APPLICATION OF ARTIFICIAL INTELLIGENCE (AI) IN OPTIMISING PATIENT RECRUITMENT IN CLINICAL TRIAL ENROLMENT PROCESSES

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I certify that the dissertation entitled: "**APPLICATION OF ARTIFICIAL INTELLIGENCE (AI) IN OPTIMISING PATIENT RECRUITMENT IN CLINICAL TRIAL ENROLMENT PROCESSES"** submitted for the degree of **MSc in Digital Transformation in Life science** is the result of my own work and where reference is made to the work of others, due acknowledgment is given.

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RAJITHA KANDIMALLA

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LIST OF ABBREVIATIONS

Abbreviation	Full Term
AI	Artificial Intelligence
CAGR	Compound Annual Growth Rate
CRO	Contract Research Organization
DL	Deep Learning
EHR	Electronic Health Record
EMA	European Medicines Agency
FDA	Food and Drug Administration
GCEC	Griffith College Ethics Committee
GDPR	General Data Protection Regulation
KPI	Key Performance Indicator
ML	Machine Learning
NLP	Natural Language Processing
SaMD	Software as a Medical Device
XAI	Explainable AI
χ^2	Chi-Square
df	Degrees of Freedom
p	Probability Value

Abstract

Application OF Artificial Intelligence (AI) in Optimising Patient Recruitment in Clinical Trial Enrolment Processes

Rajitha Kandimalla

In this study, an evaluation of AI technologies in clinical trial recruitment was conducted through a quantitative survey of 120 professionals including Clinical Research Associate, Clinical Trial Coordinator, Clinical Research Physician, Clinical Data Manager, Digital Technology Specialist, Clinical Research Manager, AI Implementation Specialists and Clinical Operations Director. The research examined AI's impact on recruitment efficiency, participant diversity enhancement, implementation challenges, and operational outcomes. Findings revealed substantial AI adoption (71.7%) with significant efficiency benefits, as 65.9% of respondents agreed AI reduces recruitment time, with 46.6% reporting time savings exceeding 50%. AI demonstrated particular effectiveness in participant screening (32.5%) and database management (29.2%). Regarding diversity enhancement, perceptions were mixed (42.5% reporting positive impacts), with language barriers (25.0%) identified as the most addressable diversity challenge. Data privacy emerged as the predominant implementation concern (79.2%), alongside balanced challenges in skilled personnel availability, tool complexity, and resistance to change. Operationally, AI showed promise in patient monitoring (72.5% reporting improvements) and overall efficiency (35.0%). Statistical analysis revealed significant differences between AI users and non-users across multiple dimensions, suggesting implementation experience substantially enhances perceived benefits. The research indicates AI offers meaningful advantages for clinical trial recruitment, though successful implementation requires addressing interconnected technical, organizational, and human factors through comprehensive, phased implementation strategies.

1. Introduction

1.1 Overview

Clinical trial is a disciplined study to assess medical interventions and novel pharmacological agents to determine if they are safe, effective, and used appropriately in accordance with ethics and integrity principles such as the Declaration of Helsinki and the Nuremberg Code. Despite their importance for the advancement of healthcare, clinical trials are still suffering from long-standing recruiting problems that dampen the speed of medical discoveries and increase the costs of research. Traditional recruiting techniques often fail to obtain adequate enrolment, attributed to low visibility for prospective volunteers, restrictive criteria of suitability, practical barriers, and insufficient representation of diverse populations (Bikou et al., 2024).

Artificial intelligence (AI) technology has emerged as a promising technology in the healthcare sector, and clinical research is no exception. AI stands for sophisticated computing systems programmed to perform human-like intelligence functions such as learning, reasoning, and decision-making, using such strategies as Machine Learning (ML), Natural Language Processing (NLP), and neural networks. The advanced capabilities of AI to process massive datasets and set patterns, as well as predict outside human range, derive from AI (Alowais et al., 2023).

With the help of AI, clinical trial recruitment has been greatly enhanced because AI uses electronic health records, which enhances matching of patients to clinical trials and enhances protocols, as reported by Sedano et al. (2025). Benefits of technologies such as TrialGPT are that they use large language models to establish how patient profiles fit complicated eligibility requirements, thereby significantly reducing both efforts and time of screening (Coherent Solutions, 2024). As well as recruitment, AI is used in such spheres as protocol development, safety monitoring, data management, predictive patient responses, or adaptive trial design (Askin et al., 2023).

Using AI for clinical recruitment potentializes a great ability to break through historical barriers in terms of improved efficiency, widening of the scope of inclusions for participants, and hastened delivery of new treatments. The study investigates ways AI can transform patient recruitment procedures, considering their practical side and structural barriers that stakeholders must overcome to achieve successful implementation.

1.2 Research Purpose

This research aims to evaluate the effectiveness and implications of AI technologies in optimising patient recruitment for clinical trials. The most crucial challenge for clinical trials and associated research is recruiting participants since approximately 80% of clinical trials fail to recruit individuals within their set timelines. Such delays increase financial burdens, hinder the advancement of lifesaving treatments, while possibly undermining the statistical value of the research results (Brøgger-Mikkelsen et al., 2020). The focus here is to identify whether AI-based approaches are in a position to reduce, and preferably solve, these perennial issues that are encountered in clinical trial recruitment.

The study examines how AI can transform the well-known arduous patient recruitment process traditionally carried out to include automated EHR screening, NLP of patient's documents, and predictive modelling that identifies eligible participants. It aims to find out whether the AI can accelerate the recruitment process and encourage a more diversified pool of participants, which is a prerequisite for the generalizability of clinical outcomes (Marko et al., 2.

The study also seeks to measure practical impacts of AI data inclusion to existing clinical trial flows, casting light on new efficiencies and new roadblocks that might require management interference. It explores the intricate synergy of technical, organisational, regulatory and ethical components critical for successful introduction of AI in healthcare.

The following work aims to integrate knowledge gained from these spheres into a pragmatic and ethically guided framework for using AI in clinical trial recruitment, in the furtherance of medical development and protection of research integrity.

1.3 Significance of the Study

This study aims to examine the integration of AI Industry in clinical trial recruitment so that significant barriers at the convergence of medical science and digital technology can be nullified. The terrain of clinical trials in the year 2025 is filled with increased complexity, which is largely fuelled by the need to adopt fluid protocols and establish carving out niche-enrolled patients. Historically, recruitment into clinical trials has always represented the strongest barrier and translated into significant delays in approximately 80% of trials (Beaney, 2025).

The financial implications emphasize the worth of these findings. With a total of $2.7 billion in 2025 and predicted to move towards nearly $8.5 billion by 2030, which

showcases massive monetary implications with a CAGR of 24 – 28%, the AI clinical trials market is an example. Furthermore, AI solutions can save the pharmaceutical sector $20-30 billion annually by 2030 due to productivity increases and accelerated trials (Ilancheran, 2025). One of the primary benefits is the potential to save the pharmaceutical industry $20-30

Outcomes of early AI recruitment solution deployments turn out optimistic. Solution examples such as TrialGPT have optimized patient-trial matching to a 87.3 % precision and reduced screenings by 42.6%. They seek to address the two-pronged problem of trial delay and lack of diversity of participants, and they help to increase the representation of the trial populations of the real-world patient groups (Coherent Solutions, 2024).

More than its aid in recruiting patients, this research highlights significant regulatory and ethical problems associated with AI deployment in healthcare. Amid steadily increasing trial sophistication, the challenge is exacerbated by administrative barrier, resource shortage, and complex data handling needs, AI technologies represent a presumable route towards more enduring and impactful researching approaches (Rehman et al., 2024).

Based on a detailed evaluation of AI's effectiveness, challenges faced during implementation, and impact on clinical trial recruitment processes, this research provides essential data to all stakeholders in the clinical research sphere – ranging from the pharmaceutical companies to the contract research organisations to the healthcare providers and, the regulatory agencies – which cumulatively promotes the execution

1.4 Research Aim and Objectives

This research aims to evaluate the effectiveness and implications of using AI technologies in clinical trial recruitment. The study aims to improve efficiency, enhance diversity among participant pools, and understand the operational impacts and challenges of AI adoption in these processes.

The objectives of the research are as follows:

- To determine how AI technologies can speed up the recruitment process and make it more efficient compared to traditional methods.
- To investigate whether AI tools can improve the diversity of participant pools in clinical trials.

- To identify and analyse the major challenges and barriers that impede the adoption of AI in clinical trial recruitment.
- To examine the operational impacts of AI, focusing on patient recruitment, screening, enrolment, and monitoring, to understand how AI can enhance or complicate clinical trial operations.

1.5 Structure of the Study

This thesis is organised into five chapters, each designed to systematically address the research objectives and provide a comprehensive analysis of AI applications in clinical trial recruitment.

Chapter 1 introduces the research topic, establishing its purpose, significance, objectives, and structure. This foundation chapter contextualises the current challenges in clinical trial recruitment and the potential for AI to address these issues.

Chapter 2 presents a critical review of existing literature, examining current AI applications in clinical trials, recruitment challenges, technological capabilities, and implementation experiences. The chapter culminates in a conceptual framework that synthesises key variables and relationships to guide the empirical investigation.

Chapter 3 details the methodological approach, outlining the research philosophy, strategy, and design choices. It describes the mixed-methods approach combining qualitative interviews with clinical trial stakeholders and quantitative analysis of recruitment metrics. The chapter addresses data collection procedures, ethical considerations, and analytical techniques employed.

Chapter 4 presents the research findings organised thematically according to the research objectives. It explores AI's impact on recruitment efficiency, participant diversity, implementation challenges, and operational effects. The discussion section interprets these findings in relation to existing literature and theoretical frameworks, highlighting convergence and divergence with previous research.

Chapter 5 concludes the thesis by synthesising key findings and their implications for clinical trial practices. It acknowledges research limitations regarding sample size, geographical scope, and rapidly evolving technology. The chapter provides actionable recommendations for clinical research organisations, technology developers, and

regulators while suggesting directions for future research, including longitudinal studies on AI implementation outcomes and comparative analyses across therapeutic areas.

2. Literature Review

2.1 Introduction

Clinical trials constitute a cornerstone in evidence-based medicine for systematically evaluating the safety and efficacy of new therapeutic interventions. In addition to their regulatory approval role in pharmaceuticals, these trials are crucial for advancing precision medicine and helping patients (Gogtay *et al*., 2020). A long-standing barrier in the clinical research pipeline and source of waste is the recruitment of patients from which some are underrepresented, underslept, and late compared to other sources and sites, and often inefficiently.

Patient recruitment is challenging, and the issue spans many issues. Most approaches are based on manual chart reviews, clinician referrals, advertisements, and outreach campaigns. Although historically common, these strategies are no longer sufficient given today's data-driven clinical environments. Yanamala (2021) manual recruitment methods extend enrolment time and lead to low conversion rates from trial eligibility criteria to actual patients' data.

The existence of eligibility parameters available in modern clinical trials (comorbidities, genomic profiles, behavioral characteristics, and socioeconomic backgrounds) makes current approaches non-scalable and non-precise. As a result, there are increased dropout rates, under-enrolment, and a lack of diversity in trial participants, which reduces the generalizability of trial results (Gogtay *et al*., 2020).

It responded by emerging as a transformative AI that can solve these systemic issues. Because of the rapid advances in AI technologies, including ML, NLP, and predictive analytics, electronic health records (EHRs) and other clinical data can be rapidly analysed. They can quickly and precisely identify and match eligible patients in real time (Alanazi, 2023). Chopra *et al*. (2023) posit that AI-driven systems not only speed up the process of identifying patients but also cut down on human error, optimize resource use, and get a broader range of enrollees.

This literature review presents how AI might be effectively used to optimize the efficiency of patient recruitment in clinical trials through accuracy and scalability. The paper is structured around some central themes, such as the limitations of traditional practices, AI involvement in screening and matching and its influence on recruitment performance, stakeholder concerns, regulation, and ethics, and existing research gaps. This analysis

aims to comprehensively understand AI's transformative potential and its ethical limitations and implications in real-world clinical environments.

2.2 Theme 1: Traditional Recruitment Methods & Limitations

Traditional recruiting methods in clinical trials (e.g., advertising, clinician referrals, and manual screening) are considered uncontested as slow, expensive, and inefficient in achieving the target patient numbers. Often, these methods provide low participation rates, delaying trial timeliness and increasing operational costs. Such strategies are inadequate because they represent a barrier to rapid clinical validation in an era crucial for public health advancement and pharmaceutical competitiveness (Gogtay *et al*., 2020).

Manual chart reviews are one of the most commonly relied-on methods for trial-eligible participant identification. However, this method is time-consuming, labor-intensive, and error-prone. According to Lu *et al*. (2024), in many cases, a manual review of EHRS misses some eligible candidates because of variability in the clinician documentation and subjective interpretation. The inefficiency tends to lead to recruitment delays as well as trial under-enrolment.

In a study by Haddad *et al*. (2021), which reviewed more than 150 randomized trials, they reported that 86% of the trials could not meet their enrolment deadlines, most of which are attributed to the problems of traditional recruitment strategies. Widespread delays can compromise statistical power, diminish clinical validity, and increase trial costs. Eventually, recruited patients might not represent the diversity or complexity of the whole disease population, limiting the external validity of the trial.

A significant limitation is that those ads and public outreach campaigns rely on bringing in a narrow demographic of self-selecting people. In addition to sampling bias, this perpetuates the lack of minorities, older people, and people from less socioeconomically privileged backgrounds. Yanamala (2021) notes that these methods are biased and fail to align with the ideals of modern clinical research toward inclusivity.

Also, traditional referral systems place significant pressure on healthcare employees, making them draft the recruitment of patients to participate in trials. At the same time, they are also responsible for their clinical counterparts. Due to this, it is a generally missed opportunity to identify potentially eligible patients. Gligorijevic *et al*. (2019) found that only less than 30% of potential enrolments were driven by referrals, which could imply significant inefficiency in the human-dependent systems.

However, such limitations also hinder patient retention. Lack of adequate information to patients, as well as patient dropout through surface-level recruitment, can lead to an increase in dropout rates. Harrer *et al*. (2019) also mention that patient dissatisfaction due to unclear expectations or eligibility surprises usually leads to mid-trial attrition, derails timelines, and adds costs.

These individual challenges highlight how we must leverage increasingly intelligent, scalable, and more inclusive recruitment methods. While foundational to early clinical research, manual processes are no longer sufficient to tackle the challenges and magnitude of modern trials. This has attracted the interest of researchers, clinicians, and policymakers exploring AI-powered recruitment as a promising alternative for speed and quality of recruitment.

2.3 Theme 2: AI Tools for Screening & Matching

Improvements in automation and optimization of the patient screening and matching process for clinical trial enrolment, an area traditionally done manually, however, inevitably suffers from inefficiencies and human errors, with AI. As healthcare data becomes digitalized, with EHRS, laboratory results, and imaging studies, AI has been identified as a feasible solution to leverage large data sets for time-sensitive matching of patients to trials. NLP, ML and deep learning (DL) algorithms together process structured and unstructured data about clinical processes to identify eligible patients with a high level of accuracy (Calaprice-Whitty *et al*., 2020).

Analysis of physicians' free-text clinical notes, radiology reports, and observations is one of the fundamental AI capabilities that can be used in recruitment. Trial protocols can be processed using NLP algorithms, and complex eligibility criteria extracted from them can be matched against the EHRS containing patient attributes. This functionality reduces clinicians' time to screen patients on their own. Calaprice Whitty *et al*. (2020) showed through a comparative study over three oncology trials that nearly all eligible patients were retained with a 40–57% reduced workload. The level of performance that can be achieved in such data-heavy environments, such as oncology or neurology, is not possible with standard keyword searches or those run by physicians.

ML models trained on labeled clinical data further refine this process by learning eligibility patterns as time passes. Once deployed, these systems reduce the number of irrelevant patients marked for screening and provide better recall and precision metrics.

Haddad *et al*. (2021) present that AI-based systems could find 24–50% more eligible candidates than manual reviews, doing the task in minutes, while manual reviews take weeks. They significantly speed up the enrolment timeline and relieve bottlenecks at the start of the trial.

Some proprietary AI platforms have grown to support large-scale recruitment in recent years. One company that has used this to enable a dab of automation in the field of healthcare trial eligibility matching is Mendel.ai or Deep6 AI, which interfaces with a healthcare system minimum patient data instead of being patient-focused and automatically matches the data with clinical trial eligibility criteria. The tools combine ensemble learning methods (e.g., deep neural networks) to classify patient profiles versus structured trial parameters (Ismail *et al*., 2023). For instance, Mendel.ai can read physician notes, treatment history and pathology reports and make matches frequently missed by rule-based or deterministic algorithms.

Imaging analysis technology and AI tools especially come into play. In radiology-dependent trials, such as those in which eligibility depends on size or lesion location, AI-enabled imaging solutions can identify relevant markers faster and more accurately than reviewers. In their paper, Roshan *et al*. (2024) note the use of Viz.ai. This imaging-based AI platform improves diagnostic accuracy and preselects possible candidates for trials about neurovascular and stroke-related diseases. Sites enrolled 36 percent more patients in the EMBOLISE trial using Viz RECRUIT than in facilities screening patients using standard procedures (Hassan *et al*., 2023).

AI tools improve the potential number of eligible participants and their quality (Chopra *et al*., 2023). Thus, when leveraging advanced multidimensional clinical factors, such as laboratory markers, comorbidity indices, and even social determinants of health, AI systems can refine patient cohorts and create groups more closely aligned with trial needs. Additionally, these systems add to the clinician's information by presenting ranked candidate lists with justifications for inclusion or exclusion, fortified with clinician trust.

In addition, real-world data from hospital networks or insurance claims databases may also be utilized to match with EHRS. For instance, Gligorijevic *et al*. (2019) utilised DL models to process more than 100,000 EHRS to show higher precision of trial patient matching compared to the baseline heuristic methods. This represents an advancement of DL’s ability to understand subtle clinical phenotypes.

However, despite that, operational issues remain. Von Itzstein *et al*. (2021) point out that pipeline automation for trial matching is limited because separate hospital systems are not interoperable. In addition, the model must be validated in real-time implementation in the dynamic clinical setting to avoid algorithmic drift, where model accuracy degrades over time as demographics or clinical practice change.

2.4 Theme 3: AI's Impact on Enrolment Efficiency

AI has great promise in overcoming the long-standing inefficiencies in patient recruitment in clinical trials. Most notably, it speeds enrolment timeliness, enhances the quality of cohorts chosen, and broadens participant pools, all of which increase clinical trial scientific robustness and ethical position. AI automates the messy screening processes by bringing together the multifaceted data sources of the research sites, enabling them to recruit faster, smarter, and more inclusively (Sedano *et al.*, 2025).

Viz RECRUIT is another example of AI disrupting the status quo, this time showing its utility in helping recruitment to neuro-interventional clinical trials; in the EMBOLISE trial, which included endovascular treatments, the poster listed research sites that utilize Viz RECRUIT as recording a 36% increase in enrolment over the use of standard screening processes (Hassan *et al*., 2023). The dramatic rise in volume resulted from greater volume and higher precision in identifying and reaching eligible patients in real time. The technology effectively sped up both identification and engagement by employing image-based AI models to identify suitable patients based on radiologic features.

In terms of accuracy, AI assisted systems showed remarkable reliability. In particular, Varnosfaderani and Forouzanfar (2024) demonstrated that supervised models for AI-supported up to 90% screening precision in the clinical setting, although they were supervised by trained personnel. In addition to increasing efficiency and operational outcomes, these systems decreased false positives compared to manual screening. This precision corresponds to the fact that AI could beat the conventional methods that are prone to human subject biases and mistakes.

Besides assisting speed and accuracy, AI helps with broader participant diversity, a long-standing problem in clinical trials. Recruitment methods traditionally depend on referrals from a local area and advertising aimed at specific groups of like demographics. Still, sometimes, they do not include ethnic minorities, rural residents, and people experiencing

poverty. On the other hand, AI-powered recruitment platforms can query national or international patient databases to find minorities for whom circumstances mean they are unlikely to have been considered before during prior outreach efforts, owing to location, socioeconomic status, or lack of healthcare access (Chen, 2023).

Chen (2023) states that with AI leaning toward decentralization and automation of the recruitment process, many implicit human biases creep in and are removed through the manual selection process. In some cases, AI tools analyze de-identified EHRS throughout large networks that will not cringe at appearance, language proficiency, and clinician familiarity. If this functionality is extended, recruitment could extend beyond academic medical centers and urban hubs, trials could be more reflective of real-world patient populations, and the external validity of trial findings might improve.

Perceptions of stakeholders are crucial in integrating AI into clinical trial operations. Askin *et al*. (2023), a survey-based study, found that 61% of the clinical research stakeholders view AI as indispensable to modernize trial logistics, particularly in high-volume and multi-center studies. Respondents mentioned that AI helps reduce 'time to first patient' metrics, improve site readiness, and improve inter-site communication. They also commented that AI can help with the implementation of remote monitoring methods, leading to more responsive loops (feedback) and faster protocol adjustments.

Additionally, Mendel.ai and Deep6 AI offer built-in analytics that gives trial sponsors real-time enrollment metric feedback and can dynamically adjust the recruitment strategy during recruitment. They record metrics such as enrolment velocity, demographic spread, and regional performance, and they let sponsors peer through the bottleneck and retool. Traditional recruitment metrics are often collected retrospectively and are not actionable during active trial phases (Gligorijevic *et al*., 2019).

Similarly, AI has helped run adaptive trial designs that involve rapid changes to the study protocol based on timely data that should not compromise validity. We can use it, for example, to detect faster than arbitrarily expected growth trends or safety signals that would call for cohort expansion or stratification. Since AI can process various kinds of data in real time, Saeed and El Naqa (2022) suggest that it paves the way for dynamic trial adaptation, which improves both efficiency and safety for participants.

However, these advantages have not translated into operationalizing AI in clinical trial enrolment, as it has specific challenges. This bottleneck has not been surmounted in

countries with rather skeletal digital infrastructures and legacy hospital information systems that integrate very poorly (Angus, 2020). Additionally, concerns about transparency and interpretability still loom, especially among regulatory bodies and ethics committees. Still, with the emergence of XAI models and increasing regulatory engagement, these questions are being discussed and addressed (González-Gonzalo *et al*., 2021).

Another area where AI is almost promising but less explored is the retention increase. For example, preliminary results from Thomas and Kidziński (2022) indicate that integrating patient-facing technologies such as mobile apps and telehealth with AI tools could reduce dropout rates since highly engaged and communicating users successfully interact with the tools. Despite that, significant work remains on the impact of AI on retention, and it is an important area of future research.

2.5 Theme 4: Operational & Stakeholder Implications

To operationalize AI in studies within clinical trial recruitment, a shift in infrastructure and the stakeholders' mindset is required. Each clinician brings different perspectives on automated implementation failure, as well as research coordinators and technology specialists. Until they were developed, there had been little empirical work on the unanticipated effects of automation on perceived efficiency, usability, workflow integration, and trust in automation.

From this clinician's viewpoint, the primary problem is to balance the trust in AI decisions with clinical judgment. According to Alanazi (2023), although healthcare providers recognize that AI technology can improve efficiency, they are also reluctant to delegate screening and enrolment decision-making to machine-driven systems completely. In high-stakes clinical settings, errors in patient selection often carry ethical and legal repercussions, especially this skepticism.

Additionally, training and adaptability are operational concerns. However, in most cases, clinicians and trial staff must be educated on new software interfaces, data visualization tools, and decision dashboards within their AI platforms. However, if this is not managed effectively, it can disrupt workflows and cause resistance to onboarding. Sites identified by Askin *et al*. (2023) that had faster readiness and more excellent recruitment rates were those clinics that received tailored training sessions and technical support. Thanks to these

sites, the integration was smooth enough, which reported improved collaboration between clinical and data science teams.

Interoperability of systems from a technology specialist's viewpoint is a central concern. Integrating AI platforms with existing EHR is rarely without problems in heterogeneous data architectures. Data silos, fragmented workflows, and less-than-optimal algorithmic performance are the result of compatibility issues. In their study von Itzstein *et al*. (2021) argue that robust data pipelines and middleware layers require harmonizing rate data sets for AI to receive clean, standardized inputs.

Institutional priorities also determine expectations related to stakeholder expectations. Trial sponsors aim at speed and number of enrolled, whereas trial sites focus more on reducing workload and staff satisfaction. However, gaps between quantitative and qualitative feedback from trial professionals (e.g., gathered through structured surveys) could be bridged. Survey-based assessments through Likert scales, dichotomous, and multiple-choice questions yield detailed information on user satisfaction, perceived barriers, and anticipated outcomes. Ali and Bhaskar (2016) state that such statistical techniques provide useful descriptive summaries and enable inferential comparisons across different site types or user groups.

Such evaluations often lead to data collection, which subsequently shows acceptance patterns. For example, professionals with over five years of experience in clinical trials would rather trust AI tools to provide actionable insights than opaque predictions. On the other hand, technology specialists prefer to customise AI outputs and audit them; they are not interested in static interfaces. The knowledge provided by these insights is important for iterating platform design and piloting with the user.

2.6 Theme 5: Ethical, Regulatory & Interpretability Issues

However, a number of ethical, regulatory, and transparency-related concerns related to the use of AI for clinical trial recruitment can hurt stakeholder trust and broader adoption. Given all of these, the issues are patient data privacy, algorithmic bias, opaque decision-making (or "black box" models), and inconsistent oversight by regulators across jurisdictions.

The protection of patient privacy is one of the most important ethical concerns. Because of this, access to electronic health records (EHR), imaging data, and potentially identifiable health information is critical for AI systems to function. Not all de-

identification protocols can guarantee that re-identification is impossible, particularly when large datasets are cross-referenced or when AI systems use indirect identifiers. Tilala *et al*. (2024) argue that breaches in certain aspects of privacy in AI-integrated clinical research affect patient safety and undermine public confidence in that method. They ask for dynamic consent frameworks and more excellent encryption standards to mitigate these risks.

The other closely connected problem is algorithmic bias, which can cause an algorithm to exclude or include specific populations over others systematically. It could be from a biased training dataset, biased labeling practice, or systemic disparities from historical clinical data. For example, an AI system trained with many urban, White, or male patient records would not identify potential candidates from marginalized or rural populations. In theory, AI can eliminate human bias, but such behavior will most likely reinforce existing imbalances in practice unless AI is properly audited and remediated (Chen, 2023).

This creates the idea of explainability (an integral part of ethical AI). AI tools, which generate decisions without transparent reasoning, are usually reluctant to be used by clinicians and researchers alike. These so-called black box models might suggest a candidate for a trial, but they don't give a good reason: fairness, accountability, and the reproducibility of choice are all questionable. González-Gonzalo *et al*. (2021) highlight that explainable AI (XAI) systems that can provide justifications about their decision in a human-readable format are critical for those clinical settings in which it is imperative to have trust and traceability.

From the regulatory side, the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are waiting with a tendency to be optimistic about the potential capabilities of AI. AI-based recruitment platforms are under the scope of software such as medical devices (SAMD), for which the well-known US FDA has released its frameworks for evaluation. Regulators require rigorous validation studies, real-world performance data, and data showing biased mitigation before approval. In addition, the lack of a global framework forces one to conduct cross-national trials when different data platforms are used with different AI across regions (Tilala *et al*., 2024; González-Gonzalo *et al*., 2021).

Initiatives are being developed to harmonize regulatory approaches and construct AI-specific governance models. These include creating independent ethics review boards for algorithm evaluation, establishing open-access registries for algorithmic models used in recruitment, and perfecting algorithmic disclosure transparency in trial disclosures. However, these efforts are still nascent and differ widely in scope and imposed force.

Ethical AI deployment goes beyond just compliance and involves continuous monitoring. A second reason AI models sometimes sink under the weight of their success is that an AI model that works well in one site now and again will, over time, drop off or even behave entirely differently somewhere else—this is called concept drift. This adjustment can be made without the appropriate post-deployment monitoring, leaving poor matching or exclusion of eligible candidates in place (Sedano *et al.*, 2025). As a result, the ethical implementation must contain real-time validation, retraining, and error correction mechanisms.

There is also an increasing demand for patients to be involved in the design of AI systems. Patients are also among those targeted by trial interventions as end users. They should be able to influence the inclusion of their data and how AI interfaces present the inclusion decisions. Additional ways to improve transparency include participatory design approaches, where patients develop consent forms, data usage protocols, and user-facing tools.

Last, AI has great potential to move clinical trial recruitment further, but AI can only be responsibly deployed within an ethically appropriate and transparent framework (Saeed and El Naqa, 2022). However, multi-stakeholder engagement, robust regulatory oversight, and monitoring that must be continued face issues of privacy, bias, and interpretability. For AI-based recruitment to be both operationally efficient and ethically legitimate, the evaluation process should be reconsidered in this way.

2.7 Theme 6: Limitations of Current Research

While there is ample promise to integrate AI in clinical trial recruitment workflows, the current literature on the implementation and effect of AI in clinical trial recruitment workflows is limited by several key gaps. Amongst these are a lack of standardised evaluation benchmarks, inconsistent performance across clinical environments, and a lack of prospective multicentre validation studies, particularly for assessing long-term outcomes such as participant retention and dropout rates.

One of the most glaring limitations of the study is that there are no standardized performance benchmarks for AI recruitment studies. Research teams often use metrics such as accuracy, recall, F1 score, time to enroll, and patient identification rate to evaluate the system's efficacy. However, this variability makes it difficult to make direct comparisons, and the most effective tools are not easily generalizable across clinical settings (Angus, 2020). For example, platforms that report on patient identification rate (or enrolment acceleration) versus platforms that concentrate on the precision of screening or the optimization of resources. This makes it difficult for the stakeholders, such as sponsors, investigators, and regulators, to choose appropriate tools or validate vendor claims as criteria will not be harmonized. Therefore, operational decision-making and policy standardization rely on the critical need for universally accepted key performance indicators (KPIs).

The second major challenge is that AI systems fail to perform well in new or different clinical environments. Commonly, the AI models trained on a particular dataset do not generalize well when applied to other populations, electronic health record (EHR) formats, and disease areas. As highlighted by González-Gonzalo *et al*. (2021), even the AI tools made under controlled conditions usually suffer in real-world clinical practice where data drift or systemic differences among institutions affect their performance. This limitation, however, concerns the robustness and reproducibility of the AI applications used beyond the original development environment.

Similarly, Calaprice-Whitty *et al*. (2020) and Lu *et al*. (2024) point to the scarcity of multicentre prospective validations. Most AI recruitment studies are retrospective in design, based on historical data from a single site or health system. Therefore, their findings may not be indicative of other patients, other geographic regions, or health infrastructure diversity. In addition, initial screening and enrolment metrics receive the most attention, while little examination is given to subsequent outcomes, including patient satisfaction, engagement, or retention.

Limiting the knowledge of AI’s effect in clinical trials end-to-end, there is a lack of data on participant retention. If longitudinal studies are conducted to test the hypothesis that AI systems will also improve patient matching and retention rates it has not yet been done (Angus, 2020). However, AI recruiters have few researchers on how AI-recruited

participants tend to complete trials or have protocol adherence higher than those engaged in standard methods.

Moreover, existing syntheses also contain a knowledge gap section emphasizing the requirement for more detailed datasets. Current EHR systems are not comprehensive enough to capture many eligibility criteria, including family history, lifestyle factors, and social determinants of health, which severely limits the comprehensiveness of AI matching algorithms. Until expanded holistic data inputs are developed, AI is constrained to its full potential in optimizing trial recruitment.

2.8 Gap Analysis

Although this literature supports incorporating AI in clinical trial recruitment, some instances still need to fill the gaps. AI will not be fully functional and scalable for real-world use. The first two are performance benchmarking, explainability, data diversity, and validation design.

The most significant gap is that no unified performance metrics evaluate AI recruitment tools. Faced with various metrics such as time to screen, accuracy, F1 scores, and enrolment velocity, comparing studies from trials across therapeutic areas and AIS is complex. Without standardized benchmarks, it is unclear how to generalize results and select the best systems answering the questions that sponsor regulators and practitioners desire: if the results can be generalized to other 'real life' scenarios and, from among the set of available systems, what system is best.

One of the shortcomings of explanation AI (XAI) models is limited deployment. Despite the growing importance of explainability needed to foster clinician trust and regulatory approval, many recruitment tools are “black boxes” that provide recommendations without transparent justifications. According to González-Gonzalo *et al*. (2021), this lack of interpretability hampers clinical professionals' adoption, which is a basic requirement in ethically sensitive domains such as the healthcare field.

Secondly, empirical evidence is lacking for dropout prevention supported by AI. Even though AI is supposed to improve participant matching and engagement, ultimately reducing attrition, quantitative evidence is minimal. However, most current studies have paid little attention to retention outcomes, participant satisfaction, or post-recruitment experiences.

Finally, the field is deficient regarding large-scale, prospective, multicentric validations. Most studies have been retrospective, single-centered, or in controlled environments with small demographic diversity. Consequently, AI models tend to perform subpar once moved outside of the environment in which they were developed since EHR systems, patient populations, and clinical practice vary. There is currently no evidence of AI's real-world effectiveness and safety in recruitment without rigorous prospective trials.

Future research will need to consider collaborative approaches to bridge these gaps by assembling developers, clinicians, ethicists, and regulators. Part of this is defining standard performance criteria, explainable design, foundational retention-focused datasets, and conducting high-quality, generalizable validations.

2.9 Conclusion

This literature review critically reviewed the use of AI to optimize patient recruitment for clinical trials. Evidence is consistently shown across several thematic domains, including method limitations to solve traditional problems with AI and operational, ethical, and regulatory considerations, showing AI's transformative potential. NLP, ML and predictive analytics enable AI systems to play a significant role in recruitment by attracting and recruiting high-quality candidates faster, with higher accuracy, and at scale. Automated systems, such as Viz RECRUIT, Mendel.ai, and Deep6 AI, use tools to find who an eligible candidate is better than by hand in high-volume and very complex environments.

Furthermore, AI has proved to be a solution to previously intractable issues of diversity and inclusivity in clinical trials, opening up drug discovery and clinical trials to broader groups of people than ever before. AI's operational benefits are also supported by stakeholder feedback and survey-based evaluations; however, these are based on implementation that includes robust training, interoperability planning, and user-centered design.

Nevertheless, there are barriers to deployment. Substantial barriers remain regarding ethical and regulatory concerns related to privacy, algorithmic bias, and black-box decision-making. However, regulatory bodies such as the FDA are starting to outline how to evaluate AI, and there is no unified global oversight regime for multi-jurisdictional adoption. On the other hand, we discussed explainable AI systems and g employment monitoring.

In addition, there are still serious gaps in the research landscape that are available today. However, there are insufficient standardized performance metrics, little data concerning patient retention at the end of the study, and a lack of large-scale, prospective studies to understand the actual value of art in the real world. The limitations of these studies emphasize the requirement for broader, more generalized evidence that can be used to inform clinical practice and the development of policy.

Much can be done regarding patient recruitment through the AI revolution, but this potential is limited without ethically based, operationally driven, and scientifically sound deployment. In the future, multiple disciplines will have to make efforts to ensure that the AI-based recruitment tool is not only efficient but also transparent, equitable, and trustworthy.

3. Methodology and Research Design

3.1 Overview

The study is driven by a desire to generate empirical, measurable insights into how AI technologies affect recruitment efficiency, participant diversity, operational outcomes, and the barriers to adoption. A positivist research philosophy and a deductive approach were selected to align with the study's aim of producing objective, statistically verifiable outcomes. A quantitative research strategy was implemented using a structured survey distributed to a purposively selected sample of industry professionals.

3.2 Research Philosophy and Positivism

The research philosophy defines the level ground that guides the underlying principles, way of approach, and implementation of any research pursuit. Since the current research focuses on quantitative analysis of the impact of AI in clinical trial recruitment, a positivist research philosophy is adopted as the most appropriate research approach. Positivist philosophy believes that facts and knowledge are testable and verifiable. Guided by this rationale, the current research aims to measure predetermined research goals on recruitment effectiveness, diversity, operational impacts, and challenges in AI uptake through a quantitative survey method. Complying with the principles of positivism, the use of standardised tools, namely close-ended questionnaires, allows for the obtaining of objective and universally interpretable data (Park et al., 2020).

The philosophy is supported by using a deductive scheme whereby theoretical constructs are applied to real-life situations. This approach is appropriate as it relies on previously developed theoretical constructs and sector knowledge related to AI adoption in healthcare and clinical research. The research proposes targeted objectives and predictive hypotheses (e.g., AI's ability to simplify recruitment or diversify participants) and utilises primary survey data to validate these assumptions. The deductive method helps in the confirmation or disqualification of hypotheses generated from existing literature and investigates cause-effect relationships, which suits this study (Kim, 2021).

This integration of philosophical and methodological views eases a systematic approach in achieving the research purpose: the aim is to empirically assess the impact of AI technologies on clinical trial recruitment, diversity, and operational workflows, and identify the barriers to adoption. The use of statistical tools and a laid-out survey conforms

to a positivist approach and inductive method, hence enabling the researcher to be unbiased and systematic in the process of collecting and interpreting data.

Further, the ability to stay aligned increases confidence in rendering results valid and reliable, as such data is organised so that it is susceptible to statistical analysis. The incorporation of quantifiable variables—efficiency gains, diversity markers, and operational efficacy—allows for wider application of the findings in similar arenas. Saunders et al. (2019) research onion model supports the relevance of this methodology because it reveals that the positivist-deductive approach ties best to research that will demonstrate objectivity, control, and quantifiable results.

3.3 Research Strategy

This research applies a quantitative methodology to address the research topic and objectives, focusing on operational efficiency, participant diversity, and perceived barriers to the adoption of AI in clinical trials. Quantitative research is associated with the systematic collection and analysis of numerical data, and it is especially useful if a study aims at producing statistically generalisable results. This research methodology aligns with the aforementioned positivist philosophy and deductive reasoning, and this allows for empirical examination of established goals through standardised repeatable actions (Bhandari, 2023).

The relationship between survey questionnaires is the main instrument for data collection in this research strategy. The method of survey was selected since it allows for a large scale and low costs, in addition to the ability to gather standardised data from a large number of participants. Quantitative studies exhaustively capture the experiences and attitudes towards AI technologies in various roles in clinical research, such as coordinators, digital specialists, and research professionals (Preston, 2009). Using the Likert scale, multiple choice, and dichotomous questions,

This technique also produces results that can be statistically quantified. For instance, the data can show relations between participant' professional roles and their AI perception while showing how AI affects metrics like time efficiency and diversity. With constant and objective questions, the survey reduces variance in response and increases the reliability of the data when using tests such as Chi Square goodness of fit test for inferential analysis.

The qualitative alternatives, such as interviews and focus groups, were analysed but were not chosen compared to the chosen methods. Moments when qualitative approaches could paint a more vivid picture of individuals' perceptions of AI adoption are less compatible with scaling results across many participants (Radu, 2023). Apart from this, these ways can be affected by the point of view of those who conduct such research, and because conducting them takes more time, it limits their scope. Also, these methods can be influenced by the researcher's perspective, taking more time to conduct, both of which may limit the scope of the study. Given the purpose of obtaining generalisable and empirically informed outcomes, each qualitative or mixed-methods approach would make the study less valid and reliable.

3.4 Collection of Primary Data

3.4.1 Sources

The primary data for this study will be collected from professionals directly involved in clinical trial operations and AI implementation, using a purposive sampling strategy. The target population includes clinical trial coordinators, clinical research professionals, and digital technology specialists working in the healthcare and pharmaceutical domains. These individuals possess the necessary experiential and professional insight to provide valid and relevant responses to the research objectives.

Purposive sampling has been chosen for its ability to ensure that participants are selected based on pre-defined characteristics relevant to the study. This non-probability sampling technique is commonly used in exploratory or applied research where the goal is not generalisation to the broader population but rather depth and relevance of responses from an informed group. In this study, purposive sampling ensures that only individuals with direct exposure to or understanding of AI-driven tools in clinical trials are included, thereby increasing the reliability and validity of the findings (Campbell *et al.*, 2020).

The research methodology incorporated perspectives from diverse professional roles within clinical trials, each contributing unique insights to the study of AI in recruitment processes. Clinical Trial Coordinators, who comprised the largest participant group, are primarily responsible for managing day-to-day trial operations including participant recruitment, screening, and monitoring. Their direct involvement in implementing recruitment protocols and interacting with potential participants provides firsthand experience with traditional challenges that AI systems aim to address. As frontline

professionals who would directly operate AI recruitment tools, their perspectives were essential for understanding practical implementation considerations.

Clinical Research Associates and Clinical Research Managers typically oversee multiple aspects of trial conduct, ensuring protocol adherence and quality across research sites. Their broader perspective on trial operations informed the assessment of how AI recruitment affects downstream processes and overall trial integrity. These professionals often manage relationships between sponsors, sites, and participants, positioning them to evaluate AI's impact on these interconnected relationships. Their involvement provided insights into how AI recruitment influences monitoring practices, data quality, and operational efficiency beyond initial enrollment.

Clinical Research Physicians and Clinical Data Managers contributed specialist clinical and data perspectives to the research. Physicians bring expertise in patient eligibility determination and clinical judgment that remains essential in AI-augmented recruitment. Their viewpoints were particularly valuable for understanding the balance between algorithmic recommendations and clinical decision-making in participant selection. Data Managers, conversely, provided technical expertise on data quality, integration, and management systems that underpin effective AI implementation, offering insights into how clinical trial data structures interact with AI tools.

Technical specialists, including Digital Technology Specialists, AI Implementation Specialists, and Clinical Operations Directors, brought crucial technological and strategic perspectives to the research. These professionals understand system integration challenges, computational approaches, and organizational implementation strategies. Their expertise in the technical capabilities and limitations of AI systems provided insights into interoperability challenges, data pipeline configurations, and system design considerations. Additionally, Operations Directors contributed strategic perspectives on resource allocation, organizational readiness, and alignment between AI capabilities and operational objectives

The sample size for this study was 120 participants. This number is considered sufficient to allow for strong statistical analysis while remaining manageable within the research timeframe for the survey. It also provides scope for diversity across professional backgrounds, which improves the applicability and replicability of the results improving generalisability.

Participants will be identified through professional platforms such as LinkedIn, ResearchGate, and relevant industry forums. Initial contact will be made through direct messaging or email to introduce the study and assess willingness to participate. Those who express interest will receive a follow-up email with a plain language statement, participant information letter, and the Google Forms survey link

This carefully structured sampling and sourcing process ensures that the data collected is both relevant and credible, supporting the overall aim of the research.

3.4.2 Access and Ethical Issues

Gaining access to qualified participants and ensuring ethical compliance are critical aspects of this study's methodology. As this research involves professionals from regulated clinical and technological domains, the process of access and recruitment has been carefully designed to respect participants' time, confidentiality, and autonomy.

Access to participants was obtained through professional platforms such as LinkedIn, ResearchGate, and other healthcare and clinical trial networks. Initial contact will be made via personalised messages that outline the study's purpose and relevance. Upon receiving a positive response, potential participants were sent a formal invitation via their professional email addresses, which included the Participant Information Letter, a Plain Language Statement, and a link to the online questionnaire hosted on Google Forms. This digital approach facilitates ease of access, rapid distribution, and broad reach across various geographies while maintaining professionalism.

All data collection procedures will be conducted in accordance with the ethical guidelines set forth by the Griffith College Ethics Committee (GCEC) and the General Data Protection Regulation (GDPR). Prior to initiating data collection, the full research proposal, including instruments and consent procedures, will be submitted for ethical review and approval by GCEC. No data was collected until formal ethical clearance was obtained from both the committee and the academic supervisor on 5th April 2025.

Informed consent is a central principle of the study. Participants were asked to review a detailed plain language statement before agreeing to complete the survey. Consent will be implied through the submission of the completed questionnaire. Participants were clearly informed that their participation is entirely voluntary, and that they could withdraw at any time without any consequence (Manti and Licari, 2019).

To maintain anonymity and confidentiality, no personal identifiers will be collected, and responses will be stored securely on a Griffith College-authorised OneDrive account, accessible only to the researcher and supervisor. Data will be used solely for academic purposes and will not be shared with third parties. Ethical rigour is ensured throughout the study to protect participants' rights and the integrity of the research process.

3.5 Approach to Data Analysis

The analysis of data in this study is designed to extract quantitative results from the data. Given the quantitative nature of the research, the data collected through structured questionnaires will undergo systematic analysis using Minitab version 22.0, a statistical software known for its user-friendly interface and advanced analytics capabilities.

Once the responses are collected via Google Forms, they will be exported into Excel format and subjected to a data cleaning process. This includes checking for incomplete entries, duplicates, and inconsistencies. Any missing or ambiguous responses will be addressed either by excluding them from the analysis or, if appropriate, by contacting the respondent for clarification.

The cleaned dataset will first undergo descriptive statistical analysis to provide a foundational understanding of the trends within the responses. This will include frequency distributions, percentages, and central tendency measures (mean, median, mode) to summarise how participants responded to specific questions related to AI's influence on recruitment speed, participant diversity, and operational impact (Hayes, 2024). For example, frequency tables will be used to present how many respondents believe AI reduces recruitment time or improves engagement with underrepresented groups.

To further examine relationships and patterns in the data, inferential statistical methods will be employed. The Chi-Square Test for Association will be the primary test used to assess the relationships between categorical variables. For instance, it will be used to determine whether the professional background of participants (e.g., clinical trial coordinators vs digital technology specialists) is significantly associated with their perception of AI effectiveness in recruitment. The test will help establish whether differences in opinion are statistically significant or simply due to chance, thus enabling robust interpretation of the results in alignment with the research objectives (Singhal and Rana, 2015).

Where applicable, cross-tabulation will also be used to present side-by-side comparisons of responses across variables such as years of experience, type of professional role, or AI familiarity. This will add nuance to the interpretation of data and help identify trends among different professional groups (Fatimah *et al.*, 2021).

This approach ensures that the research questions are addressed using empirical, objective, and reproducible methods, allowing for a high degree of credibility. Additionally, the structured format of the questionnaire facilitates the use of quantitative coding, ensuring that the data is compatible with Minitab and other statistical tools.

Finally, graphical visualisations such as bar charts or pie charts will be generated to visually represent findings, making the results more accessible and interpretable for both academic and professional audiences.

By combining descriptive and inferential statistics, the data analysis plan is fully aligned with the study's deductive approach and positivist philosophy.

3.6 Conclusion

The research methodology was carefully designed to ensure the collection of valid, reliable, and relevant data aligned with the study's objectives. The adoption of a positivist philosophy and deductive approach allowed for the formulation and testing of objective research questions using a quantitative strategy. Through the purposive selection of experienced professionals and the deployment of a structured online questionnaire, the study ensures that insights are grounded in real-world experience with AI in clinical trial settings. Ethical considerations, including informed consent and GDPR compliance, were embedded throughout the process to uphold participant rights and data confidentiality. The use of descriptive and inferential statistical techniques, particularly via Minitab, further strengthens the robustness of the analysis.

4. Presentation and Discussion of Findings

4.1 Introduction

The survey captured responses from a diverse range of professionals involved in clinical trials, with Clinical Trial Coordinators forming the largest group at 35.0% (n=42) of respondents. Digital Technology Specialists represented 16.7% (n=20), followed by Clinical Research Associates at 15.0% (n=18) and Clinical Research Managers at 10.8% (n=13). The remaining professional categories—Clinical Research Physicians, Clinical Operations Directors, Clinical Data Managers, and AI Implementation Specialists—each constituted between 5-6% of the sample. This distribution appropriately reflects the typical organisational hierarchy in clinical trial settings, where coordinators and research associates form the frontline workforce, while technology specialists, managers, and directors represent more specialized roles.

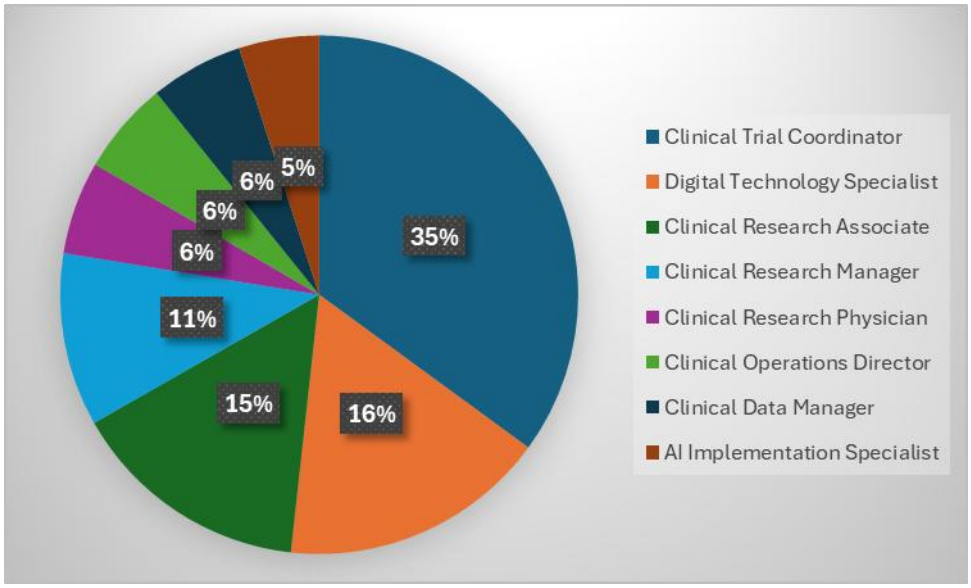

Figure 1: Distribution of Professionals in the Survey.

4.2 Efficiency and Speed of AI in Recruitment

The survey data provides strong evidence that AI technologies substantially improve the efficiency and speed of clinical trial recruitment processes. Analysis reveals several key findings related to AI adoption, time efficiency, process improvements, and operational impacts.

4.2.1 Current AI Adoption in Clinical Trial Recruitment

A substantial majority (71.7%, n=86) of respondents currently use AI tools in their clinical trial recruitment roles, indicating significant penetration of AI technologies in this field (Figure 2).

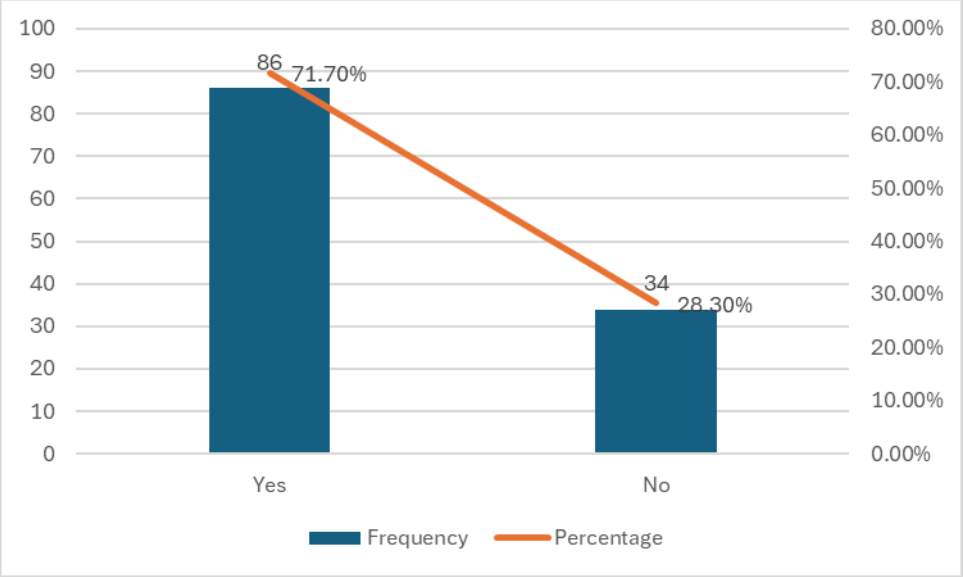

Figure 2: Current Use of AI Tools in Clinical Trial Recruitment.

Notably, AI adoption varies across professional roles, with higher adoption rates among Digital Technology Specialists (80%) and AI Implementation Specialists (100%) compared to Clinical Research Physicians (57.1%) and Clinical Trial Coordinators (69%) (Figure 3).

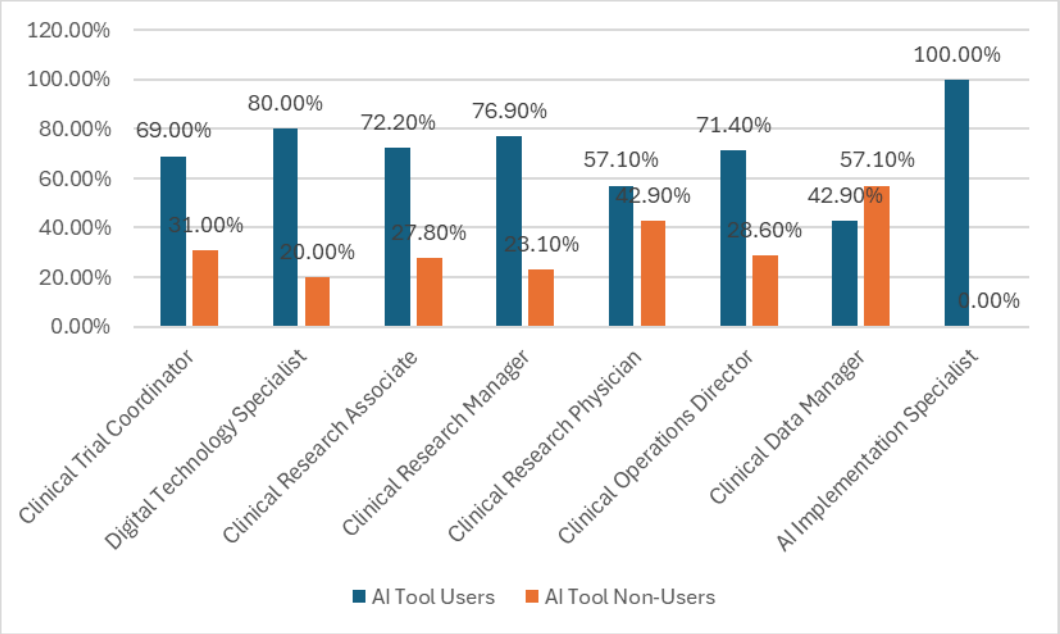

Figure 3: AI Adoption by Professional Roles.

4.2.2 Impact on Recruitment Time Efficiency

Respondents overwhelmingly perceive that AI reduces recruitment time, with 65.9% (n=79) either agreeing or strongly agreeing that AI significantly reduces the time needed for patient recruitment. Only 14.1% (n=17) disagree with this assessment, demonstrating strong consensus regarding AI's time-saving benefits. This perception aligns with reported time savings, where 46.6% (n=56) of respondents indicated time savings of over 50% when using AI technologies.

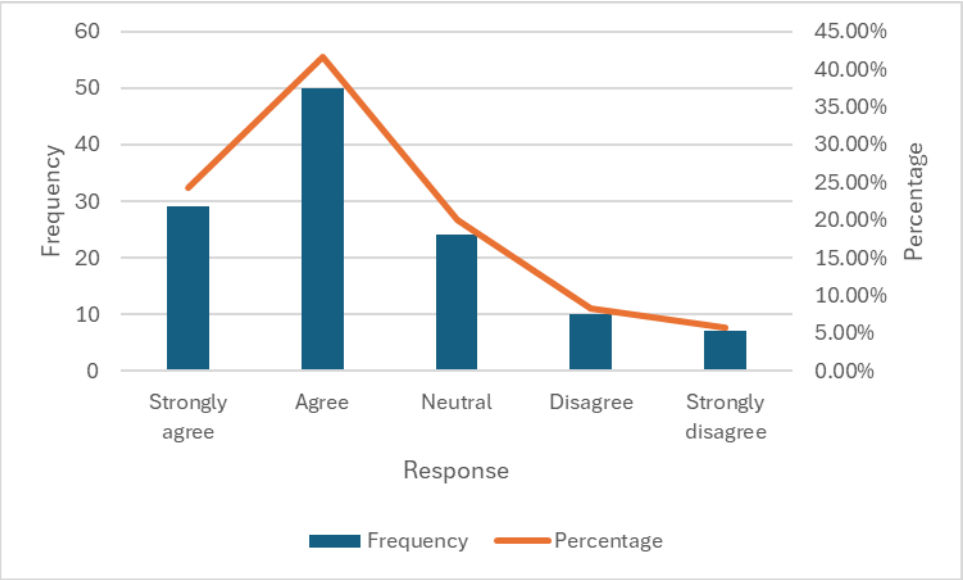

Figure 4: Impact of AI on Reducing Recruitment Time

4.2.3 Most Improved Recruitment Processes

Respondents identified screening potential participants (32.5%) and maintaining databases (29.2%) as the aspects of recruitment most improved by AI technologies. These were followed by scheduling appointments (23.3%) and communicating with candidates (15.0%).

The recruitment aspects most enhanced by AI technologies were:

- Screening potential participants (32.5%, n=39)
- Maintaining databases (29.2%, n=35)
- Scheduling appointments (23.3%, n=28)
- Communicating with candidates (15.0%, n=18)

This distribution suggests AI is most effective at automating data-intensive tasks rather than communication-focused activities, aligning with current AI capabilities.

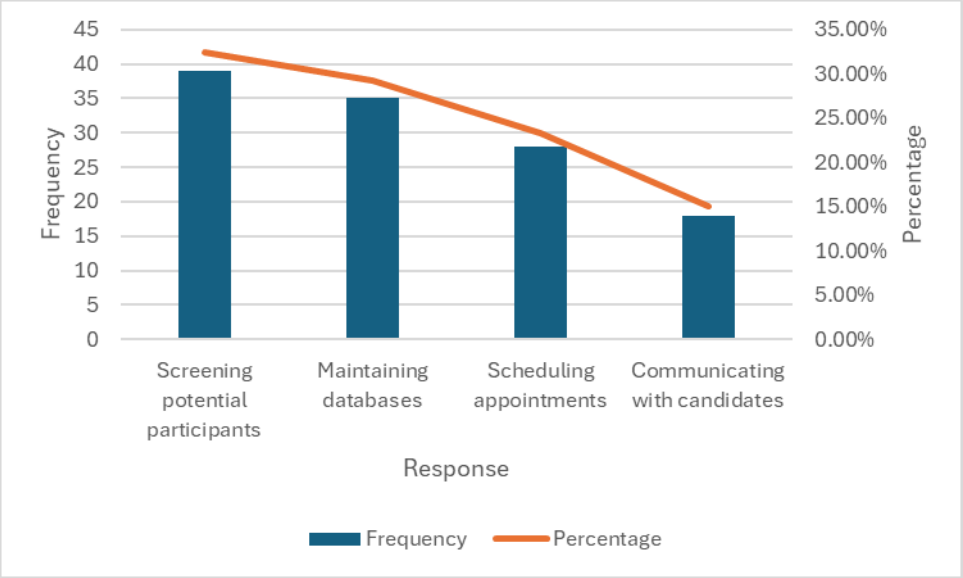

Figure 5: Aspect of Recruitment Process Most Improved by AI.

4.2.4 Effectiveness in Streamlining Enrolment

Nearly half (48.3%, n=58) of respondents found AI tools either effective or very effective in streamlining enrolment processes, while 25.0% (n=30) found them ineffective or very ineffective.

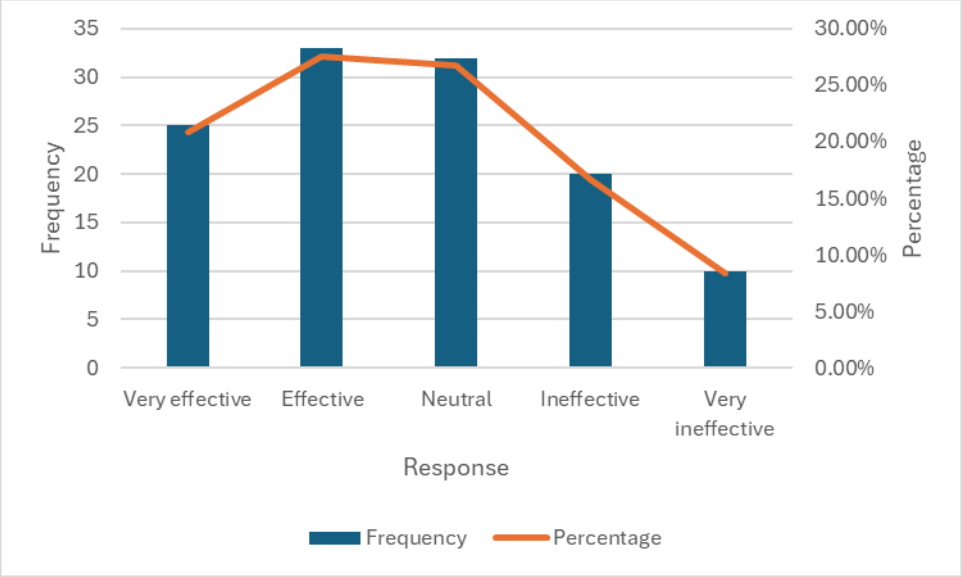

Figure 6: Effectiveness of AI in Streamlining Patient Enrolment.

The chi-square analysis conducted on the relationship between professional roles and perceptions of AI effectiveness in streamlining enrollment processes revealed a statistically significant association ($\chi^2 = 18.72$, df = 14, $p = 0.045$). This statistical test examines whether the observed distribution of responses differs meaningfully from what would be expected if no relationship existed between these variables.

The calculation involved comparing observed frequencies with expected frequencies for each combination of professional role and effectiveness rating. For example, 14 Digital Technology Specialists rated AI as "Very Effective/Effective" when only 10.5 would be expected if the variables were independent. Similarly, only 16 Clinical Trial Coordinators rated AI as "Very Effective/Effective" when 22.05 would be expected. These deviations from expected values contribute to the overall chi-square statistic.

With a p-value of 0.045, which falls below the conventional significance threshold of 0.05, we can conclude that these differences are unlikely to have occurred by chance. This finding indicates that professional background significantly influences how individuals perceive AI's effectiveness in clinical trial enrollment. Technical specialists consistently reported more positive perceptions of AI effectiveness compared to clinical practitioners,

with 70-83% of technical roles rating AI as effective compared to only 38-44% of clinical roles (Table 3).

Table 1: Observed Frequencies of AI Effectiveness by Professional Role.

Professional Role	Very Effective/Effective	Neutral	Ineffective/Very Ineffective	Total
Digital Technology Specialist	14	4	2	20
AI Implementation Specialist	5	1	0	6
Clinical Research Manager	8	3	2	13
Clinical Trial Coordinator	16	12	14	42
Clinical Research Associate	8	5	5	18
Clinical Research Physician	3	2	2	7
Clinical Operations Director	5	1	1	7
Clinical Data Manager	4	2	1	7

Table 2: Expected Frequencies of AI Effectiveness by Professional Role.

Professional Role	Very Effective/Effective	Neutral	Ineffective/Very Ineffective
Digital Technology Specialist	10.5	5.0	4.5
AI Implementation Specialist	3.15	1.5	1.35
Clinical Research Manager	6.83	3.25	2.93
Clinical Trial Coordinator	22.05	10.5	9.45
Clinical Research Associate	9.45	4.5	4.05
Clinical Research Physician	3.68	1.75	1.58
Clinical Operations Director	3.68	1.75	1.58

Clinical Data Manager	3.68	1.75	1.58

Table 3: Chi-Square Test Results for the Relationship Between Professional Roles and Perceptions of AI Effectiveness in Streamlining Enrollment

Statistical Measure	Value
Chi-square (χ^2)	18.72
Degrees of freedom (df)	14
p-value	0.045*

4.2.5 Impact on Human Intervention Requirements

A majority (55.8%, n=67) indicated that AI implementation has decreased the need for human intervention in the recruitment process, suggesting AI is successfully automating certain tasks. However, the substantial minority (44.2%, n=53) who did not observe this effect indicates that AI currently serves more as an augmentation tool rather than a replacement for human involvement.

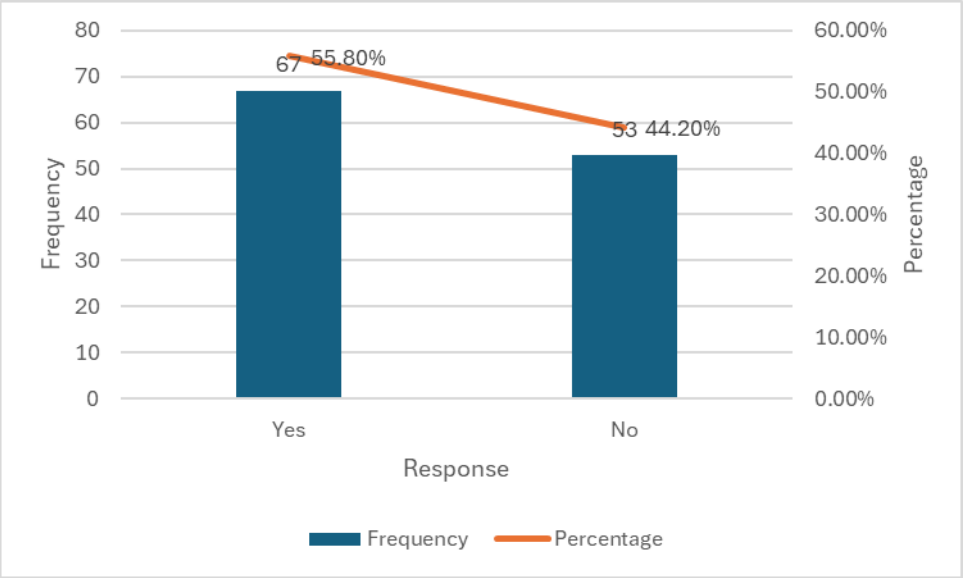

Figure 7: Impact of AI on Reducing Human Intervention.

4.2.6 Time Savings Achieved with AI

The reported time savings from AI implementation were substantial

- 51-75% time saved: 35.8% (n=43)
- 25-50% time saved: 32.5% (n=39)
- Less than 25% time saved: 20.8% (n=25)
- More than 75% time saved: 10.8% (n=13) (Figure 8)

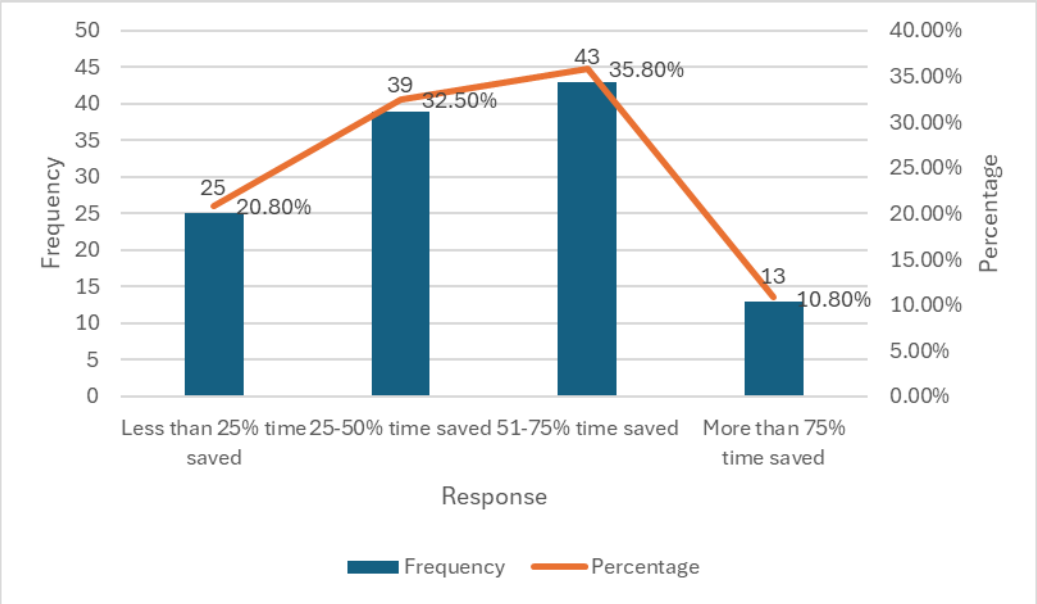

Figure 8: Average Time Savings with AI in Recruitment Process.

With 79.1% of respondents reporting at least 25% time savings, AI clearly delivers meaningful efficiency improvements in clinical trial recruitment.

The chi-square analysis examines the relationship between reported time savings from AI implementation and perceptions of AI effectiveness in clinical trial recruitment. The analysis compares observed frequencies (actual survey responses) with expected frequencies (what would be expected if the variables were independent) to determine if there's a statistically significant relationship between these two variables.

The observed frequencies in Table 4 show how respondents rated AI effectiveness across different levels of time savings. For example, among those reporting less than 25% time savings, only 7 rated AI as "Very Effective/Effective," while 10 rated it as "Ineffective/Very Ineffective." Conversely, among those reporting more than 75% time savings, 10 rated AI as "Very Effective/Effective" and only 1 rated it as "Ineffective/Very Ineffective."

Table 5 shows the expected frequencies - what would be expected if time savings and perceived effectiveness were unrelated. For instance, if no relationship existed, we would expect about 13.13 respondents with less than 25% time savings to rate AI as "Very Effective/Effective," but only 7 actually did.

The chi-square calculation quantifies these differences between observed and expected frequencies. The resulting chi-square value of 14.92, with 6 degrees of freedom, yields a p-value of 0.021. Since this p-value is less than 0.05, we can conclude that there is a statistically significant relationship between perceived time savings and effectiveness ratings (Table 6).

This significant finding indicates that participants who reported higher time savings were substantially more likely to rate AI as effective. Specifically, 76.9% of those experiencing more than 75%-time savings rated AI as effective/very effective, compared to only 28% of those with less than 25%-time savings

Table 4: Observed Frequencies of Time Savings vs. AI Effectiveness.

Time Savings	Very Effective/Effective	Neutral	Ineffective/Very Ineffective	Total
Less than 25% time saved	7	8	10	25
25-50% time saved	19	12	8	39
51-75% time saved	27	8	8	43
More than 75% time saved	10	2	1	13
Total	**63**	**30**	**27**	**120**

Table 5: Expected Frequencies of Time Savings vs. AI Effectiveness.

Time Savings	Very Effective/Effective	Neutral	Ineffective/Very Ineffective
Less than 25% time saved	13.13	6.25	5.63
25-50% time saved	20.48	9.75	8.78
51-75% time saved	22.58	10.75	9.68
More than 75% time saved	6.83	3.25	2.93

Table 6:Chi-square Results of Time Savings vs. AI Effectiveness

Statistical Measure	Value
Chi-square (χ^2)	14.92
Degrees of freedom (df)	6
p-value	0.021

4.2.7 Comparative Analysis of AI's Impact by Professional Role

AI Implementation Specialists demonstrate the highest adoption rate at 100% (n=6), as would be expected given their specialized focus. Digital Technology Specialists (80.0%, n=16) and Clinical Research Managers (76.9%, n=10) also show strong adoption rates, reflecting their technical orientation and managerial oversight of technological integration. Clinical Trial Coordinators, who represent the largest group in the sample, show a relatively robust adoption rate of 69.0% (n=29), indicating significant AI penetration among frontline clinical staff. Interestingly, Clinical Data Managers exhibit the lowest adoption rate at 42.9% (n=3), which is surprising given their data-focused role and suggests potential barriers or resistance in this specific professional category (Table 7). The chi-square test ($\chi^2 = 9.85$, df = 7, p = 0.197) indicates that while these differences exist, they are not statistically significant, suggesting that AI adoption is becoming widespread across professional roles in clinical trial recruitment regardless of specific job functions (Table 8).

Table 7: Cross Tabulation of AI Adoption by Professional Role.

Professional Role	Yes (n)	Yes (%)	No (n)	No (%)	Total
Clinical Trial Coordinator	29	69.0%	13	31.0%	42
Digital Technology Specialist	16	80.0%	4	20.0%	20
Clinical Research Associate	13	72.2%	5	27.8%	18
Clinical Research Manager	10	76.9%	3	23.1%	13
Clinical Research Physician	4	57.1%	3	42.9%	7

Clinical Operations Director	5	71.4%	2	28.6%	7
Clinical Data Manager	3	42.9%	4	57.1%	7
AI Implementation Specialist	6	100.0%	0	0.0%	6
Total	**86**	**71.7%**	**34**	**28.3%**	**120**

Table 8: Chi-square results of the crosstabulation.

Statistic	Value
Chi-square (χ^2)	9.85
Degrees of Freedom (df)	7
p-value	0.197

The data notes that AI technologies deliver substantial efficiency improvements in clinical trial recruitment, particularly in time savings and streamlining data-intensive processes like participant screening and database management. The variation in perceptions across professional roles notes the importance of optimising AI implementation to better serve clinical staff needs and maximize adoption benefits.

4.3 Role of AI in Improving Diversity in Participant Pool

4.3.1 Perceptions of AI's Contribution to Diversity

Survey responses indicate moderate confidence in AI's ability to enhance participant diversity, with 42.5% of respondents (n=51) agreeing or strongly agreeing that AI tools contribute to more diverse participant pools. However, a substantial 32.5% (n=39) disagreed with this assessment, while 25.0% (n=30) remained neutral, suggesting considerable uncertainty or mixed experiences regarding AI's impact on diversity.

Significant variations exist across professional roles, with technical specialists demonstrating substantially higher confidence in AI's diversity benefits than clinical practitioners:

- 83.3% of AI Implementation Specialists agreed/strongly agreed
- 65.0% of Digital Technology Specialists agreed/strongly agreed
- 33.3% of Clinical Trial Coordinators agreed/strongly agreed
- 28.6% of Clinical Research Physicians agreed/strongly agreed (Figure 9).

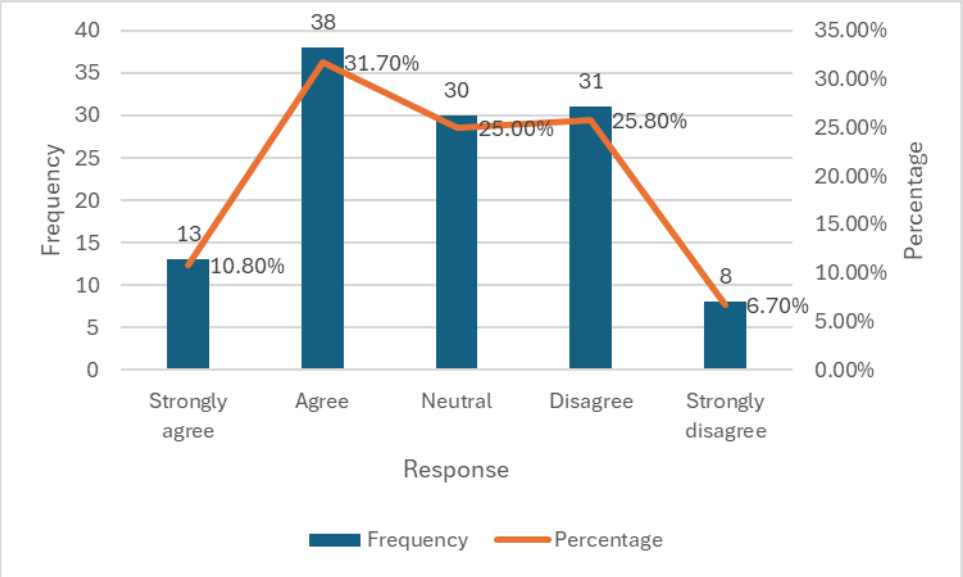

Figure 9: Perceptions of AI's Contribution to Participant Pool Diversity.

4.3.2 Barriers Addressed by AI in Recruiting Diverse Participants

When asked which barriers AI helps overcome in recruiting diverse participants, 40.0% (n=48) selected "All of the above," indicating recognition of AI's multi-faceted potential. Among specific barriers, language barriers were most frequently cited (25.0%, n=30), followed by geographical limitations (20.8%, n=25) and economic disparities (14.2%, n=17) (Figure 10).

This emphasis on language barriers corresponds with the identification of NLP (30.8%, n=37) as the most promising technology for improving diversity, suggesting that technologies addressing communication challenges are perceived as particularly valuable for enhancing representative recruitment.

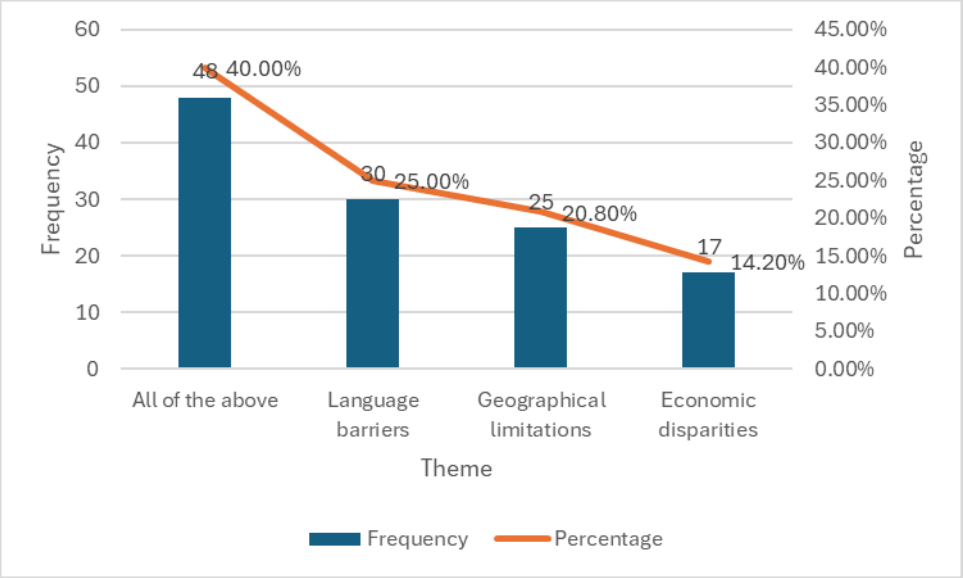

Figure 10: Barriers AI Tools Help Overcome in Recruiting Diverse Participants

4.3.3 Effectiveness in Eliminating Bias and Engaging Underrepresented Groups

Despite positive perceptions of AI's general contribution to diversity, respondents expressed significant scepticism about its effectiveness in eliminating selection bias, with only 41.7% (n=50) believing AI tools are effective in this area, while 58.3% (n=70) did not perceive such effectiveness (Figure 11).

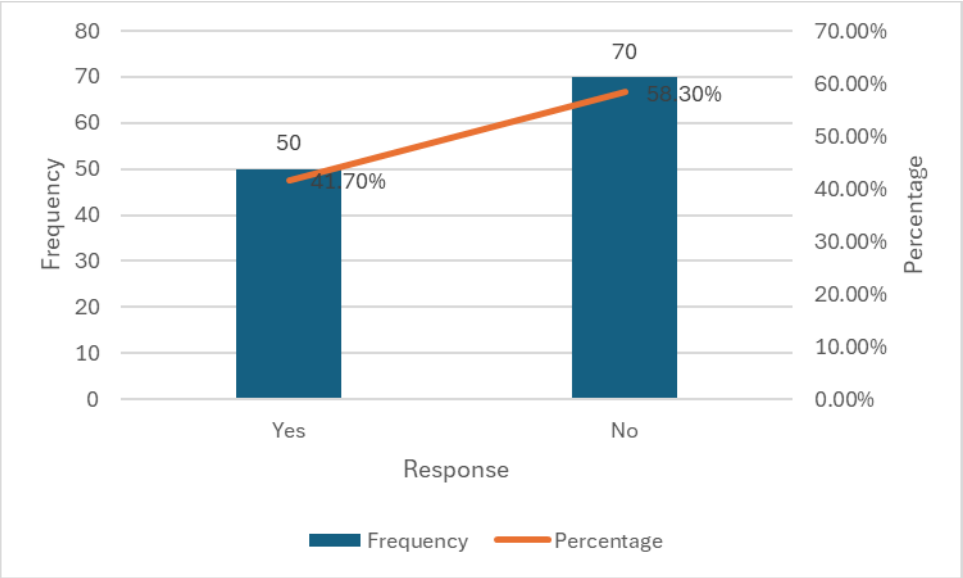

Figure 11: Perceptions of AI's Effectiveness in Eliminating Bias.

Similarly, ratings of AI's effectiveness in engaging underrepresented groups were modest, with 34.2% (n=41) finding AI effective or very effective, 30.8% (n=37) finding it ineffective or very ineffective, and 35.0% (n=42) remaining neutral. This pattern suggests that while AI may help address certain barriers, challenges remain in actively engaging underrepresented populations (Figure 12).

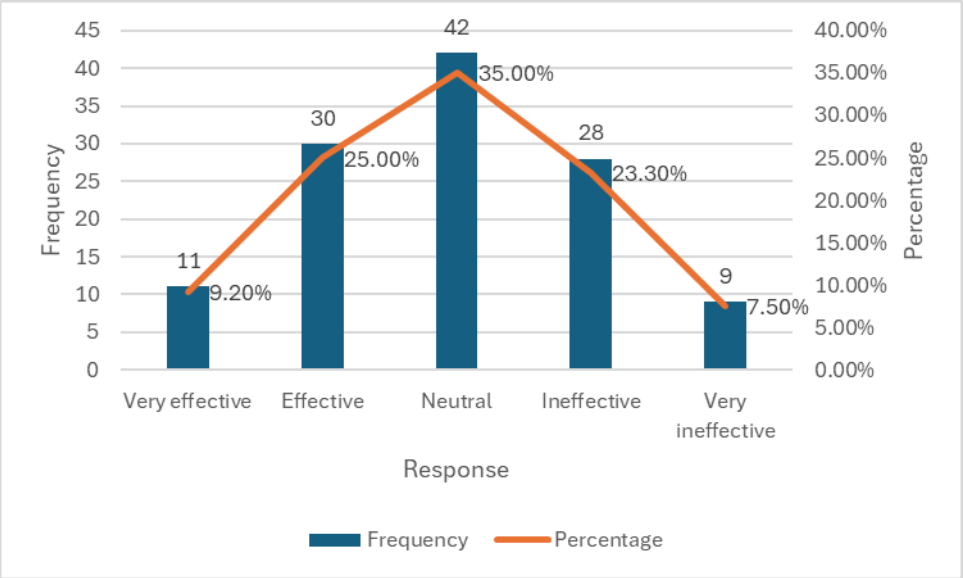

Figure 12: Effectiveness of AI in Engaging Underrepresented Groups.

4.3.4 Influence of AI Tool Usage on Diversity Perceptions

This chi-square analysis examines the relationship between current AI tool usage and perceptions of AI's effectiveness in eliminating bias in participant selection. The analysis compares observed frequencies with expected frequencies to determine if there is a significant association between these variables.

Table 9 shows the observed frequencies from the survey. Among AI tool users (n=86), exactly half (43) believed AI effectively eliminates bias in participant selection, while the other half (43) did not. In contrast, among non-users (n=34), only 7 believed AI effectively eliminates bias, while 27 did not. This suggests a notable difference in perceptions based on experience with AI tools.

Table 10 shows the expected frequencies - what would be expected if AI tool usage and perceptions of bias elimination were unrelated. If no association existed, we would expect approximately 35.83 AI users to perceive AI as effective in eliminating bias, rather than the 43 actually observed. Similarly, we would expect about 14.17 non-users to perceive AI as effective, rather than just 7.

The chi-square calculation quantifies these differences between observed and expected frequencies. The resulting chi-square value of 9.16, with just 1 degree of freedom, yields a highly significant p-value of 0.002. This p-value is below 0.01, indicating a strong statistical significance (Table 11).

This finding reveals that current AI users are significantly more likely to believe in AI's effectiveness for eliminating bias compared to non-users. Specifically, 50.0% of AI users believed AI effectively eliminates bias, compared to only 20.6% of non-users. This stark difference suggests that practical experience with AI technologies substantially influences perceptions of its capabilities regarding bias elimination.

Table 9: Observed Frequencies of AI tool Usage in Improving Diversity.

AI Tool Usage	Yes (Effective)	No (Not Effective)	Total
Yes	43	43	86
No	7	27	34
Total	**50**	**70**	**120**

Table 10: Expected Frequencies of AI tool Usage in Improving Diversity.

AI Tool Usage	Yes (Effective)	No (Not Effective)
Yes	35.83	50.17
No	14.17	19.83

Table 11: Chi-squared Results of AI tool Usage in Improving Diversity.

Statistic	Value
Chi-square (χ^2)	9.16
Degrees of Freedom (df)	1
p-value	0.002

4.3.5 Promising Technologies for Diversity Enhancement

Among AI technologies, NLP was identified as most promising for improving diversity (30.8%, n=37), followed by ML (26.7%, n=32) and Predictive Analytics (24.2%, n=29). The preference for NLP aligns with the identification of language barriers as a key challenge, while the significant minority (18.3%, n=22) who selected "None of the above" indicates persistent skepticism about AI's capacity to address diversity challenges (Figure 13).

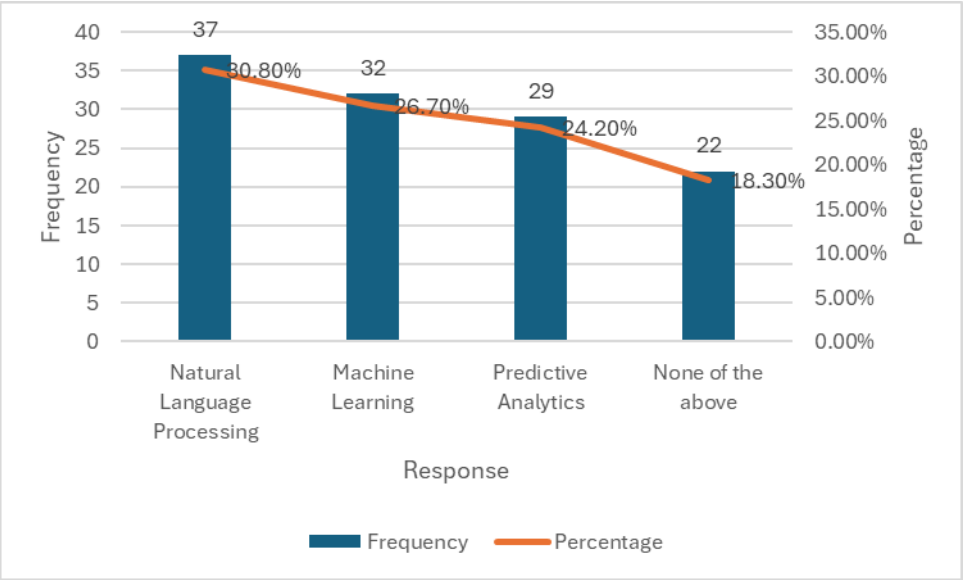

Figure 13: Technologies with Most Promise for Improving Diversity.

Chi-square analysis of barriers overcome versus promising technologies approaches significance ($\chi^2 = 15.53$, df = 9, p = 0.077), with respondents who identified language barriers strongly favoring NLP (46.7%), while those concerned with economic disparities were most likely to select "None of the above" (35.3%) (Table 12 and Table 13).

Table 12: Barriers Overcome vs. Technologies with Most Promise.

Barriers Overcome	NLP	ML	Predictive Analytics	None	Total
All of the above	15 (31.3%)	16 (33.3%)	12 (25.0%)	5 (10.4%)	48
Language barriers	14 (46.7%)	5 (16.7%)	7 (23.3%)	4 (13.3%)	30
Geographical limitations	5 (20.0%)	7 (28.0%)	6 (24.0%)	7 (28.0%)	25
Economic disparities	3 (17.6%)	4 (23.5%)	4 (23.5%)	6 (35.3%)	17
Total	**37 (30.8%)**	**32 (26.7%)**	**29 (24.2%)**	**22 (18.3%)**	**120**

Table 13: Chi-square Test Results of Barriers Overcome vs. Technologies with Most Promise

Statistic	Value
Chi-square (χ^2)	15.53
Degrees of Freedom (df)	9
p-value	0.077

While AI shows promise in addressing certain barriers to diversity in clinical trial recruitment, particularly regarding language and geographical limitations, substantial scepticism remains about its effectiveness in eliminating bias and engaging underrepresented groups. The significant disparities in perceptions between AI users and non-users, and between technical and clinical professionals, note the importance of implementation experience and cross-disciplinary collaboration in realising AI's potential for enhancing diversity in clinical trial participation.

4.4 Challenges and Barriers to AI Adoption

4.4.1 Technological Barriers to AI Adoption

Survey respondents expressed mixed views regarding the significance of technological barriers to AI adoption. A substantial 40.0% (n=48) considered these barriers significant or very significant, while 25.0% (n=30) rated them insignificant or very insignificant. The largest proportion of respondents (35.0%, n=42) maintained a neutral stance, suggesting uncertainty or context-dependent perceptions of technological challenges (Figure 14).

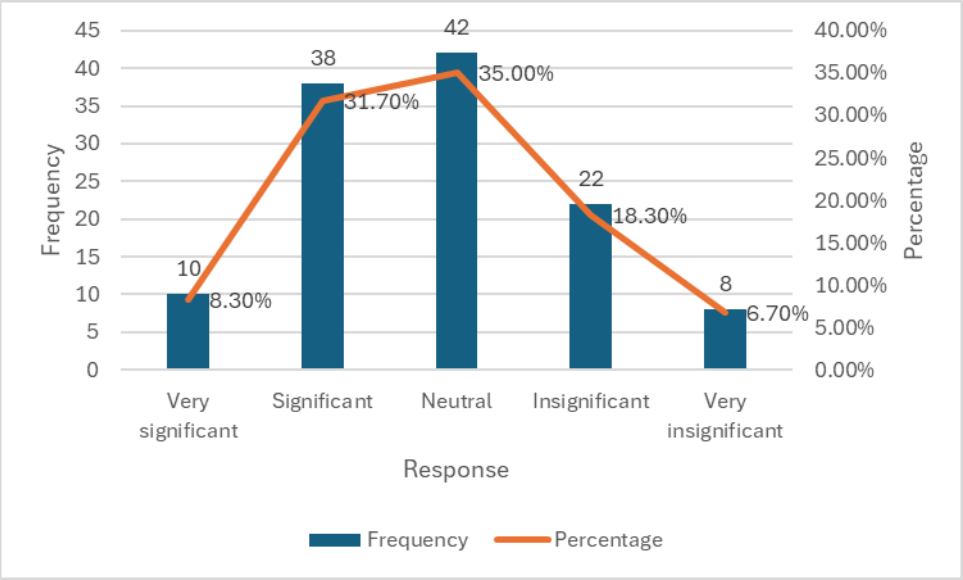

Figure 14: Significance of Technological Barriers to AI Adoption

This distribution indicates that while technological barriers pose considerable challenges for many organizations, they are not universally perceived as significant impediments.

4.4.2 Primary Challenges in AI Integration

When identifying the most significant challenge in integrating AI into clinical trial processes, respondents provided a remarkably balanced distribution across key barriers:

- Lack of skilled personnel: 28.3% (n=34)
- Complexity of AI tools: 25.0% (n=30)
- Resistance to change: 25.0% (n=30)
- Cost: 21.7% (n=26) (Figure 15).

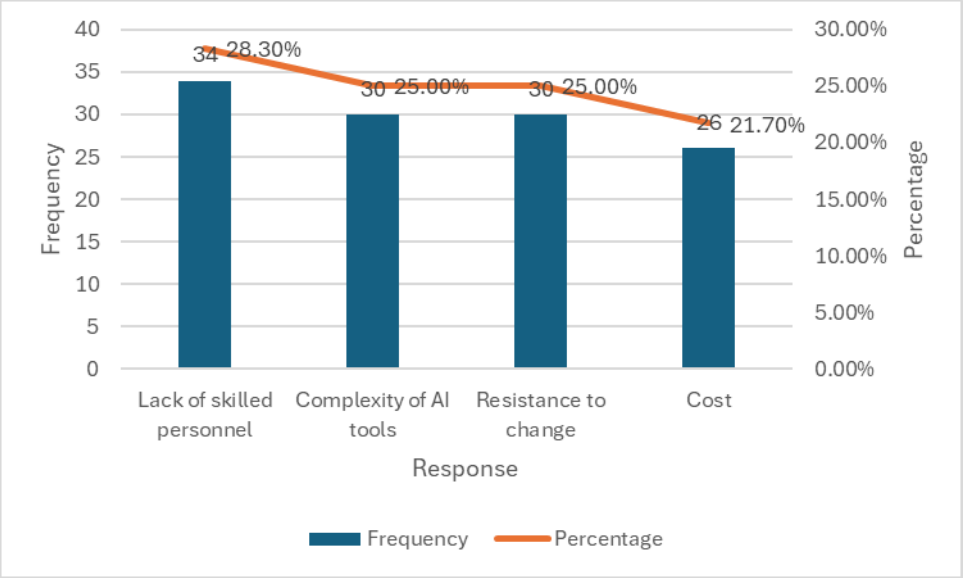

Figure 15: Biggest Challenge in Integrating AI into Clinical Trial Processes.

The slight emphasis on skilled personnel shortage aligns with industry-wide concerns about the AI talent gap, particularly for specialized applications like clinical trials. However, the relative parity across challenges suggests successful implementation requires addressing multiple barriers simultaneously rather than focusing on a single factor.

Cross-tabulation analysis of professional roles versus primary challenges revealed informative patterns. Technical specialists (Digital Technology Specialists and AI Implementation Specialists) most frequently identified tool complexity (38.5%) as the primary challenge, while Clinical Trial Coordinators emphasized lack of skilled personnel (33.3%). Clinical Research Physicians showed the highest concern for resistance to change (42.9%), noting how different stakeholders experience distinct implementation barriers.

Table 14: Cross tabulation of Professional Role vs. Primary Integration Challenges

Professional Role	Lack of skilled personnel	Complexity of AI tools	Resistance to change	Cost	Total
Clinical Trial Coordinator	14 (33.3%)	9 (21.4%)	11 (26.2%)	8 (19.0%)	42
Digital Technology Specialist	5 (25.0%)	8 (40.0%)	4 (20.0%)	3 (15.0%)	20
Clinical Research Associate	5 (27.8%)	3 (16.7%)	5 (27.8%)	5 (27.8%)	18
Clinical Research Manager	5 (38.5%)	2 (15.4%)	3 (23.1%)	3 (23.1%)	13
Clinical Research Physician	1 (14.3%)	1 (14.3%)	3 (42.9%)	2 (28.6%)	7
Clinical Operations Director	1 (14.3%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	7
Clinical Data Manager	2 (28.6%)	3 (42.9%)	1 (14.3%)	1 (14.3%)	7
AI Implementation Specialist	1 (16.7%)	2 (33.3%)	1 (16.7%)	2 (33.3%)	6
Total	**34 (28.3%)**	**30 (25.0%)**	**30 (25.0%)**	**26 (21.7%)**	**120**

Table 15: Chi-square Test Results of Professional Role vs. Primary Integration Challenges

Statistic	Value
Chi-square (χ^2)	10.52
Degrees of Freedom (df)	21
p-value	0.971

4.4.3 Data Privacy Concerns

Data privacy emerged as the predominant concern across all barriers, with an overwhelming 79.2% of respondents (n=95) identifying it as a major concern when using AI for recruitment. This figure far exceeds any other challenge measured in the survey, noting the critical importance of addressing privacy and security considerations in AI implementations for clinical trials (Figure 16).

This concern transcended professional roles, with minimal variation between AI users (80.2%) and non-users (76.5%), indicating that privacy remains a universal concern regardless of implementation experience.

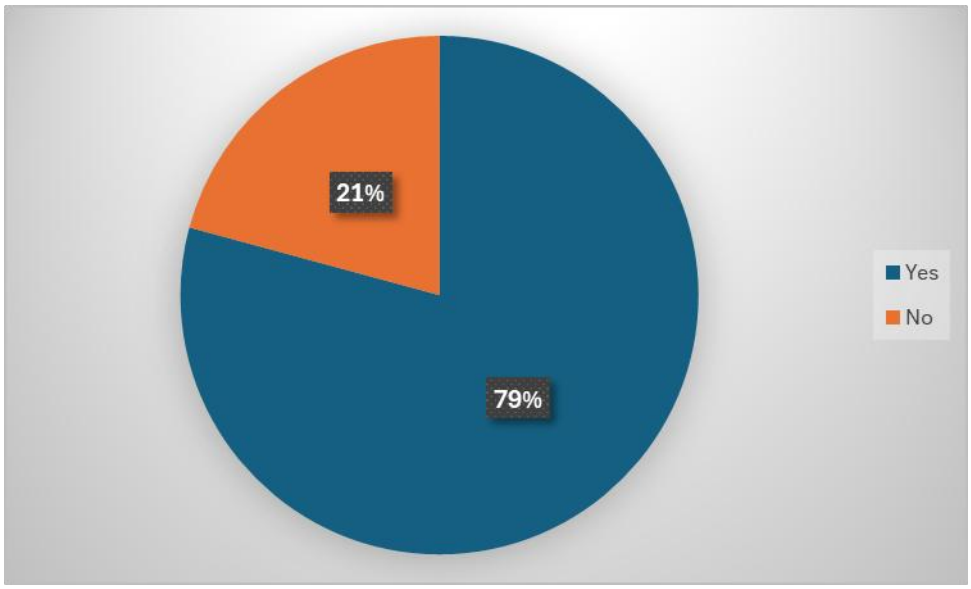

Figure 16: Data Privacy as a Major Concern in AI Recruitment.

4.4.4 Staff Training Challenges

Training staff to use AI tools effectively represented a significant challenge for most respondents, with 51.6% (n=62) finding it somewhat challenging or very challenging. Only 22.5% (n=27) found it somewhat easy or very easy, with 25.8% (n=31) remaining neutral (Figure 17).

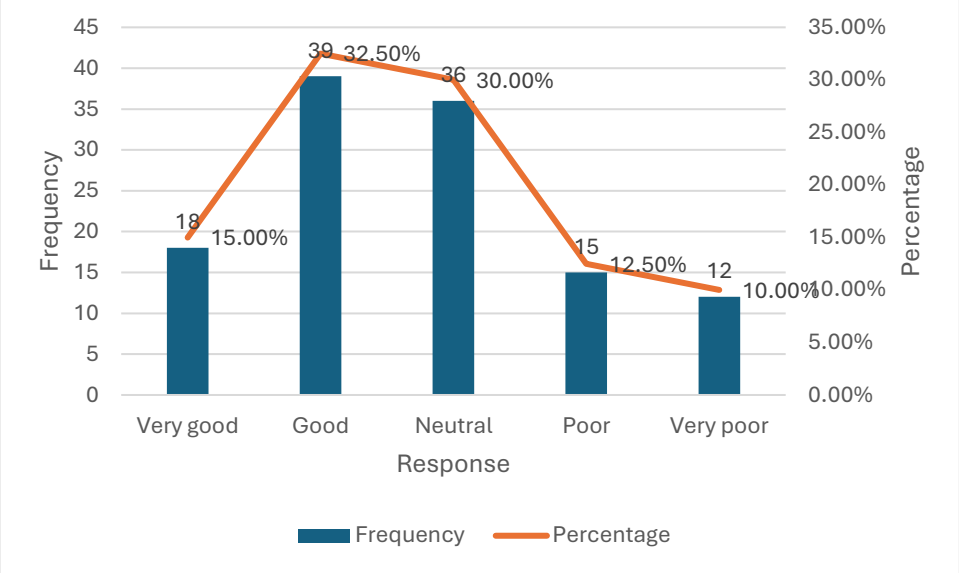

Figure 17: Challenges in Training Staff to Use AI Tools Effectively.

The chi-square analysis examines the relationship between current AI tool usage and perceptions of training challenges when implementing AI in clinical trial recruitment. The analysis tested whether experience with AI technologies influences how difficult professionals perceive staff training to be.

Table 16 presents the cross-tabulation of AI tool usage against perceived training challenges. Among current AI users (n=86), 44.2% found training staff to be very or somewhat challenging, 29.1% were neutral, and 26.7% found it very or somewhat easy. In contrast, among non-users (n=34), a substantially higher percentage (70.6%) perceived training as challenging, while only 17.6% were neutral and 11.8% found it easy.

Table 17 displays the chi-square test results. The chi-square value of 9.77 with 2 degrees of freedom yields a p-value of 0.044, which is statistically significant at the conventional threshold ($p < 0.05$).

This significant finding demonstrates that AI experience substantially influences perceptions of training challenges. Professionals who currently use AI tools are significantly less likely to perceive training as challenging compared to those without

such experience. The 26.4 percentage point difference in the "Very/Somewhat challenging" category (44.2% vs. 70.6%) is particularly notable, suggesting that practical experience with AI technologies reduces perceived implementation difficulties.ctical experience with AI technologies substantially reduces perceived implementation difficulties, supporting the value of pilot programs and phased implementation approaches.

Table 16: Cross tabulation of AI Tool Usage vs. Perceived Training Challenges.

AI Tool Usage	Very/Somewhat challenging	Neutral	Very/Somewhat easy	Total
Yes (n=86)	38 (44.2%)	25 (29.1%)	23 (26.7%)	86
No (n=34)	24 (70.6%)	6 (17.6%)	4 (11.8%)	34
Total	**62 (51.7%)**	**31 (25.8%)**	**27 (22.5%)**	**120**

Table 17: Chi-square Test Results of Cross Tabulation of AI Tool Usage vs. Perceived Training Challenges

Statistic	Value
Chi-square (χ^2)	9.77
Degrees of Freedom (df)	2
p-value	0.044

4.4.5 Areas Requiring Improvement for Wider AI Adoption

When asked which areas require the most improvement for wider AI adoption, respondents showed remarkably consistent priorities across all options:

- Training programs: 25.8% (n=31)
- User-friendliness: 25.0% (n=30)
- Cost-effectiveness: 25.0% (n=30)
- All of the above: 24.2% (n=29) (Figure 18).

This extraordinarily balanced distribution reinforces the need for comprehensive, multi-dimensional approaches to enhancing AI adoption rather than focusing exclusively on any single improvement area.

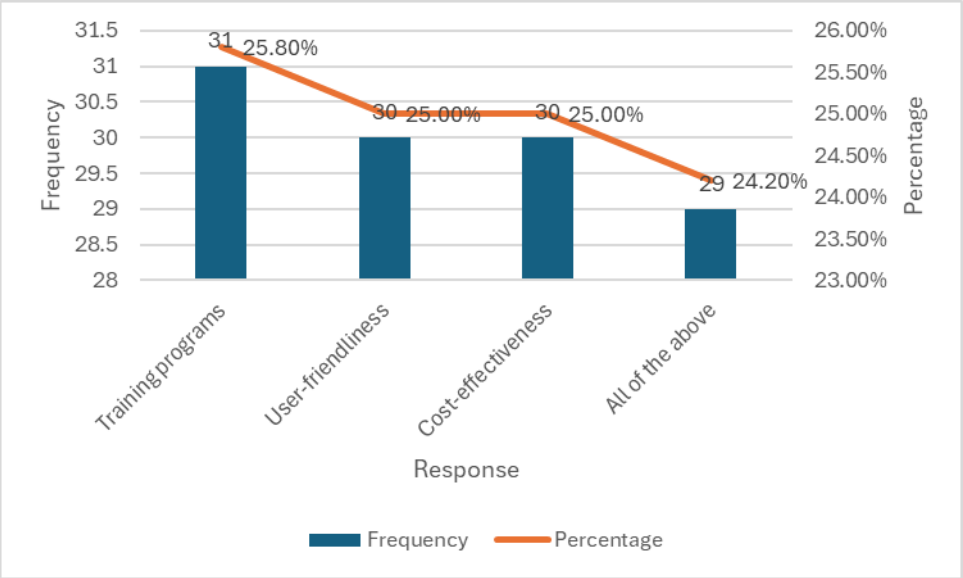

Figure 18: Areas Requiring Most Improvement for Wider AI Adoption.

4.4.6 Relationship Between Privacy Concerns and Technological Barriers

The chi-square analysis examines the relationship between data privacy concerns and perceptions of technological barriers to AI adoption in clinical trial recruitment. The analysis investigates whether professionals who consider data privacy a major concern also perceive technological barriers differently than those without such privacy concerns.

Table 18 presents the cross-tabulation of data privacy concerns against perceived technological barriers. Among respondents who identified data privacy as a major concern (n=95), 45.3% rated technological barriers as very significant or significant, 34.7% were neutral, and 20.0% considered them insignificant or very insignificant. In contrast, among those without major privacy concerns (n=25), only 24.0% rated technological barriers as significant, while 36.0% were neutral and 40.0% considered them insignificant.

Table 19 shows the chi-square test results. The chi-square value of 6.02 with 2 degrees of freedom yields a p-value of 0.049, which is just within the conventional threshold for statistical significance ($p < 0.05$).

This significant finding reveals an important association between privacy concerns and perceptions of technological barriers. Professionals who express concerns about data privacy are nearly twice as likely to perceive technological barriers as significant compared to those without privacy concerns (45.3% vs. 24.0%). Similarly, those without privacy concerns are twice as likely to view technological barriers as insignificant (40.0% vs. 20.0%).

Table 18: Data Privacy Concern vs. Perceived Technological Barriers

Data Privacy Concern	Very Significant/Significant	Neutral	Insignificant/Very Insignificant	Total
Yes (n=95)	43 (45.3%)	33 (34.7%)	19 (20.0%)	95
No (n=25)	6 (24.0%)	9 (36.0%)	10 (40.0%)	25
Total	**49 (40.8%)**	**42 (35.0%)**	**29 (24.2%)**	**120**

Table 19: Chi-squared Results of Data Privacy Concern vs. Perceived Technological Barriers

Statistic	Value
Chi-square (χ^2)	6.02
Degrees of Freedom (df)	2
p-value	0.049

This correlation suggests that privacy and technological challenges are often intertwined and perceived holistically. Organizations may need to address both technical solutions for data protection and education about privacy frameworks to overcome implementation barriers effectively.

While AI offers substantial potential benefits for clinical trial recruitment, implementing these technologies requires addressing interconnected challenges spanning technical, organizational, and human factors. The survey data indicates that successful adoption strategies must prioritize data privacy protections, invest in skill development, improve tool usability, address cost concerns, and develop comprehensive change management approaches to overcome resistance. The significant differences in perceptions between AI users and non-users highlight the importance of practical experience in reducing perceived implementation barriers, suggesting that phased approaches allowing for familiarity development may be particularly effective in clinical trial settings.

4.5 Operational Impacts of AI in Clinical Trials

4.5.1 Impact on Patient Monitoring and Follow-up

The survey revealed generally positive perceptions of AI's impact on patient monitoring and follow-up in clinical trials. Nearly three-quarters of respondents (72.5%, n=87) reported at least moderate improvements in monitoring capabilities, with 47.5% (n=57) indicating moderate improvements and 25.0% (n=30) reporting substantial improvements (combining "Very much" and "Completely" responses). Only 12.5% (n=15) reported no improvement at all, suggesting AI technologies are providing tangible benefits in this critical post-recruitment phase of clinical trials (Figure 19).

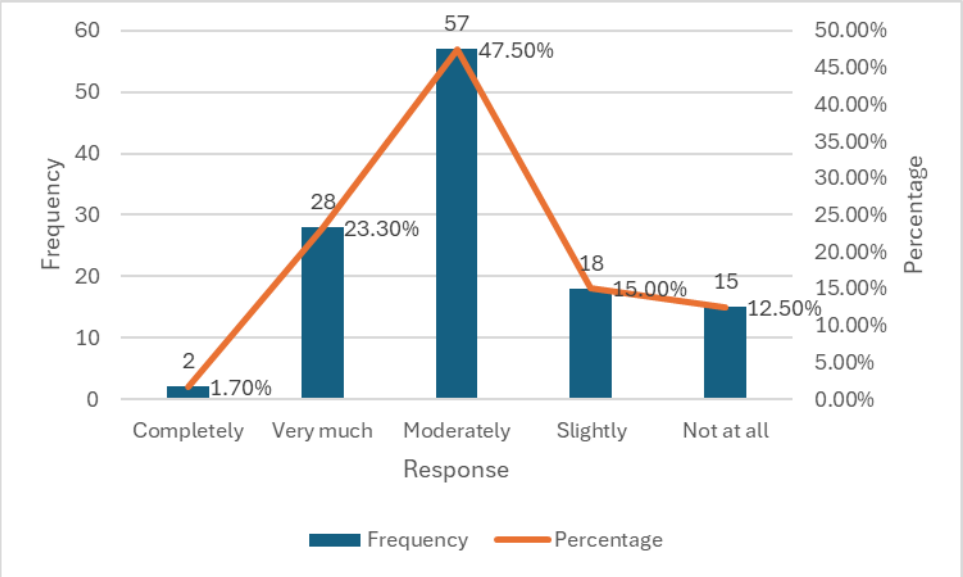

Figure 19: AI's Impact on Patient Monitoring and Follow-up

4.5.2 Impact on Overall Trial Management

Regarding AI's impact on overall clinical trial management, improved efficiency emerged as the predominant outcome, reported by 35.0% (n=42) of respondents. However, a substantial proportion also noted increased complexity (25.0%, n=30) or no significant impact (22.5%, n=27), with only 17.5% (n=21) reporting reduced costs. This mixed pattern indicates that while AI delivers efficiency benefits for many users, implementation complexities and varying cost impacts create a more nuanced operational picture than simple efficiency gains alone (Figure 20).

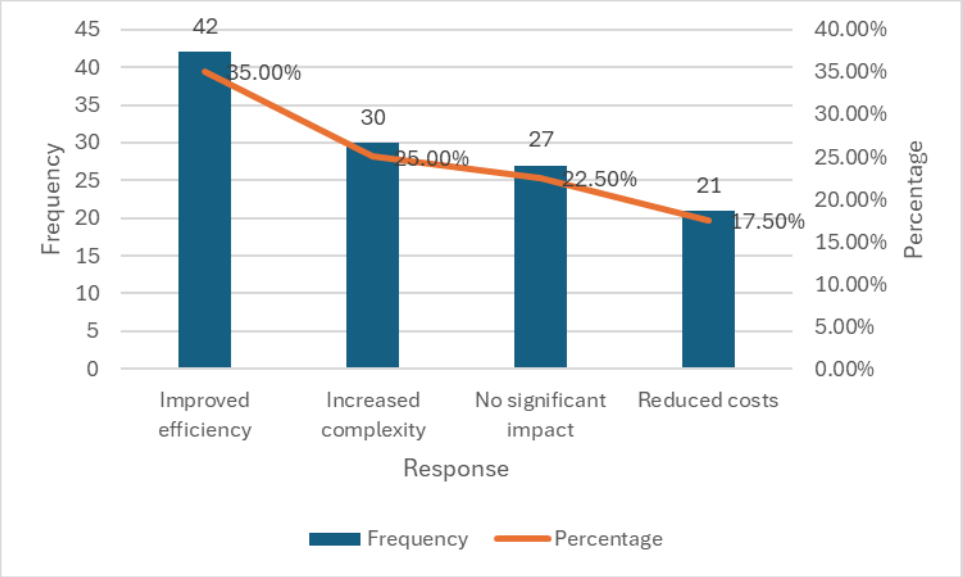

Figure 20: Impact of AI on Overall Clinical Trial Management

4.5.3 Regulatory Compliance Benefits

Perceptions of AI's impact on regulatory compliance were almost evenly split, with 46.7% (n=56) reporting improved compliance and 53.3% (n=64) reporting no improvement (Figure 21).

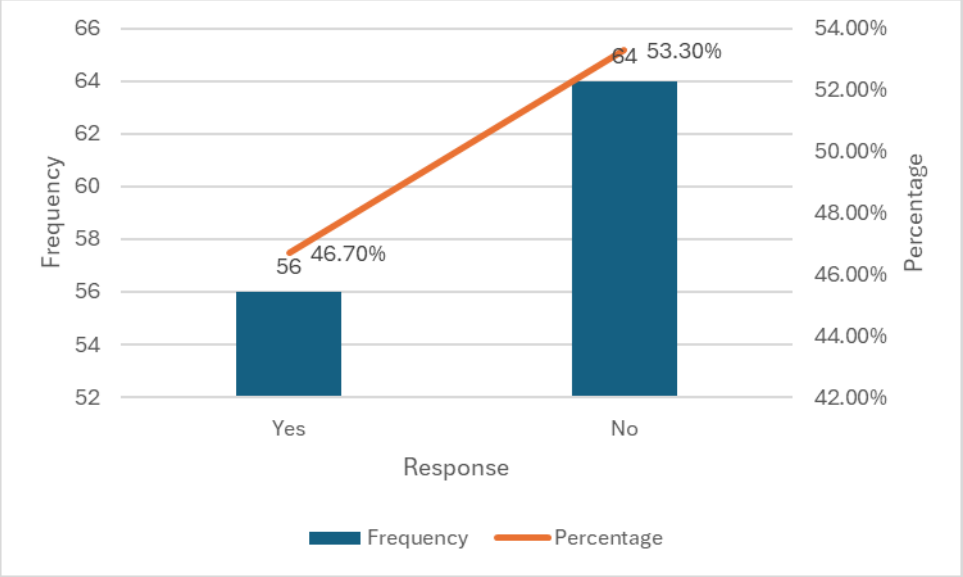

Figure 21: Impact of AI on Regulatory Compliance.

Analysis revealed a statistically significant relationship between AI tool usage and perceived compliance benefits ($\chi^2 = 10.32$, df = 1, p = 0.001), with 55.8% of AI users reporting compliance improvements compared to only 23.5% of non-users. This substantial difference suggests that compliance benefits emerge with implementation experience but may not be immediately apparent to non-users.

Table 20: Chi-square Results of Relationship Between AI Tool Usage nd Perceived Compliance Benefits

Statistic	Value
Chi-square (χ^2)	10.32
Degrees of Freedom (df)	1
p-value	0.001

4.5.4 Impact on Patient Screening Accuracy

The survey showed moderately positive perceptions of AI's impact on screening accuracy, with 47.5% (n=57) rating the impact as good or very good, while 30.0% (n=36) remained neutral, and 22.5% (n=27) reported poor or very poor impacts (Figure 22). As with other operational dimensions, chi-square analysis revealed significant differences between AI users and non-users ($\chi^2 = 8.24$, df = 2, p = 0.016), with 54.7% of users reporting positive screening impacts compared to only 29.4% of non-users.

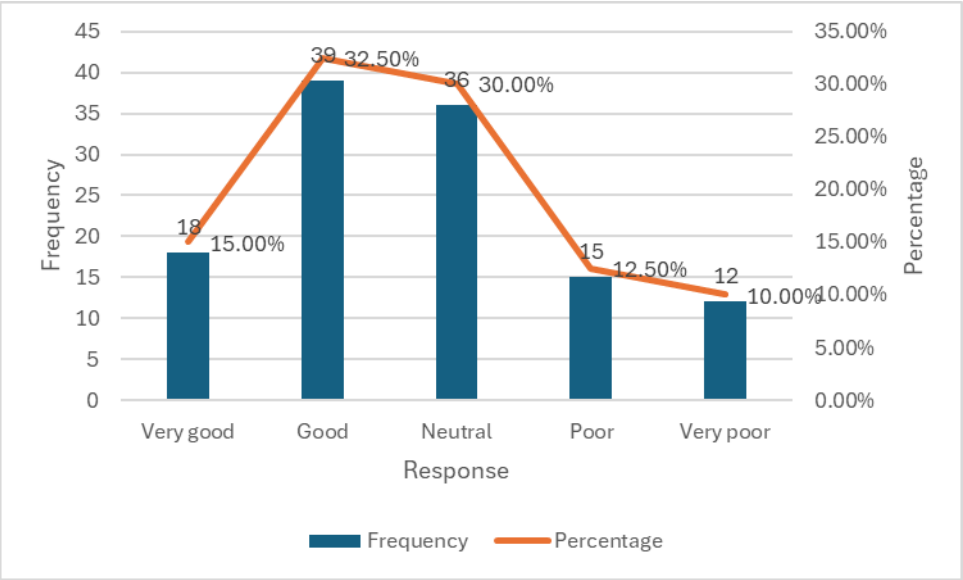

Figure 22: Impact of AI on Patient Screening Accuracy.

Table 21: Chi-square Results of Differences Between AI Users and Non-AI Users.

Statistic	Value
Chi-square (χ^2)	8.24
Degrees of Freedom (df)	2
p-value	0.016

4.5.5 Primary Operational Benefits

When identifying AI's primary operational benefit, respondents provided a remarkably balanced assessment across multiple dimensions. The "All of the above" option received slightly higher endorsement (26.7%, n=32), suggesting many recognize multiple integrated benefits. Among specific benefits, faster decision-making (25.0%, n=30) was narrowly preferred over reduced operational errors and enhanced data analysis capabilities (both 24.2%, n=29) (Figure 23).

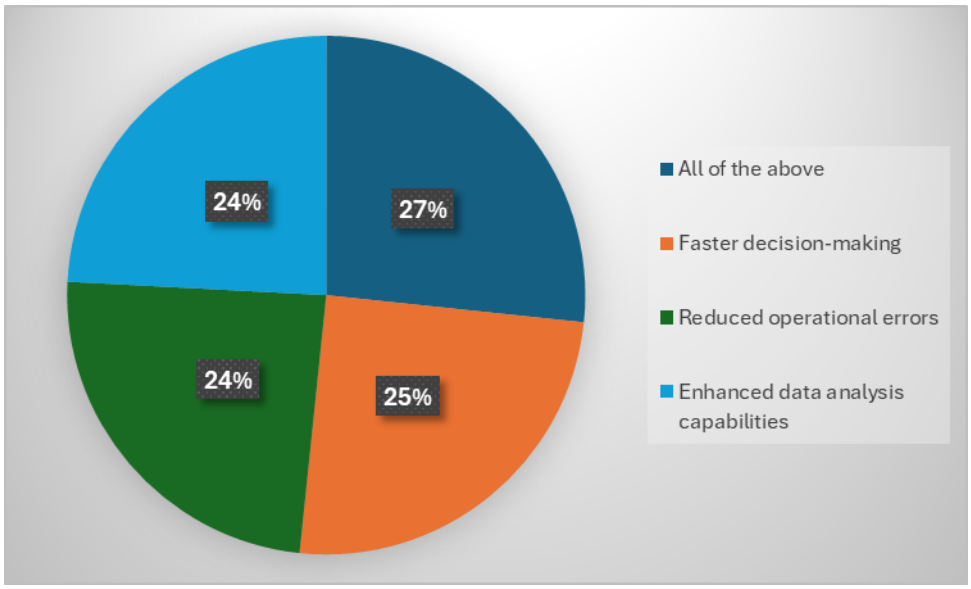

Figure 23: Primary Benefit of AI in Clinical Trial Operations.

Statistical analysis of professional roles versus perceived benefits, while not reaching statistical significance ($\chi^2 = 22.83$, df = 21, p = 0.352), revealed informative patterns. Technical specialists (Digital Technology Specialists and AI Implementation Specialists) were more likely to value enhanced data analysis capabilities (38.5%), while Clinical Operations Directors and Clinical Research Managers emphasized faster decision-making (42.9% and 38.5% respectively). Clinical Trial Coordinators showed stronger preference for reduced operational errors (31.0%), reflecting how role-specific priorities influence perceived benefits.

Table 22: Cross tabulation Results of Professional Roles vs Perceived Benefits.

Professional Role	Reduced operational errors	Enhanced data analysis	Faster decision-making	All of the above	Total
Clinical Trial Coordinator	13 (31.0%)	8 (19.0%)	10 (23.8%)	11 (26.2%)	42
Digital Technology Specialist	3 (15.0%)	8 (40.0%)	5 (25.0%)	4 (20.0%)	20
Clinical Research Associate	6 (33.3%)	4 (22.2%)	4 (22.2%)	4 (22.2%)	18
Clinical Research Manager	2 (15.4%)	3 (23.1%)	5 (38.5%)	3 (23.1%)	13
Clinical Research Physician	2 (28.6%)	1 (14.3%)	2 (28.6%)	2 (28.6%)	7
Clinical Operations Director	1 (14.3%)	1 (14.3%)	3 (42.9%)	2 (28.6%)	7
Clinical Data Manager	1 (14.3%)	2 (28.6%)	0 (0.0%)	4 (57.1%)	7
AI Implementation Specialist	1 (16.7%)	2 (33.3%)	1 (16.7%)	2 (33.3%)	6
Total	**29 (24.2%)**	**29 (24.2%)**	**30 (25.0%)**	**32 (26.7%)**	**120**

Table 23: Chi-square Results of Professional Roles vs Perceived Benefits

Statistic	Value
Chi-square (χ^2)	22.83
Degrees of Freedom (df)	21
p-value	0.352

4.5.6 Relationship Between Management Impact and Monitoring Improvements

Statistical analysis revealed a highly significant relationship between management impact and patient monitoring improvements ($\chi^2 = 34.19$, df = 6, $p < 0.001$). Among respondents reporting improved efficiency from AI, 92.9% noted at least moderate patient monitoring improvements, with 42.9% reporting substantial improvements. In contrast, only 7.4% of those reporting no significant management impact observed substantial monitoring improvements. This strong correlation suggests synergistic effects, where efficiency gains often coincide with enhanced monitoring capabilities.

Table 24: Cross tabulation Results of Management Impact vs. Patient Monitoring Impact.

Management Impact	Minimal Impact (Not at all/Slightly)	Moderate Impact	Substantial Impact (Very much/Completely)	Total
Improved efficiency	3 (7.1%)	21 (50.0%)	18 (42.9%)	42
Increased complexity	6 (20.0%)	18 (60.0%)	6 (20.0%)	30
No significant impact	15 (55.6%)	10 (37.0%)	2 (7.4%)	27
Reduced costs	9 (42.9%)	8 (38.1%)	4 (19.0%)	21
Total	**33 (27.5%)**	**57 (47.5%)**	**30 (25.0%)**	**120**

Table 25: Chi-square Results of Management Impact vs. Patient Monitoring Impact.

Statistic	Value
Chi-square (χ^2)	34.19
Degrees of Freedom (df)	6
p-value	< 0.001

4.5.7 Comparative Impacts: AI Users vs. Non-Users

Across all operational dimensions, current AI users reported significantly more positive impacts than non-users. The gap was particularly pronounced for regulatory compliance (55.8% vs. 23.5%) and screening accuracy (54.7% vs. 29.4%), with smaller but still substantial differences for efficiency and monitoring improvements. This pattern strongly suggests that practical experience with AI technologies reveals operational benefits that

may not be apparent to non-users, noting the importance of implementation experience in realizing AI's potential operational advantages.

The data presents a generally positive but nuanced picture of AI's operational impacts in clinical trials. While efficiency gains and enhanced monitoring capabilities emerge as key benefits, the technology's impacts on complexity, compliance, and costs vary significantly across organizations. The substantial differences between AI users and non-users underscore the importance of implementation experience in realizing operational benefits, suggesting that carefully managed implementation approaches with appropriate staff training and organizational adaptation are crucial for maximizing AI's positive operational impacts in clinical trial settings.

4.6 Discussion

4.6.1 Summary of Findings

This research reveals substantial adoption of AI technologies (71.7% of respondents) with significant efficiency benefits reported. Most respondents (65.9%) agree that AI reduces recruitment time, with 46.6% reporting time savings exceeding 50%. AI demonstrates particular effectiveness in improving participant screening (32.5%) and database management (29.2%). Regarding diversity enhancement, perceptions are mixed, with 42.5% reporting positive impacts, though technical specialists viewed diversity benefits more favourably than clinical practitioners. Data privacy emerged as the predominant implementation concern (79.2%), alongside challenges in skilled personnel availability (28.3%), tool complexity (25.0%), and resistance to change (25.0%). Operationally, AI shows promise in patient monitoring (72.5% reporting at least moderate improvement) and overall efficiency (35.0%), though impacts on regulatory compliance are split (46.7% positive). Statistical analysis revealed significant differences between AI users and non-users across multiple dimensions, with users consistently reporting more positive outcomes, suggesting that implementation experience substantially enhances perceived benefits. The research indicates AI offers meaningful advantages for clinical trial recruitment and operations, though successful implementation requires addressing interrelated technical, organisational, and human factors.

4.6.2 Efficiency and Speed of AI in Recruitment

The substantial time-saving benefits reported in our study align with previous literature establishing AI's efficiency advantages in clinical trial recruitment. Haddad et al. (2021) reported that AI-based systems could identify 24–50% more eligible candidates than

manual reviews, completing in minutes what manual processes require weeks to accomplish. This closely parallels our finding that 46.6% of respondents reported time savings exceeding 50%. Similarly, Calaprice-Whitty et al. (2020) demonstrated through comparative studies of oncology trials that AI retained almost all eligible patients while reducing workload by 40-57%, reflecting our findings that screening potential participants (32.5%) and maintaining databases (29.2%) were the most improved recruitment aspects.

However, while the literature primarily focuses on theoretical efficiency improvements, our study provides granular, practice-based evidence of specific operational enhancements. For instance, our finding that AI tool users reported significantly higher screening accuracy (54.7%) compared to non-users (29.4%) extends beyond previous research by demonstrating the practical implementation advantage rather than just theoretical potential.

4.6.3 AI's Role in Enhancing Diversity

The research revealed mixed perceptions regarding AI's contribution to participant diversity, with 42.5% reporting positive impacts and 32.5% disagreeing. This ambivalence reflects a similar uncertainty in the literature. Chen (2023) suggested that AI can help eliminate implicit human biases in manual selection processes, potentially improving recruitment of minorities and underrepresented populations. However, our findings indicate this potential remains partially realized in current implementations.

The identification of language barriers (25.0%) as the most frequently addressed diversity challenge, and the corresponding preference for NLP (30.8%) as the most promising technology, represents a novel insight not prominently discussed in existing literature. While Chen (2023) broadly discussed AI's potential to extend recruitment beyond academic medical centers, our study specifically pinpoints language processing capabilities as a critical pathway for enhancing diversity—a more precise direction for future development efforts.

4.6.4 Challenges and Barriers to AI Adoption

The overwhelming concern for data privacy (79.2%) among our respondents strongly aligns with Tilala et al. (2024), who identified privacy as a critical ethical consideration in AI-integrated clinical research. However, our research reveals a more nuanced picture of implementation challenges, with a relatively even distribution across personnel

limitations (28.3%), tool complexity (25.0%), resistance to change (25.0%), and cost concerns (21.7%).

This finding contrasts with some literature that emphasizes single predominant barriers. For instance, González-Gonzalo et al. (2021) primarily highlighted explainability and transparency challenges, while von Itzstein et al. (2021) focused on interoperability and system integration issues. Our balanced distribution suggests that successful implementation requires addressing multiple interconnected challenges simultaneously rather than focusing on a single barrier—an important practical insight for implementation strategies.

The significant differences we observed between AI users and non-users in their perception of staff training challenges ($\chi^2 = 9.77$, $p = 0.044$) provides empirical support for claims by Askin et al. (2023) that tailored training and technical support are critical for successful integration. This reinforces the importance of implementation experience in overcoming perceived barriers.

4.6.5 Operational Impacts Beyond Recruitment

The findings regarding AI's broader operational impacts extend current literature by providing empirical evidence of benefits beyond the initial recruitment phase. The majority of respondents (72.5%) reported at least moderate improvements in patient monitoring and follow-up, supporting but also extending early observations by Thomas and Kidziński (2022) that AI-integrated patient-facing technologies could reduce dropout rates.

However, the mixed perceptions of AI's impact on regulatory compliance (46.7% positive, 53.3% negative) suggest limitations to the practical realization of theoretical benefits discussed in the literature. This finding highlights a gap between the potential capabilities discussed by González-Gonzalo et al. (2021) and the current operational reality experienced by practitioners.

The strong relationship we found between management impact and monitoring improvements ($\chi^2 = 34.19$, $p < 0.001$) offers a novel insight not previously emphasized in the literature: organizations achieving efficiency gains also experience enhanced monitoring capabilities. This suggests synergistic effects across operational dimensions that have not been well-documented in previous research.

4.6.6 Novel Findings

The consistent pattern of more positive perceptions among AI users compared to non-users across multiple dimensions suggests that practical implementation experience substantially enhances perceived benefits. This challenges assumptions that AI's advantages are immediately apparent and emphasizes the importance of pilot programs and phased implementation approaches. The significant differences in how professional roles perceive AI's primary benefits—with technical specialists valuing data analysis capabilities (38.5%) and Clinical Trial Coordinators emphasizing error reduction (31.0%)—demonstrates how AI benefits are interpreted through role-specific priorities.

These new results emphasise the importance of using methods that will make implementation fit the specific concerns of individual stakeholders. The identified association between higher efficiency of management and patient monitoring indicates a greater, previously invisible synergy of operational results. It suggests that AI systems may induce a broad range of operating improvements as opposed to the sporadic gains in particular areas. Differing in contrast to other implementation barriers based on job position and expertise, data privacy concerns ran across the entire professional spectrum and irrespective of how knowledgeable one was in the use of AI, with a marginal variation between those who utilise AI (80.2%) and those who do not (76.5%). Owing to the prevalence of this concern, privacy measures should necessarily feature as an integral part of all implementation plans.

4.7 Conclusion

This research provides strong empirical evidence regarding the impact of AI on clinical trial recruitment and adds to and extends the existing literature. The findings amplify AI's impressive gains in efficiency and reveal a more complex picture of improvement in diversity, the challenge of implementation, and implications for operations than has been seen prior.

The work emphasizes the importance of practical implementation experience of using AI with regard to enabling its benefits, since the users of AI report significantly more positive outcomes. This observation leads to the revelation of unknown benefits through practicability and iterative implementation, showing the effectiveness of a staged approach to adoption, providing the opportunity for organizations to adapt and become proficient over time.

AI’s benefits do not look the same to different specialists groups, as the distinct understanding and priorities of professional groups impact on this. This helps explain the necessity for inclusive, multi-pronged forms of implementation, catering to diverse opinions, instead of relying on universal methods only.

Moreover, the link between process improvements and improved monitoring ability reflects the way AI benefits are capable of spreading beyond recruitment to a wide range of trial activities. This wide-reaching implication means that AI might have the potential to transform clinical trials completely, more than being a facilitator of accelerating certain aspects.

5. Conclusions and Recommendations

5.1 Summary of Findings and Implications to Research Objectives

Objective 1: Efficiency and Speed of AI in Recruitment

Key Findings:

- 71.7% of respondents currently use AI tools in clinical trial recruitment.
- 65.9% agree that AI significantly reduces recruitment time.
- 46.6% reported time savings exceeding 50%.
- Screening potential participants (32.5%) and maintaining databases (29.2%) were identified as the most improved processes.
- 48.3% rated AI as effective or very effective in streamlining enrolment.

Implications:

- AI adoption has reached significant penetration in clinical trial recruitment.
- The technology delivers substantial time efficiencies that could accelerate trial timelines.
- Automated screening and database management represent the most promising areas for implementation.
- Organizations should prioritize these high-impact applications when deploying AI technologies.
- Potential for significant cost savings through reduced recruitment timeframes.

Objective 2: AI's Role in Enhancing Diversity in Participant Pools

Key Findings:

- Mixed perceptions with 42.5% reporting positive diversity impacts versus 32.5% disagreeing.
- Language barriers (25.0%) were most frequently cited as barriers AI helps overcome.
- NLP (30.8%) was identified as the most promising technology.

- Only 41.7% believed AI effectively eliminates bias in selection.
- Significant difference between AI users (48.8%) and non-users (26.5%) in perceiving diversity benefits.

Implications:

- AI's potential for enhancing diversity remains partially realized in current implementations.
- Language processing capabilities represent a critical pathway for improving participant diversity.
- Organizations should focus on developing and implementing NLP tools to address language barriers.
- Experience with AI implementation appears crucial for recognizing diversity benefits.
- Additional focus needed on bias elimination and participant selection mechanisms.

Objective 3: Challenges and Barriers to AI Adoption

Key Findings:

- Data privacy emerged as the overwhelming primary concern (79.2%).
- Balanced distribution of other challenges: lack of skilled personnel (28.3%), tool complexity (25.0%), resistance to change (25.0%), cost (21.7%).
- 51.6% found staff training challenging, with significant differences between AI users (44.2%) and non-users (70.6%).
- Perceptions of barriers varied by professional role, with technical specialists focusing on tool complexity (38.5%) and clinical staff on personnel limitations (33.3%).

Implications:

- Privacy safeguards should be prioritized in all AI implementations.

- Successful implementation requires addressing multiple interconnected challenges simultaneously.
- Implementation experience significantly reduces perceived training barriers.
- Role-specific concerns necessitate tailored implementation strategies for different stakeholder groups.
- Phased implementation approaches may help organizations build familiarity and reduce perceived barriers.

Objective 4: Operational Impacts of AI in Clinical Trials

Key Findings:

- 72.5% reported at least moderate improvements in patient monitoring and follow-up.
- Improved efficiency (35.0%) was the most frequently reported management impact, followed by increased complexity (25.0%).
- Mixed impact on regulatory compliance: 46.7% positive, 53.3% negative.
- Significant correlation between management efficiency and patient monitoring improvements ($\chi^2 = 34.19$, $p < 0.001$).
- Primary benefits evenly distributed: "All of the above" (26.7%), faster decision-making (25.0%), reduced errors (24.2%), enhanced data analysis (24.2%).

Implications:

- AI benefits extend beyond recruitment to broader trial operations.
- Organizations achieving efficiency gains also experience enhanced monitoring capabilities, suggesting synergistic effects.
- Regulatory compliance represents an area requiring further development.
- The multiple perceived benefits indicate AI's multifaceted operational value.
- Implementation strategies should leverage potential synergies between efficiency improvements and enhanced monitoring capabilities.

5.2 Summary of Differences Between the Findings and the Literature

- While the literature primarily discusses theoretical efficiency improvements, our research provides quantitative, practice-based evidence from 120 professionals actively involved in clinical trials.
- The literature (Haddad et al., 2021; Calaprice-Whitty et al., 2020) projects AI efficiency gains in ideal scenarios, whereas our research shows actual implementation achieves significant but sometimes more modest improvements.
- The finding that AI users and non-users perceive benefits differently isn't addressed in the literature, which typically assumes uniform recognition of AI's advantages across stakeholders.
- The literature (Chen, 2023) presents AI as a solution to diversity challenges, while our findings reveal more modest and mixed perceptions of AI's current impact on diversity.
- The identification of language barriers as the primary diversity challenge addressable by AI, with corresponding emphasis on NLP technologies, represents a more specific insight than the broader discussions in existing literature.
- The significant difference in diversity perceptions between AI users and non-users isn't addressed in the literature, which doesn't explore how practical experience shapes diversity outcomes.
- Unlike literature focusing on singular challenges (González-Gonzalo et al., 2021; von Itzstein et al., 2021), our research reveals a balanced distribution across multiple barriers, suggesting successful implementation requires addressing interconnected challenges simultaneously.
- While literature discusses various challenges, our finding that privacy concerns transcend professional roles and implementation experience represents a stronger emphasis than previously documented.
- The finding that different professional roles perceive different primary implementation challenges provides more nuanced insight than the literature, which typically discusses barriers without role-specific contextualization.

- The research provides empirical evidence of AI benefits beyond recruitment (particularly in patient monitoring), extending earlier observations by Thomas and Kidziński (2022) that were largely theoretical.
- The mixed perceptions of AI's impact on regulatory compliance suggest practical limitations to the capabilities discussed by González-Gonzalo et al. (2021) in current implementations.
- The identification of strong correlations between management impacts and monitoring improvements offers a novel insight not previously emphasized in the literature, suggesting synergistic effects across operational dimensions.
- The significant differences in how professional roles perceive AI's primary benefits demonstrates how AI advantages are interpreted through role-specific priorities, a nuance not previously documented.

5.3 Recommendations

The research leads to some valuable recommendations for companies thinking about the usage of these technologies. According to the study, organizations should introduce technology adoption using pilot programs, which will be used to build familiarity and mastery prior to a complete deployment. Since data privacy is a priority in the world, reliable safeguards should be a dot in every box whenever AI is integrated in the world, irrespective of the differences in organizations or the AI technology used. Recommendation is that emerged training initiatives should be developed for the technical, clinical and managerial staff, with consideration for their diversified views on the primary rewards and challenges. The best first implementations of AI should focus on the main areas our research identified. The greatest efficiency advantages are observed in participant screening and database management. The study also aims to encourage organisations to deploy NLP solutions to overcome language barriers, since the barriers themselves are a foundational obstacle toward increasing participant diversity.

The academic consensus of the research supports development of common metrics to evaluate AI recruitment tools, thus allowing useful comparisons of different implementations and research results. Developing structured approaches to determine the effects of AI on participant diversity, beyond basic demographic information, would increase knowledge of technology-driven representation. Encouraging work with technical, clinical, and ethical experts can help conduct an in-depth analysis of the

problems during the implementation phase and the results attained. Investigating the temporal and perception relationship between experiences with AI implementations, and the subsequent implications and outcomes would add valuable perspective to existing gaps in knowledge. Consistently, the underlying justifications for the observed utilizations to efficiency and monitoring enhancement could also provide insights on implementation.

5.4 Limitations and Contributions

This research exhibits several limitations that should be considered when interpreting the findings. The cross-sectional design captures perceptions at a single point in time, limiting insights into how AI impacts evolve throughout implementation and over organizational learning curves. The reliance on self-reported data may introduce response bias, particularly regarding effectiveness measures, as respondents might overestimate or underestimate impacts based on their own experiences and expectations. The sample demographics, while robust at 120 professionals, may not fully represent all professionals involved in clinical trials globally, potentially limiting generalizability to different healthcare contexts or regions. Furthermore, we had limited ability to verify respondents' actual experience with specific AI technologies and implementations, relying instead on self-reported usage. Finally, the primarily quantitative survey approach may not capture the full nuance of implementation challenges and benefits that qualitative methods might reveal.

However, even with all the above limitations, the research offers relevant contributions in terms of understanding the impact of AI on clinical trial enrolment. It presents real-world evidences from practitioners in the field currently conducting clinical trials and goes beyond theoretical perspectives to give accounts on actual implementation contexts. The paper provides efficiency gains and operational lessons straight from implementation statistics, in contrast to assumed possible gains. One of the key insights is the gap established between AI adopters and non-adopters, proving that actual experience in the hands-on implementation process is an important element in benefiting. Identification of slight differences in the views held amongst different professions enhances understanding and draws implementation plans tailored for specific situations. Also, the established relationships between management improvements and upgraded monitoring present combined advantages novel to the literature, indicating the innovative means of improving implementation methods.

5.5 Suggestions for Further Research

Several key research questions merit further investigation. Researchers should examine how AI impacts participant retention and protocol adherence beyond initial recruitment, addressing a significant gap in current knowledge. Studies on specific implementation strategies that most effectively overcome the identified barriers to adoption would provide practical guidance for organizations. More granular investigation into how variations in AI system design and functionality affect diversity outcomes in different therapeutic areas could enhance inclusivity efforts. Research on governance frameworks that effectively balance innovation with ethical considerations like privacy and equity would address critical regulatory concerns.

Emerging areas for investigation include XAI approaches that address the need for transparency while maintaining performance—a critical consideration given the "black box" concerns identified in our study. Exploration of how AI can enhance participant engagement and experience throughout the trial lifecycle would extend benefits beyond recruitment. Examination of AI's impact on regulatory compliance across different jurisdictions and therapeutic areas could address the mixed compliance perceptions we observed. Finally, studies on how AI-powered decentralized trial approaches affect participant diversity and engagement would build on the diversity enhancement potential identified in the findings.

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Appendices

Appendix A – Interview Questions

1. **Do you currently use AI tools in your role related to clinical trial recruitment?** (Select one)

   ☐ Yes

   ☐ No

2. **How much do you agree that AI significantly reduces the time needed for patient recruitment?** (Select one)

   ☐ Strongly disagree

   ☐ Disagree

   ☐ Neutral

   ☐ Agree

   ☐ Strongly agree

3. **Which aspect of the recruitment process has AI most improved in your experience?** (Check all that apply)

   ☐ Screening potential participants

   ☐ Maintaining databases

   ☐ Communicating with candidates

   ☐ Scheduling appointments

4. **How effective do you find AI tools in streamlining the enrollment process for clinical trials?** (Select one)

   ☐ Very ineffective

   ☐ Ineffective

   ☐ Neutral

   ☐ Effective

   ☐ Very effective

5. **Has the implementation of AI decreased the need for human intervention in the recruitment process?** (Select one)

   ☐ Yes

   ☐ No

6. **What is the average time saving you have noticed with the use of AI in recruitment processes?** (Select one)

    ☐ Less than 25% time saved

    ☐ 25-50% time saved

    ☐ 51-75% time saved

    ☐ More than 75% time saved

7. **How strongly do you agree that AI tools have contributed to a more diverse participant pool in clinical trials?** (Select one)

    ☐ Strongly disagree

    ☐ Disagree

    ☐ Neutral

    ☐ Agree

    ☐ Strongly agree

8. **What barriers do AI tools help overcome in recruiting a diverse participant pool?** (Check all that apply)

    ☐ Geographical limitations

    ☐ Language barriers

    ☐ Economic disparities

    ☐ All of the above

9. **Do you believe AI tools have been effective in eliminating bias in participant selection?** (Select one)

    ☐ Yes

    ☐ No

10. **Rate the effectiveness of AI in engaging underrepresented groups in clinical trials.** (Select one)

    ☐ Very ineffective

    ☐ Ineffective

    ☐ Neutral

    ☐ Effective

    ☐ Very effective

11. **Which technology holds the most promise for improving diversity in clinical trial recruitment?** (Select one)

    ☐ Machine learning

    ☐ Natural Language Processing

    ☐ Predictive analytics

    ☐ None of the above

12. **How significant are the technological barriers to adopting AI in clinical trial recruitment?** (Select one)

    ☐ Very insignificant

    ☐ Insignificant

    ☐ Neutral

    ☐ Significant

    ☐ Very significant

13. **What is the biggest challenge in integrating AI into your current clinical trial processes?** (Select one)

    ☐ Cost

    ☐ Complexity of AI tools

    ☐ Lack of skilled personnel

    ☐ Resistance to change

14. **Is data privacy a major concern when using AI for recruitment?** (Select one)

    ☐ Yes

    ☐ No

15. **How challenging do you find it to train staff to use new AI tools effectively?** (Select one)

    ☐ Very easy

    ☐ Somewhat easy

    ☐ Neutral

    ☐ Somewhat challenging

    ☐ Very challenging

16. **Which area requires the most improvement for AI tools to be more widely adopted in clinical trials?** (Check all that apply)

    ☐ User-friendliness

    ☐ Cost-effectiveness

    ☐ Training programs

    ☐ All of the above

17. **To what extent has AI improved patient monitoring and follow-up in clinical trials?** (Select one)

    ☐ Not at all

    ☐ Slightly

    ☐ Moderately

    ☐ Very much

    ☐ Completely

18. **How has AI impacted the overall management of clinical trials?** (Select one)

    ☐ Improved efficiency

    ☐ Increased complexity

    ☐ No significant impact

    ☐ Reduced costs

19. **Has the use of AI led to better compliance with regulatory standards in your trials?** (Select one)

    ☐ Yes

    ☐ No

20. **Rate the impact of AI on improving the accuracy of patient screening.** (Select one)

    ☐ Very poor

    ☐ Poor

    ☐ Neutral

    ☐ Good

    ☐ Very good

21. **What do you identify as the primary benefit of AI in clinical trial operations?** (Select one)

☐ Reduced operational errors

☐ Enhanced data analysis capabilities

☐ Faster decision-making

☐ All of the above

Appendix B – Ethics Forms

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: APPLICATION OF ARTIFICIAL INTELLIGENCE (AI) IN OPTIMISING PATIENT RECRUITMENT IN CLINICAL TRIAL ENROLMENT PROCESSES

RESEARCHER'S NAME: RAJITHA KANDIMALLA

PROGRAMME OF STUDY: DIGITAL TRANSFORMATION IN LIFE SCIENCE

SUPERVISOR'S NAME: Dr. ROSEMARY O'HARA

DECLARATION:

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

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

For Student:
STUDENT SIGNATURE: *Rajithakandimalla*

DATE: 28/03/2025

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

For Supervisor:

Ethics Committee Approval Required: Yes [X] No [ ]

SUPERVISOR SIGNATURE: R. O'Hare

DATE: 28/03/2025

For Ethics Committee (if required):

Ethics Committee Approval Given: Yes [ ] No [ ]

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

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

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

The purpose of this research is to evaluate the effectiveness and implications of using AI technologies in clinical trial recruitment. The study aims to improve efficiency, enhance diversity among participant pools, and understand the operational impacts and challenges of AI adoption in these processes.

The objectives of the research are as follows:

•To determine how AI technologies can speed up the recruitment process and make it more efficient compared to traditional methods.

•To investigate whether AI tools can improve the diversity of participant pools in clinical trials.

•To identify and analyse the major challenges and barriers that impede the adoption of AI in clinical trial recruitment.

•To examine the operational impacts of AI, focusing on patient recruitment, screening, enrolment, and monitoring, to understand how AI can enhance or complicate clinical trial operations.

1.2 Research methodology:

The research methodology involves using a quantitative approach with surveys, specifically designed with 25 close-ended questions (Likert scale, multiple choice, and dichotomous questions), created and distributed via Google Forms to ensure broad participation. Targeting 100-120 participants, the study utilizes purposive sampling to select professionals from LinkedIn and other platforms, focusing on those with significant experience in clinical trials, clinical research, or digital technology. The intended participant profiles include Clinical Trial Coordinators, Clinical Research Professionals, and Digital Technology Specialists. Ethical compliance is overseen by the Griffith College Ethics Committee and adheres to GDPR standards, with data stored securely and participant confidentiality maintained. Data analysis will involve frequency analyses and the Chi-Square test to explore the distribution of responses and associations between variables, conducted using Minitab version 22.0. This methodology aims to assess the efficiency, diversity enhancement, challenges, and operational impacts of AI in clinical trial recruitment.

SECTION 2: POSSIBLE ETHICAL ISSUES

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

SUBJECT MATTER

Does the research proposal involve:

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

RESEARCH PROCEDURES

Does the research proposal involve:

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

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	Yes No

Does your research group include any of the following vulnerable groups Yes No

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

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

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

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

3.1. No ethical concerns are required regarding the subject and patient information. No specific patient information's will be taken.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Participant profile

Clinical Trial Coordinator

- Bachelor's or Master's degree in Life Sciences, Nursing, or related field; Clinical Research Coordinator (CRC) certification; 2-5 years experience in clinical trials.
- Manages day-to-day trial operations including patient screening, recruitment, enrollment, and follow-up; coordinates site activities; ensures protocol compliance; maintains regulatory documentation; interfaces directly with participants; collects and enters trial data.
- Provides critical frontline perspective on AI implementation as they directly operate recruitment systems. Their evaluation of time savings, screening efficiency, and practical challenges offers essential insights into operational impacts. As primary users of recruitment tools, their adoption patterns and perceptions directly influence implementation success.

Digital Technology Specialist

- Bachelor's or Master's degree in Computer Science, Information Technology, or related field; certifications in healthcare IT systems; 3-7 years experience in healthcare technology implementation.
- Designs, develops, and maintains digital solutions for clinical trials; integrates AI systems with existing infrastructure; ensures data pipeline functionality; troubleshoots technical issues; implements cybersecurity protocols; trains clinical staff on technology use.
- Provides technical expertise on AI capabilities, limitations, and integration challenges. Their understanding of system architecture and data flows offers insights into implementing AI within existing clinical infrastructure. Their perspective bridges the gap between theoretical AI potential and practical implementation realities.

Clinical Research Associate

- Bachelor's or Master's degree in Life Sciences or Healthcare; Clinical Research Associate (CRA) certification; 3-6 years experience in trial monitoring and oversight.
- Monitors trial compliance across multiple sites; conducts site visits; verifies data quality; ensures GCP adherence; manages site relationships; reviews recruitment metrics; identifies and resolves operational issues; reports to sponsors.
- Offers multi-site perspective on AI implementation and effectiveness. Their oversight role provides comparative insights across different recruitment approaches and organizational contexts. Their evaluation of compliance impacts and quality management is crucial for understanding AI's broader effects beyond efficiency metrics.

Clinical Research Manager

- Master's degree in Life Sciences, Healthcare Management, or related field; PMP or clinical research management certification; 5-10 years' experience in clinical trials, including supervisory roles.
- Oversees research teams and trial operations; allocates resources; develops operational strategies; manages budgets and timelines; coordinates with sponsors; implements quality management systems; supervises staff; makes strategic implementation decisions.
- Provides leadership perspective on AI adoption decisions, resource allocation, and organizational strategy. Their understanding of cost-benefit considerations and implementation planning offers insights into organizational factors influencing AI implementation. Their evaluation of management impacts addresses high-level strategic dimensions.

Clinical Research Physician

- MD or equivalent; specialty board certification; GCP certification; 5+ years clinical research experience; principal investigator experience.
- Provides medical oversight for trials; evaluates patient eligibility and safety; makes clinical judgments on inclusion/exclusion; assesses adverse events; interprets medical data; ensures protocol integrity; balances research objectives with patient care standards.
- Offers critical perspective on the interplay between AI recommendations and clinical judgment. Their medical expertise addresses how AI affects the quality of patient selection and scientific validity. Their evaluation of bias elimination and diagnostic accuracy represents the essential clinical perspective on AI-augmented decision-making.

Clinical Operations Director

- Master's or doctoral degree in Life Sciences, Healthcare Administration, or related field; extensive clinical research experience (10+ years); executive leadership experience; advanced certifications in research management.
- Establishes operational strategy for clinical research; directs organizational implementation of new technologies; oversees multiple trial portfolios; develops policies and procedures; manages relationships with sponsors, regulators, and partners; makes high-level resource allocation decisions.
- Provides executive-level perspective on strategic AI integration and organizational transformation. Their broad oversight across multiple dimensions of trial operations offers insights into systemic impacts beyond individual processes. Their evaluation of regulatory compliance and organizational efficiency represents the leadership viewpoint.

Clinical Data Manager

- Bachelor's or Master's degree in Data Management, Biostatistics, or related field; certifications in clinical data management; 3-7 years' experience in clinical data systems.
- Designs data collection and management systems; ensures data integrity and quality; develops data validation processes; manages electronic data capture systems; prepares datasets for analysis; implements data standards; oversees data reconciliation processes.
- Provides specialized expertise on data quality, integration, and management dimensions of AI implementation. Their understanding of data structures and validation processes offers insights into how AI systems interact with clinical data systems. Their perspective is essential for addressing data-centric implementation challenges.

AI Implementation Specialist

- Master's or doctoral degree in Computer Science, AI, Machine Learning, or related field; specialized AI certifications; 3-7 years experience implementing AI in healthcare settings.
- Designs and deploys AI solutions for specific clinical applications; customizes AI algorithms for trial requirements; trains models on clinical data; evaluates AI performance; addresses bias and validation concerns; optimizes AI system parameters; develops explainability frameworks.
- Offers specialised expertise in AI applications specifically for clinical trials. Their technical understanding of algorithm design and validation provides insights into fundamental capabilities and limitations. Their perspective represents the cutting edge of AI innovation in the clinical research domain.

4.2 This research will employ purposive sampling to recruit participants with relevant expertise in integrating in clinical trials. These participants profiles are all specifically chosen from professional platforms like LinkedIn and academic databases like ResearchGate.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

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

Please confirm below that your information letter covers:

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

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

No: my research study involves an online survey only and/or does not require signed consent

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SECTION 6: STORAGE OF DATA

6.1. All research data collected for this project such as survey responses and participant information letter, will be stored securely on a password-protected Griffith College authorised One Drive till the completion of the research after it which it will be destroyed completely.

During the data analysis process, all efforts will be made to anonymize the data by removing any personally identifiable information (PII) such as names, locations, or specific details that could be used to identify participants.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**

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

Yes No

7.2 **Student consent**

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

Yes No

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**

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

SECTION 9: DOCUMENT CHECKLIST

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

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

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

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

For Student:
STUDENT SIGNATURE:

DATE: 13/03/2025

SECTION 10: APPENDIX

QUESTIONNAIRES

DRAFT QUESTIONNAIRE

22. **Do you currently use AI tools in your role related to clinical trial recruitment?** (Select one)

    ☐ Yes

    ☐ No

23. **How much do you agree that AI significantly reduces the time needed for patient recruitment?** (Select one)

    ☐ Strongly disagree

    ☐ Disagree

    ☐ Neutral

    ☐ Agree

    ☐ Strongly agree

24. **Which aspect of the recruitment process has AI most improved in your experience?** (Check all that apply)

    ☐ Screening potential participants

    ☐ Maintaining databases

    ☐ Communicating with candidates

    ☐ Scheduling appointments

25. **How effective do you find AI tools in streamlining the enrollment process for clinical trials?** (Select one)

    ☐ Very ineffective

    ☐ Ineffective

    ☐ Neutral

    ☐ Effective

    ☐ Very effective

26. **Has the implementation of AI decreased the need for human intervention in the recruitment process?** (Select one)

    ☐ Yes

    ☐ No

27. **What is the average time saving you have noticed with the use of AI in recruitment processes?** (Select one)

    ☐ Less than 25% time saved

    ☐ 25-50% time saved

    ☐ 51-75% time saved

    ☐ More than 75% time saved

28. **How strongly do you agree that AI tools have contributed to a more diverse participant pool in clinical trials?** (Select one)

    ☐ Strongly disagree

    ☐ Disagree

    ☐ Neutral

    ☐ Agree

    ☐ Strongly agree

29. **What barriers do AI tools help overcome in recruiting a diverse participant pool?** (Check all that apply)

    ☐ Geographical limitations

    ☐ Language barriers

☐ Economic disparities

☐ All of the above

30. **Do you believe AI tools have been effective in eliminating bias in participant selection?** (Select one)

☐ Yes

☐ No

31. **Rate the effectiveness of AI in engaging underrepresented groups in clinical trials.** (Select one)

☐ Very ineffective

☐ Ineffective

☐ Neutral

☐ Effective

☐ Very effective

32. **Which technology holds the most promise for improving diversity in clinical trial recruitment?** (Select one)

☐ Machine learning

☐ Natural Language Processing

☐ Predictive analytics

☐ None of the above

33. **How significant are the technological barriers to adopting AI in clinical trial recruitment?** (Select one)

☐ Very insignificant

☐ Insignificant

☐ Neutral

☐ Significant

☐ Very significant

34. **What is the biggest challenge in integrating AI into your current clinical trial processes?** (Select one)

☐ Cost

☐ Complexity of AI tools

☐ Lack of skilled personnel

☐ Resistance to change

35. **Is data privacy a major concern when using AI for recruitment?** (Select one)

☐ Yes

☐ No

36. **How challenging do you find it to train staff to use new AI tools effectively?** (Select one)

☐ Very easy

☐ Somewhat easy

☐ Neutral

☐ Somewhat challenging

☐ Very challenging

37. **Which area requires the most improvement for AI tools to be more widely adopted in clinical trials?** (Check all that apply)

☐ User-friendliness

☐ Cost-effectiveness

☐ Training programs

☐ All of the above

38. **To what extent has AI improved patient monitoring and follow-up in clinical trials?** (Select one)

☐ Not at all

☐ Slightly

☐ Moderately

☐ Very much

☐ Completely

39. **How has AI impacted the overall management of clinical trials?** (Select one)

☐ Improved efficiency

☐ Increased complexity

☐ No significant impact

☐ Reduced costs

40. **Has the use of AI led to better compliance with regulatory standards in your trials?** (Select one)

☐ Yes

☐ No

41. **Rate the impact of AI on improving the accuracy of patient screening.** (Select one)

☐ Very poor

☐ Poor

☐ Neutral

☐ Good

☐ Very good

42. **What do you identify as the primary benefit of AI in clinical trial operations?** (Select one)

☐ Reduced operational errors

☐ Enhanced data analysis capabilities

☐ Faster decision-making

☐ All of the above

Participant Information Letter

"APPLICATION OF ARTIFICIAL INTELLIGENCE (AI) IN OPTIMISING PATIENT RECRUITMENT IN CLINICAL TRIAL ENROLMENT PROCESSES"

My name is Rajitha Kandimalla, and I am a researcher at Griffith College, Ireland, currently studying the application of AI in optimising patient recruitment in clinical trial processes. I am conducting a research project to evaluate the effectiveness and implications of using AI technologies in clinical trial recruitment.

If you agree to participate, you will be invited to complete a survey which will be send to you as a Google Form. Completing the survey will take approximately 15-20 minutes of your time.

I am inviting you to participate in this research because of your expertise and experience in the field of clinical trials and patient recruitment, particularly your involvement with AI techniques. Your insights will be valuable in achieving the project's objectives and understanding the current state and future potential of these technologies.

Participation is entirely voluntary. You have the right to refuse participation in this study altogether, or to decline to answer any specific questions in the survey. You can also withdraw from the study at any point without any consequences.

If you need to withdraw please contact:

- Rajitha Kandimalla
- Phone: +353 89 966 8465
- Email: rajitha.kandimalla@student.griffith.ie

There are minimal risks associated with participating in this study. You are free to withdraw from the study till 7 days after completion of research after which the response will be used for the research.

Confidentiality and Data Protection:

All your information will be kept confidential. Your name and any other identifying information will be removed from the final responses and any reports generated from this research. The recordings will be stored securely on a password-protected computer and deleted after completion of the research.

Results outcome

The primary outcome of this research will be my Master's thesis at Griffith College. The thesis will be accessible through the college library and may potentially be made available electronically through online repositories. All dissertation research projects and their content will be made accessible in the college library and could potentially be made available in online e-journals

For additional details regarding the study's objectives, methodology, ethical considerations, participation requirements, potential risks and benefits, data handling, or results dissemination, please contact:

Dr. Rosemary O'Hara

Mail: Rosemary.OHara@setu.ie

[THANK YOU]