval.

Insights from Clinical Trial Professionals

6. **As you have experience in clinical trials Phase III, what insights you can provide regarding the use of AI machine learning & RPA in these trials?**
   - As these tools evolve, new opportunities will continue to emerge that drive further benefits to the clinical research landscape. Applications of AI and ML in healthcare are expected to grow nearly $8 billion by 2022, up from $667.1 million in 2016; and almost half of global life science professionals say they are either using or interested in using AI in their research.

AI and RPA for Improving Clinical Trial Efficiency

7. **How can AI and RPA help to reduce clinical trial failure rates in India?**
   - Randomized Clinical Trials (RCT) are the golden standards for testing new therapeutics for safety when used in human subjects. Even though the success rates lie between 40-80% across different phases, there is a significant number of failures as well due to patient recruitment. The challenges of conducting RCTs can result in an extended research timeline, which increases the cost of the trials. The factors that

impact RCT include the availability of patients, patient retention, availability of principal investigators, trial sites, and study design. The entire RCT lifestyle from research design to its completion is a complex environment ridden with data. RPA would help in optimizing these processes while improving the success rate and efficiency of clinical trials.

- Significant development within the pharmaceutical world can be stimulated by quick data integration into complex environments and merging RPA with it to improve and streamline administrative activities.

8. **How should AI and machine learning increase clinical study efficiency and cost-effectiveness?**

• Improve the costs of productivity and outcomes of clinical development.

• Enable the continuous stream of clinical trial data to be cleaned, aggregated, coded, stored, and managed.

• Help life sciences companies build trust with communities that have been historically underrepresented in clinical trials and improve health outcomes.

• Predict outcomes in clinical trials, leading to faster drug approval times, lower costs, and more funding to develop new treatments.

9. **How can machine learning-based predictive models help in the early detection and prevention of drug-drug interactions (DDIs) in Phase III clinical trials?**

- By applying the NLP LDA model to the clinical notes dataset, we identified the following status to improve early detection and prevention of drug-drug interactions (DDIs) - (1) clinical status, (2) communication, (3) laboratory tests, (4) non-clinical status, (5) social relationships, (6) symptom, and (7) treatment.

10. **What are the possible benefits of employing AI and RPA for developing personalized therapy plans?**

- The benefits are clear. With AI and machine learning capabilities, pharmaceutical companies can collect, store, and analyze large data sets at a far quicker rate than by manual processes. This enables them to carry out research faster, based on data about genetic variation from a huge wealth of patients, and develop targeted therapies faster. In addition, it provides a clearer view on how small, specific groups of patients with certain shared characteristics react to treatments, and therefore how to precisely map the right quantities and doses of treatments to give to individuals.

D. Closing Question:

15. **Are there any other issues that you feel may be relevant to this discussion that you would like to explore?**

    No, I think I covered maximum, would research more to understand the role of AI and ML in healthcare.

A3. Survey Material

Google form survey link:

https://docs.google.com/forms/d/e/1FAIpQLSeu687JVPIQwYfH0I54Ah4so4oMydjhcQ6uAbEdG7QnJqnYCw/viewform

A4. Dissertation progress report summary:

Student Name	**Shubhangi Chaurasia**
Student Number	**3095283**
Programme	**MSc in Pharmaceutical business & technology**
Cohort	**11**
Module	**Dissertation**
Supervisor	**Dr. Sue Mulhall**
Dissertation Title	**The Application of AI (Machine Learning & Robotic process automation) Phase III Clinical Trials in India**

Gannt Chart:

Week no:			W 0	W 1	W 2	W 3	W 4	W 5	W 6	W 7	W 8	W 9	W 10	W 11	W 12	W 13
Dates:	22-May	29-May	05-Jun	12-Jun	19-Jun	26-Jun	03-Jul	10-Jul	17-Jul	24-Jul	31-Jul	07-Aug	14-Aug	21-Aug	28-Aug	04-Sep
Task Name																
Preliminary Document																
Bootcamp																
Supervisor assigned																
Final Research Proposal Submission (18-Jun)																
Ethics Workshop																
Literature review week																
Writing Introduction Chapter																
Ethics forms Submission:																
Data Visualization Workshop (06-Jul)																
Data Analytics Workshop (11-Jul)																
Writing Literature review Chapter																
Questionnaire Design Workshop (21-Jun)																
Writing Methodology Chapter																
Preparing for Interviews																
Conduct interviews																
Research Analysis																
Writing findings and analysis Chapter																
Writing Conclusion																

Chapter																
Mini Viva																
Viva Prep Workshop																
Data Final conclusion																
Supplementary information																

A4. QUESTIONS (extra)

- Have you had the opportunity to read the Participant Information Letter/Email I sent to you last week?
- Do you understand your rights to participate in this research, as agreed in the Informed Consent Form?
- Are you happy to sign the consent form? interview?

- Do you have experience in the field of Clinical trials and/or the implementation of AI i.e. artificial intelligence tools, such as machine learning & RPA? What is your role?

- What is your current understanding of 'Robotic process automation' in clinical trials phase III?

- In your experience, have efforts been made to incorporate machine learning & RPA principles for the clinical trials where you have worked in this field? If yes, what are they?

- What are the critical success factors for the successful implementation of AI (Machine Learning & Robotic Process Automation) in Phase III clinical trials in India? (i.e., what factors are necessary to ensure a successful implementation?)

- What are the critical failure factors for the adoption of AI (Machine Learning & Robotic Process Automation) in Phase III clinical trials in India? (i.e., what factors could hinder or lead to the failure of the implementation?)

- In your opinion, which aspects of real-time monitoring and safety analysis in Phase III clinical trials could benefit from the application of Continuous Improvement (CI) tools?

- What do you perceive as the main difficulties or challenges associated with integrating AI (Machine Learning & Robotic Process Automation) in Phase III clinical trials in the healthcare system in India?

- If you have experience working with AI, Machine Learning, or Robotic Process Automation in the pharmaceutical industry, have you implemented these tools in the context of Phase III clinical trials?

- From your experience, which areas within Phase III clinical trials have you seen that have benefited from the implementation of ML(machine learning) & RPA?

- What specific measures do you believe could be used to improve healthcare in Phase III clinical trials involving AI and automation technologies?

- How familiar are you with the concept of ML & RPA in the context of clinical trial operations and management?

- Have you encountered any specific challenges or obstacles when applying ML & RPA in the context of Phase III clinical trials involving AI and automation technologies?

- In your opinion, what potential future advancements and opportunities do you foresee for the application of AI (Machine Learning & Robotic Process Automation) in Phase III clinical trials in India?