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Exploring the Application of AI/ML Systems in Fostering Regulatory Compliance and Audit in Oncology Trials

GRIFFITH COLLEGE DUBLIN

A THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF

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CANDIDATE DECLARATION

I hereby declare that the dissertation entitled: **"Exploring the Application of AI/ML Systems in Fostering Regulatory Compliance and Audit in Oncology Trials"**

submitted in partial fulfilment of MSc in Pharmaceutical Business and Technology is the result of my own work and due acknowledgment is given. I also assure you that I have not plagiarized anyone else's work.

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GAYATHRI VUYYURU

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LIST OF ABBREVIATIONS

Abbreviation	Full Term
AI	Artificial Intelligence
ANOVA	Analysis of Variance
CDSCO	Central Drugs Standard Control Organization
CRA	Clinical Research Associate
CRO	Contract Research Organization
CTMS	Clinical Trial Management Systems
EDC	Electronic Data Capture
EMA	European Medicines Agency
FDA	Food and Drug Administration (U.S.)
GCEC	Griffith College Ethics Committee
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GMLP	Good Machine Learning Practice
GMP	Good Manufacturing Practice
GU	Genitourinary
GxP	Good Practice (collective term)
HPRA	Health Products Regulatory Authority
ICH	International Council for Harmonisation
IT	Information Technology
KRI	Key Risk Indicators
MIPM	Model-Informed Precision Medicine
ML	Machine Learning
NGS	Next-Generation Sequencing
NLP	Natural Language Processing
PIL	Participant Information Letter
QA	Quality Assurance
RA	Regulatory Affairs
RBM	Risk-Based Monitoring
RWD	Real-World Data

Abstract

This study investigates the integration of artificial intelligence (AI) and machine learning (ML) systems in regulatory compliance and audit processes within oncology clinical trials. Through a quantitative survey of 102 clinical research professionals, the research evaluates current adoption patterns, effectiveness, and challenges of AI/ML implementation in compliance monitoring.

The findings reveal that while 47.1% of organizations currently use AI/ML tools for compliance, adoption remains fragmented and transitional. Natural Language Processing (19.6%) emerged as the most commonly used technology, primarily for documentation management. AI/ML systems demonstrated moderate effectiveness in detecting protocol deviations (28.4% rating them moderately effective) and reducing data discrepancies (46.1% reporting improvements). Risk assessment (28.4%) and compliance monitoring (28.4%) were identified as the most improved aspects following AI/ML adoption.

However, significant barriers persist. Key challenges include data privacy concerns (23.5%), lack of regulatory clarity (21.6%), and technical complexity (20.6%). Only 41.2% of respondents believed their AI/ML tools were adequately validated for regulatory compliance, while 25.5% perceived these systems as lacking transparency. The study revealed role-based differences in perceptions, with technical professionals expressing greater confidence in AI/ML systems compared to regulatory and quality assurance staff.

Despite demonstrable benefits in error reduction (63.7% reported decreased human error) and audit efficiency, only 32.4% of respondents recommended wider adoption. This cautious stance reflects ongoing concerns about validation standards, explainability, and regulatory acceptance. The research concludes that while AI/ML offers significant potential for enhancing oncology trial compliance, successful integration requires clearer regulatory frameworks, improved system transparency, and cross-functional alignment between technical and compliance teams. These findings provide crucial insights for organizations navigating the complex landscape of AI/ML adoption in regulated clinical research environments.

1. Introduction

1.1 Purpose of the Study

The primary aim of this study is to investigate how artificial intelligence (AI) and machine learning (ML) systems are being utilised to enhance regulatory compliance and audit processes in oncology clinical trials. The field of oncology trials is one of the most complicated and strictly controlled spheres within the pharmaceutical studies, as the safety of patients, the quality of information and their compliance with the strictest standards are considered of high priority (Spreafico *et al.*, 2021). With the changing environment of clinical research, the combination of high-tech digital technologies has already received its central focus in terms of increasing the system operation with efficiency and preventing the risks of the possibilities of human error and manual controls (Rosa *et al.*, 2021).

This research seeks to accomplish three core objectives. First, it aims to identify the specific AI/ML tools and technologies currently employed for compliance and auditing purposes within oncology trials. Second, the study evaluates the effectiveness of these systems in detecting protocol deviations, data discrepancies, and non-compliance events compared to traditional approaches. Third, it explores how AI/ML enables risk-based monitoring and predictive audit readiness, while also investigating the challenges associated with regulatory acceptance, ethical considerations, and implementation barriers.

This study is justified by the fact that there is an increasing awareness that the conventional compliance and auditing exercises are falling further short of handling the trial complexity and data volumes in contemporary oncology trials. The systematic investigation of the possible and the limitations of AI/ML in the discussed scenario aims to offer meaningful knowledge to researchers and professionals in the academic and industry sector.

1.2 Context of the Study

Clinical trials in the field of oncology are at the centre of medical innovation and hold a crucial position when it comes to novel oncotherapeutics. Such trials involve a very dynamic and regulated paradigm that has to be put under intense supervision to not only safeguard the patients but also to maintain the quality of clinical data. Ethical conduct, effective protocol adherence, and reliable reporting can be done on the basis of regulatory compliance and the audit mechanism that ensures high standards of operations (Kurzrock *et al.*, 2020).

The regulatory environment of oncology trials is determined by government agencies, which include the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA),

and national agencies that provide strict guidance on how the trial is conducted, data gathering strategies, and their post-marketing investigation. It must follow Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP), and agencies often review the processes of the trial in order to protect participants and the accuracy of the data. Although the levels of compliance are normally high, auditing is still an essential component in identifying gaps, ongoing enhancement, and accountability across the research operations (Gadhe *et al.*, 2024).

Nonetheless, conventional methods hold limitations. Administrative burden, overloading information, and regional differences in the degree of regulatory maturity can impede the trial process, increase their costs and redirect focus away from patient-centred priorities. It is established that regulatory processes, audit, or international harmonisation of standards should be simplified, as well as a new concept of conducting trials in such a way that it should be patient-centred and decentralised (Thota *et al.*, 2024).

Against this background of changing demands, digital transformation is fast becoming a game-changer in the field of oncology research. The techniques of artificial intelligence (AI) and machine learning (ML) have become the focus of technological progress in cancer diagnosis, individual choice of treatment, and creation of clinical trials. Within the setting of trials, AI/ML systems provide the opportunity to automate the real-time data validation and promote the risk-based audit preparedness and the monitoring of protocol adherence. Such systems can be used to analyse large, multi-modal datasets such as genomics, imaging, and clinical records to provide precision oncology and streamline trial processes (Iqbal *et al.*, 2021).

However, using AI/ML in oncology trials has some distinctive problems. All of the above present challenges to the successful use of these technologies, coming in the form of data quality and heterogeneity, algorithmic bias, integration within the workflow, and changing expectations regarding the use of these technologies in the regulatory environment (Fountzilas *et al.*, 2025). However, not many of the AI/ML systems exist on which a solid clinical validation exists or that have received regulatory permission to be routinely applied to compliance or audit processes. As oncology research incorporates digital transformation, overcoming these challenges will be essential to ensure that AI/ML delivers on its promise of safer, more effective, and more efficient cancer clinical trials (Geaney *et al.*, 2023).

1.3 Significance of the Study

Though there have been impressive breakthroughs in AI/ML technology in healthcare, these processes are still being integrated into oncology clinical trials with sheer disparities in

knowledge, standards and reality. Among the most prominent gaps is the absence of the large-scale, prospective clinical validation of AI/ML models (El Naqa *et al.*, 2023). Most AI/ML solutions are useful at doing analysis on past data or at pilot stages, as most lack regulatory-grade evidence, limiting their use in everyday trial work. This worsens the lack of uniform rules in gathering data, creating a model, validating and open reporting of performance (Geaney *et al.*, 2023). Consequently, the comparisons between studies are low, and sponsors are uncertain as to how likely they are to employ these technologies in compliance with Good Clinical Practice (GCP) and good regulatory requirements (Mäkitie *et al.*, 2023).

Meanwhile, the regulatory environment around AI/ML in clinical research remains immature, and the corresponding guidance is being developed by centres like the FDA and EMA with just a few recent precedents. Developers and sponsors are therefore at a crossroads on which type of validation is acceptable, evidence and documentation (Niazi, 2025). Moreover, the concerns related to the quality of the data, the inability of the datasets to be diverse, and the possibility of algorithmic bias pertain to the question of whether the solutions implemented by AI are generalizable and equal across the data. It can also be noted that ethical issues and equity of are somehow missing, especially when it comes to transparency and the legitimacy of applying AI/ML instead of conventional practices (Nazer *et al.*, 2023).

The proposed line of research is significant today as it is related to urgent technological, regulatory, and clinical issues. It will help many different stakeholders, such as researchers who want to conduct more effective studies, sponsors in the industry who wish to be informed about regulations, and the regulatory authorities that must assess the emerging technologies. Finally, the patients also benefit by having more effective, efficient, and safer clinical trials. This novel research can be used to elucidate best practices and recommendations to the industry, ultimately contributing to the optimisation of the current scenario.

1.4 Aim and Objectives

The purpose of this research is to critically evaluate how AI and ML systems are improving regulatory compliance and audit practices in oncology clinical trials. By systematically evaluating both the benefits and barriers of AI/ML integration, the research intends uphold the highest standards of data integrity and patient safety in oncology trials.

The research question is: How do AI and machine learning systems impact regulatory compliance and audit effectiveness in oncology clinical trials?

The research hypothesis is: The integration of AI/ML systems in oncology clinical trials significantly improves regulatory compliance and audit effectiveness by enhancing the detection of protocol deviations, data discrepancies, and non-compliance events compared to traditional manual approaches.

The objectives of the research are as follows:

- To identify AI/ML tools currently used for compliance and auditing in oncology trials.
- To evaluate the effectiveness of AI/ML systems in detecting protocol deviations, data discrepancies, and non-compliance events.
- To examine how AI/ML facilitates risk-based monitoring and predictive audit readiness.
- To investigate challenges in AI/ML adoption from a regulatory and ethical perspective.

1.5 Structure of the Study

This dissertation is organized into five key chapters.
The Introduction chapter sets the context by outlining the rationale, significance, and objectives of the research. It presents the research questions, highlights the existing gap in knowledge, and provides a roadmap for the dissertation.
The Literature Review offers a comprehensive synthesis and critical analysis of current secondary research. Drawing on academic publications and industry sources, it reviews the state of AI/ML integration in oncology trials, regulatory challenges, and existing solutions, establishing the foundation for the primary research.
The Research Methodology chapter details the approach taken to collect and analyse primary data, including justification for the chosen design, participant selection, data collection tools, and ethical considerations. The conceptual framework guiding the research is also introduced.
The Findings and Analysis chapter presents the results of the primary research, using statistical and thematic analysis to interpret data. Findings are compared with insights from the literature review, highlighting key themes and discrepancies.
Finally, the Conclusions and Recommendations chapter summarizes the main findings, discusses their practical and academic implications, acknowledges study limitations, and offers recommendations for future research and practice. This structured approach ensures clarity and coherence, guiding the reader through each stage of the research process.

2. Literature Review

2.1 Introduction

The use of Artificial Intelligence (AI) and Machine Learning (ML) in the field of oncology has topped their clinical trials to the extent that both means of data collection, analysis, and audit have changed. Such technologies have been proven to have a significant potential to enhance the efficiency of trials, increase data integrity and allow the earlier detection of abnormalities like protocol non-compliances or safety concerns. The recent trend in oncology trials shows that with the multifactorial endpoints being the norm, AI/ML tools are being used to aid every aspect of the trial, including site selection and patient recruitment, as well as automated data validation and real-time monitoring (Antti Mäkitie *et al*., 2023). This trend has only been boosted by the increase in the need for more nimble and dynamic trial techniques, especially in fields such as precision oncology.

Nevertheless, the implementation of AI/ML in regulated clinical settings requires a comprehensive connection to the compliance system, including GCP (Good Clinical Practice), GxP, and global auditing regulations. Regulatory entities will now be confronted by the twofold challenge of promoting innovation but controlling the quality and privacy of data and the safety of patients (Askin *et al*., 2023). In the absence of strong governance, systems operated by AI/ML are likely to yield biased or opaque results that do not conform to ethical or scientific rules (Aakanksha *et al*., 2024). Thus, regulatory compliance and audit Fitness play a pivotal role in the credibility of trials besides protecting the welfare of participants.

This literature review aims to critically evaluate the role of AI/ML in improving regulatory compliance and auditing practices in oncology clinical trials. It explores current tools and applications (Theme 1), their effectiveness in protocol deviation detection and data discrepancy management (Theme 2), and their integration with risk-based monitoring approaches (Theme 3). It further examines regulatory challenges (Theme 4), ethical and operational barriers (Theme 5), and forward-looking strategies and case studies (Theme 6). Through this structured analysis, the review seeks to provide practical and scholarly insights into balancing innovation with regulatory accountability in AI-enhanced oncology trials.

2.2 AI/ML Tools in Oncology Trial Compliance and Auditing

2.2.1 Overview of Adoption Trends and Drivers in Oncology

Use of AI and ML technology in clinical trials of oncology is increasing in pace due to higher complexities of protocols used, quantity of data that is of multiple sources and speedier trial

processes are needed. As a fast-paced field with large volumes of data, oncology is one of the areas where AI/ML can be practically accommodated. Askin *et al*. (2023) state that the sponsors and contract research organisations (CROs) use AI to facilitate compliance management and auditing in clinical trials that would be costly and time-consuming without AI.

One of the key drivers is the trend of precision medicine in oncology that demands access to real-time processing of heterogeneous data (imaging, genomics and clinical records) (Bang *et al*., 2025). The use of AI/ML enables dynamic risk modelling and functions as an early warning of signals to better patient care and regulatory assurance. To provide an example, in genitourinary (GU) and immuno-oncology trials, AI can help speed up the detection of eligible patients and adverse events and also make sure that protocols are tracked at both site and sponsor levels (Bottomly and McWeeney, 2024).

Wearing style and sensor-embedded technologies also enhance this environment by delivering the uninterrupted data flow, which can be utilised in ML models to monitor compliance. According to Birla *et al*. (2024), wearable tech not only improves decision making but also aids the real-time audit trail, and hence, human error is minimised. This intersect of AI-generated insight and digital health utilities has added a lot of value, especially in the decentralised and hybrid oncology clinical trials.

Although there is an increasing wave of positive trends, the consistent integration into everyday processes that concern audit and compliance is spotty. As Brouwer *et al*. (2020) noted, machine learning has already shown its benefits in such domains as radiation oncology planning and pre-checks in treatments. Still, the lack of standardisation and regulatory insight hinders the overall application. Harmonised AI protocols are urgently required to ensure their alignment with Good Clinical Practice (GCP) and GxP to prevent pushback blocking and data reproducibility concerns.

2.2.2 Classification and Description of AI/ML Tools Used

Oncology trial compliance applications of AI/ML may operate functionally in general under four broad categories: natural language processing (NLP) systems, predictive analytics models, automated monitoring systems, and audit trail generators. These tools are usually embedded with clinical trial management systems (CTMS) and their electronic data capture (EDAC), as well as with pharmacovigilance systems.

NLP technologies are becoming more applied to unstructured information such as clinical notes, patient-reported outcomes, and investigator queries. Askin *et al*. (2023) note that NLP

models provide an opportunity to review protocol deviations, adverse event reports, and inclusion/exclusion violations in real time, making the process more accurate and audit-ready since the inconsistencies will be detected and warned automatically.

Instead, predictive analytics are used to model site performance, dropout risks, and data quality metrics. Tools such as decision-tree algorithms or neural networks may be used to compare non-compliant and compliant sites or patients at risk of treatment plan deviation. Bang *et al*. (2025) emphasise that the tools help in real-time interventions that significantly lower non-conformance within regulatory parameters.

Monitoring and audit automation tools also facilitate data traceability and the creation of audit trails. These consist of AI-enhanced dashboards that monitor non-conformance and initiate warnings, in addition to creating recovery reports. Birla *et al*. (2024) outline the concept of AI dashboards, which combine wearable data, EDC entries, and lab records to provide the sponsor and auditors with end-to-end visibility.

Although this represents some important progress, Bottomly and McWeeney (2024) warn against over-reliance on opaque AI systems, particularly in immuno-oncology trials during which interpretation of the data involves contextual awareness. Therefore, inasmuch as automation promotes efficiency, human control is vital in ensuring audit defensibility and ethical compliance.

2.3 Effectiveness of AI/ML in Protocol Deviation and Data Discrepancy Detection

2.3.1 Evidence on Protocol Deviation Detection

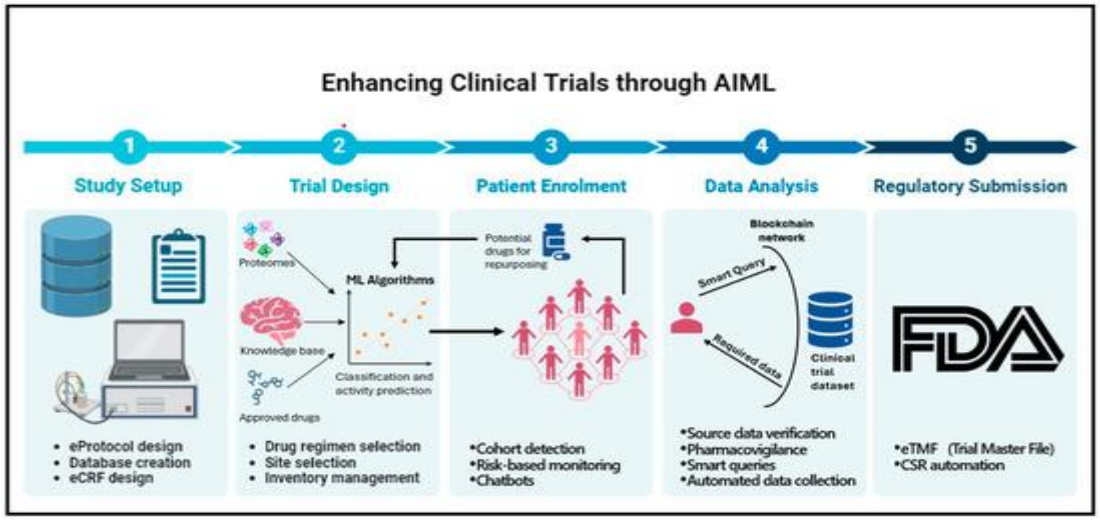


Figure: Clinical trial process AI tools (Kandhare *et al.*, 2025)

Deviations in protocol still pose a serious problem in oncology clinical trials, which usually result in inconsistency in the data, regulatory actions, and even possible patient safety risks. AI/ML is also being used to track adherence to the protocol parameters in real-time, such as compliance with visit schedules, drug dosages, and eligibility thresholds. Kang *et al*. (2023) focus on the fact that AI-powered systems, a part of the background of trial monitoring systems, can follow and mark the non-observance of protocols at several trial sites and even in the case of decentralised trial models.

The historical trial data is fed to machine learning models, specifically to supervised learning algorithms, which are trained to predict at what rate protocol deviations may happen in the future. As pointed out by Fountzilas *et al*. (2025), within the context of precision oncology, predictive ML models are capable of measuring the patient-specific factors that may include biomarker fluctuations or comorbidity profiles to predict and even prevent deviation-prone events. With these systems, proactive mitigation is possible, and the investigators could take corrective measures without having to wait until the end of the cycle monitoring reports.

The use of AI in pathology-led cancer trials has even seen anomalies in data patterns identified, which tend to be indicators of a deeper compliance problem. Hanna *et al*. (2025) state that the use of digital pathology platforms that AI has supplemented can monitor the labelling of specimens, the schedule of taking samples, and the quality of data marking, which are the key parameters that are directly related to protocol compliance. The tools are of special value in mass studies in oncology with tissue-based diagnostics and biomarker stratification.

Several strengths are associated with this despite the fact that Kandhare *et al*. (2025) warn that algorithmic models should be regularly updated and compared to new trial protocols. Otherwise, false positives or missed deviations will be possible, and they might compromise the ethical nature of the trials and the confidence in the regulations.

2.3.2 Studies on Data Quality, Discrepancy Reduction, and Real-Time Validation

Other than protocol adherence, AI/ML also maximises data accuracy by determining inconsistencies with clinical, imaging, and lab data. In their article, Iqbal *et al*. (2021) highlight that AI models are able to identify anomalies in diagnostic codes and report adverse events and lab test documentation, which are frequently overlooked when done manually during an audit. Use in oncology trials is especially beneficial since multidimensional data is constantly being produced by various sources.

In AI-enabled platforms, real-time cross-validation of entries is carried out by comparing patient-level data among the EDC systems, imaging platforms, and biospecimen databases. Fountzilas *et al*. (2025) explain the approach that deep learning models in precision oncology can identify anomalous gene expression data that are inconsistent with reported clinical outcomes, with re-examination prior to data lock. This will minimise after-the-fact requests and data scrubbing, thereby hastening the completion of databases.

Additionally, ML can be used to set up a validation process on data entry, decreasing downstream variance. For example, intelligent algorithms can warn of logical inconsistencies (e.g., a patient flagged as deceased but with follow-up data following death). According to Hanna *et al*. (2025), such real-time validations are also useful in creating a culture of continuous compliance.

In monitoring data quality, Kandhare *et al*. (2025) also capture the scalability of the AI systems and the potential that the tool might have in multicentric trials when the individual sites could have variable performance. By ensuring the same high level of data integrity at each site, AI reduces inter-site disparities and enables consistent regulatory submissions.

To sum up, human control is still necessary, but the use of AI/ML in the detection of protocol deviations and data validation helps to make oncology clinical trials more robust and audit-friendly.

2.4 AI/ML and Risk-Based Monitoring in Oncology Trials

2.4.1 How AI Supports Risk Identification and Monitoring Strategies

Risk-based monitoring (RBM) has been introduced as a favourable plan in oncology clinical trials to maximise the resources used and guarantee appropriate data quality and patient safety. Along with improving RBM, AI/ML tools allow identifying risks more dynamically and selectively. These technologies go through historical and real-time data to determine material adverse variables, protocol deviations, site underperformance, and trends in adverse events. Kourou *et al*. (2021) also stress that the machine learning algorithms trained on cancer trial datasets can reveal subtle patterns by finding outliers in the data related to the presence of risk in terms of the site and patient.

Specifically, AI-assisted centralised monitoring enables the pooling of data among different trial sites, which enhances the definition of high-risk sites that can be immediately intervened in to achieve better results. Mullankandy (2024) emphasises that AI-based dashboards may sort

sites by their risk rating using various indicators, including the time resolution of queries, visit delays, and adverse event frequency. This stratification will enable sponsors and CROs to target their monitoring efforts where they are most appropriate by enhancing efficiency and compliance.

Feng *et al*. (2022) also believe that the monitoring models based on AI are flexible enough to change with new data being added to the model continuously. Such living model designs are able to keep up a constant watch without having a manual arrangement of each time there is a shift of any variable. This is especially applicable in oncology trials because patient responses and safety profiles could change quickly because of the complexities of the treatment regimes.

Nonetheless, to achieve a successful implementation, AI systems must be combined with trial-specific key risk indicators (KRIs). boundary / No contextual calibration is prone to producing irrelevant or misleading alerts. The authors of Massella *et al*. (2022) warn that ML-based tools can be included with clear documentation and validation procedures to make them compatible with audit and regulatory acceptance.

2.4.2 Predictive Analytics and Their Role in Audit Readiness

Predictive analytics is a part of machine learning, and it is a significant means of audit preparation for oncology trials. These models can predict regulatory risk in that they can track emerging non-compliance trends so that the sponsor takes the necessary corrective measures to eliminate them before the situation turns ugly. According to Liu *et al*. (2022), regulators are becoming open to similarly interpretable and evidence-informed AI-derived insights, in both pre- and post-market surveillance.

An AI tool can replicate the audits using the prevailing compliance rates, providing a proactive solution to audit readiness. According to Mullankandy (2024), AI systems can create a mock audit scenario whereby the trial teams may determine and fix the documentation gaps, incomplete safety stories, or lack of data connections beforehand. Such designs increase the level of confidence in the formal inspections and mitigate last-minute mitigation activities.

Predictive analytics may also be used in the field of compliance prediction, e.g., predicting the risks of patient dropout or estimating the probability that a set of protocol compliance goals will be achieved. Kourou *et al*. (2021) state that the insights are invaluable in adaptive oncology studies in which changes to the protocol can be made during the study. Data-based prescience means the capacity to update procedures and communicate with rules quickly.

Feng *et al*. (2022) also point out the requirement to regularly monitor and update AI models to maintain their relevance and precision. The scientific and clinical contributions in oncology trials change rapidly, and therefore, stagnant models can be inaccurate in characterising risk or detecting new differences.

In short, the use of AI/ML in RBM and predictive analytics methods in the HLB portfolio significantly reinforces risk mitigation and regulatory audit preparedness. Their sustainable adoption continues to be based on enabling transparency, validation, and regulatory congruence.

2.5 Regulatory Compliance—AI/ML Integration Challenges

2.5.1 Review of Relevant Global Regulatory Frameworks for AI in Trials

AI and ML systems are picking up pace in oncology clinical trials, and this makes regulatory organisations across the world compete to give governance structures that can match innovations in the field. The prevailing frameworks, including the one by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and International Council for Harmonisation (ICH), focus on transparency, explainability and traceability of AI systems in regulated settings. Nevertheless, they are not entirely aligned or adjusted to changing AI uses in contexts of real-life clinical study implementation (Padmanaban, 2024).

Good Machine Learning Practice (GMLP) by the FDA and the Reflection Paper on AI in Medicinal Products by the EMA are only the first steps. However, they are still interpretative and do not provide acknowledged technical guidance on how to use ML in oncology trials. Murris (2025) emphasises that interpretability is the focus of regulatory approval, particularly in such a high-stakes field as cancer care. Regulators require that AI systems should be auditable, deterministic, and allow informed decision-making, and this puts question marks on many of the black-box algorithms in use.

Olawade *et al*. (2025) highlight that AI should become part of the clinical workflow with stable validation and retraining procedures. In the absence of such lifecycle management, there is a danger of regulation risk of non-conformity caused by model drift of algorithms performing unpredictably over time as data changes.

2.5.2 How AI Aligns or Conflicts with GxP/GCP/GMP Standards

Figure: GxP Compliance of regulated industries (Rees, 2025)

The application of AI/ML in controlled clinical trial settings directly imposes repercussions on Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and GxP standards in general. It is true that AI can extend the audit trail, automate compliance activities, and minimise manual error, but AI usually does not conform to the current regulatory expectations of accountability and traceability (Padmanaban, 2024).

One of the most significant areas of conflict is the so-called explainability gap between an AI decision and a human decision. Guo *et al*. (2024) states that this problem can be alleviated by making AI production match real-time feedback control loops, but adaptive learning systems themselves introduce new compliance considerations, notably of version control and validation.

According to Oyinkansola *et al*. (2024), a risk-based validation framework in financial fraud can be transferred to the clinical context and provide hierarchical approaches to assessing AI tools' safety in terms of patient safety or trial integrity. This potentially opens up toward less inflexible compliance systems.

However, in order to fully comply with GxP, it is required to have human supervision and documentation openness and reproducibility of AI tools. Murris (2025) suggests embracing

interpretable tree-based models or systems that can address this regulatory gap by integrating the AI findings with clinician knowledge.

In short, although AI/ML has great potential for efficiency, its usage in oncology trials should be efficiently controlled to adjust to changing compliance requirements, lessen compliance threats, and avoid ethical opaque relationships.

2.6 Ethical and Practical Barriers to AI/ML Adoption

2.6.1 Key Ethical Issues (Privacy, Bias, Explainability, Data Sharing)

The rising potential of AI/ML technologies in oncology trials is met with serious ethical issues related to privacy, algorithmic bias, explainability, and data sharing as the practice of them is integrated. Oncology patient data is very sensitive, consisting of genomic profiles, treatment response, and longitudinal health outcomes. Rasool *et al*. (2025) highlight the necessity to integrate AI on a strong base of patient confidentiality protection, at least during the possible aggregation of datasets across sites or geographical coverage. Potential risks of re-identification exist even in the anonymised databases, once correct data governance frameworks are not implemented.

Another new ethical issue is bias in AI algorithms. The AI tools that are trained using non-diverse data run the risk of giving biased outputs that are not likely to add any value but instead can be used to perpetuate the current health disparities. Ross *et al*. (2024) point out that radiology AI systems have had mixed results when rendered across diverse demographics and harbour the potential to be even more concerning in the context of oncology when treatment decisions can be time-sensitive and extremely high-stakes. This is even worsened in international trials, which are conducted in heterogeneous groups in which the failure to represent some populations will result in inappropriate models.

The concept of explainability in AI ethics is applicable and repeated. In a bid to support the argument of bidirectional human-AI alignment, Shen *et al*. (2024) claim that AI systems must be understandable and consistent with human values and clinical objectives. Most models of deep learning applied to clinical trials, however, are black-box systems, where it is hard to investigate how particular choices known only to a deep neural network were made (e.g., entering a patient into a trial or predicting an adverse event). This obstructs transparency, which is a threat to auditability and ethical responsibility.

Lastly, cross-border data sharing, although useful in training models, poses ethical and legal issues concerning data sovereignty. According to Ravish Tillu *et al*. (2023a), inconsistencies in regulations in different countries make it difficult to develop centralised AI models to apply in global oncology trials, which in many cases reduce collaborative innovations.

2.6.2 Organisational and User-Related Challenges to Implementation

Besides ethical concerns, there also exist a series of practical and organisational obstacles to using AI/ML oncology trials. A significant difficulty is that there is no standardised infrastructure used to enable AI workflows. Rehman *et al*. (2024) note that the majority of clinical trial contexts do not offer the computing resources, standards of interoperability and skilled staff that would facilitate the implementation and supporting of AI tools. Such technological discrepancy results in uneven adoption in different locations, including in multi-centre oncology clinical trials.

It is also influenced by organisational resistance to change. Clinical trial professionals' reluctance to trust AI-generated insights can be related either to a lack of confidence, unfamiliarity, or the need to maintain professional autonomy. Ravish Tillu *et al*. (2023b) emphasise that the introduction of AI should be supported with special training courses and the active involvement of users combined with the clarity of their roles so that the integration process can become comfortable and allow for reducing mistakes during interpretation or implementation.

Besides, the regulatory reporting process remains largely manual, which complicates the introduction of AI without the redrawing of the workflow. Ross *et al*. (2024) also pinpoint that, whatever the successful performance of the AI system, it will not make a difference unless it is incorporated into the current systems, whether it is site monitoring, data reviewing, or reporting to an ethics committee.

To conclude, to ensure the socially responsible and sustainable adequacy of AI/ML in oncology clinical trials, it is important to consider not only ethical but also practical barriers. The strategies should ensure a balance of innovation and transparency, data responsibility and organisational preparedness.

2.7 Opportunities, Best Practices, and Future Directions

2.7.1 Successful Case Studies, Innovations, and Lessons Learned

The combination of Artificial Intelligence (AI) and Machine Learning (ML) in oncology clinical trials has already demonstrated a few success stories that illustrate their potential to

improve clinical trial processes, enhance diagnostic efficiency, and patient selection. As an example, Vobugari *et al*. (2022) encourage the use of AI-based platforms to strengthen the identification of biomarkers and disease classification in cancers, including breast and lung, which helped to speed up recruitment in precision trials by a factor of. Viduedo *et al*. (2024) note that the integration of AI algorithms into the next-generation sequencing (NGS) tools has become a breakthrough in genomic data analysis, enabling researchers to identify genetic differences associated with resistance and develop interventions to target genetic differences.

One more interesting case is the utilisation of the ML models to forecast the effects of the treatment and the development of the diseases in oncology patients. Terranova and Venkatakrishnan (2024) discuss applying ML to model-informed precision medicine (MIPM) in which a clinician can make real-time corrections to the ML model based on individual pharmacokinetic and pharmacodynamic data. Such innovations depict the role of AI/ML in limiting the rate of attrition and managing adaptive lessons.

In addition, Wei *et al*. (2023) highlight the strength of multi-omics integration offered by AI/ML, in which researchers can integrate genomic, transcriptomic, and proteomic data to generate more accurate predictive models. This has demonstrated the potential to stratify patients according to a targeted molecular profile, which results in more specific therapeutic interventions and improved clinical trials.

Some important lessons are still emerging from these implementations against the background of these successes. To begin, it is necessary to work interdisciplinarily. The success cases involve a combination of data scientists, oncologists, and regulatory professionals. Second, transparency and validation: A number of the case studies cite failure to interpret or recreate results on a different dataset as an issue (Sun *et al*., 2025).

2.7.2 Strategic Recommendations, Frameworks for Adoption, and Future Trends

A number of strategic best practices have been identified to advance these innovations. Among the urgent pieces of advice that could be followed is moving to principle-based approaches to the deployment of AI/ML. Supplemented with minimal supervision and ethical limitations, matching language and clinical models can create compliant and context-sensitive systems, similarly to the recommendations by Sun *et al*. (2023). Regulatory reporting in oncology is especially sensitive, and in such a case, the risks of misclassification may create real problems.

Concerning the best practices in operations, Viduedo *et al*. (2024) encourage using modular and scalable AI infrastructures that can enable the iterative learning and validation of various

stages of a trial. This enables responsive actions to new data and possibilities of safety signals. External validity can also be improved using the fact that real-world data (RWD) can be transported into trial protocols through the use of AI pipelines, which can aid regulatory submission, and a wide variety of cancers.

The upcoming trends revolve around using federated learning to ensure data privacy, improve inter-institutional cooperation, and self-aligning models, which will reduce bias and be more explicable (Sun *et al*., 2023). Another area that shows interest relates to human-AI collaborative tools, which do not verify clinical decision-making but only assist it, a notion that builds trust and user adoption.

Such changes conform to the study's overall goal of discovering plausible ways of incorporating ethical, efficient, and compliant AI /ML integrations in oncology trials. Considering all that has been considered and what has not been successful, stakeholders can establish regulatory frameworks and operation models that promote innovation without putting patients at risk or jeopardising data integrity.

2.8 Gap Analysis

Although existing sources show some promising prospects of AI/ML implementation in the field of clinical trials in oncology, there is still a set of gaps, some of which are deadly serious. Remarkably, no longitudinal research is available that considers the long-term reliability and the effectiveness of AI tools in regulatory audit in practice. A lot of the available evidence relates to pilot projects or single-centre studies and thus cannot be generalised. Moreover, not much empirical evidence is available regarding the manner in which AI systems interact with the changing global regulatory systems, especially in lower- and middle-income countries. Some ethical issues, like data privacy, explainability of the model, and accountability of the AI, need to be settled in large-scale implementation studies. There is also a lack of study of legacy system integration approaches, user training methods and cost-benefit analysis across various healthcare facilities. And, finally, the overlapping of the AI with human control in risk-based monitoring is still conceptually tomorrow, but practically something elusive. Closure of such research and implementation gaps is essential in maximising the safe, fair and efficient adoption of AI/ML in the oncology trial regulation and audit.

2.9 Conclusion

This literature review indicates that the fields of regulatory compliance and auditing within oncology clinical trials are undergoing a radical change owing to AI/ML technologies.

Throughout the themes, these tools can improve the quality of data, simplify reporting, and assist in identifying compliance with protocol due to automation and predictive analytics early in the process. The case studies provide evidence of enhanced trial efficiency and adaptive monitoring frameworks using AI, and current advancements suggest that real-time integration of multiomics, as well as precision decision-making, may even be possible in the future.

Nevertheless, there are issues of ethics, stakeholder resistance, and compliance with regulatory expectations. The lack of a strong implementation framework and minimal cross-jurisdictional compliance advice indicate the necessity of additional empirical research. Pragmatic options like AI-human hybrid oversight regimes, principle-based self-alignment, and repository among best practices are becoming possible.

To researchers and regulatory bodies, future work should emphasise interdisciplinary alliances, data standardisation, and the development of more inclusive policies. With oncology trials growing in complexity, AI/ML may become the key enabler of transparent, adaptive, and patient-centric compliance, as long as ethical and infrastructural challenges are mitigated with the same sense of urgency.

3. Methodology

3.1 Overview

This chapter describes the research methodology used for the research. Adopting a positivist philosophy and a deductive approach, the study uses a quantitative strategy with structured surveys distributed to experienced clinical research professionals. Purposive and snowball sampling ensure relevant participant selection. This methodology helps elucidate strong objective evidence that directly addresses the study's aims and informs practical improvements in oncology trial compliance practices.

3.2 Research Philosophy and Approach

This study is a positivist research study, which declares that knowledge must be obtained only through observable and measurable events and results must be objective, replicable and empirical. It is particularly when a piece of study focuses on quantifiable results and factual nature that the positivist outlook is suitable (Junjie and Yingxin, 2022). Through the adoption of positivism, the research would attempt to exclude the subjective bias and personal interpretation and concentrate on the relatively measurable and collectable data that can be analysed.

The main aim of such a study is to assess the use and efficacy of AI/ML systems to facilitate regulatory compliance and audit of oncology clinical trials. In order to do this the study is based on quantifiable survey data of practitioners who actively participated in the field of clinical research, regulatory affairs, and technology application. Prioritizing objective, numerical data guarantees the independence of the research and increases the chances of a study report being reliable (Junjie and Yingxin, 2022). This philosophical base has been selected because of the need to generate strong and generalizable knowledge that will be used to propose best practices and policy choices in the area.

In line with this philosophy, the study utilises deductive research approach. Through this, the research will use already existing theories and previous studies that were discovered after conducting a comprehensive literature review on the topic of AI/ML integration and regulatory approaches in clinical trials (Fife and Gossner, 2024). It is on this theoretical foundation that the researcher develops certain hypotheses and research questions, which are empirically evidenced through use of the primary data. These premises can be either proved or disproved in the deductive process, which is in direct correlation with the aims of the research and offers a solid system of the investigation.

Such a combination between positivism and deductive reasoning is important in the sense that it impacts greatly on the collection and analysis of their data. The process of data collection will be based on standardized and closed-ended survey questions that will help to measure the variables associated with the use of AI/ML systems, their effectiveness, and their challenges. The fact that it is a quantitative survey method directly compliments the positivism philosophy in the sense that the data gathered can be statistical and be objectively interpreted. Statistical methods during the analysis help to define the hypothesis and statistical pattern related to the data, which can be then used to suggest evidence-based conclusions related to the influence of AI/ML in oncology trial compliance and audit. This will ensure that the research is kept anchored towards practical verification and lets it bring good and usable contributions to the field.

3.3 Research Strategy

The study employs a quantitative research design, utilising structured surveys as the primary data collection tool. This decision is based on the nature of the research objectives that are aimed at determining the AI/ML tools already used in regulatory compliance and audit in oncology trials, assessing the effectiveness of these tools and discussing the perceived difficulties in their implementation, where the use of specific metrics and measuring them through quantitative analysis can help elucidate best outcomes. The aim is to obtain findings that are objective, generalisable, and statistically sound, with a relatively efficient correlation with the features of quantitative studies (Kennedy et al., 2022).

The set of primary research questions is directly related to the research objectives, such as identifying the existing AI/ML tools in practice, their measurable contribution to protocol deviation and audit procedures, how these tools aid in risk-based monitoring, and regulatory or ethical impediments to adoption. Such questions are most applicable in a quantitative approach because they entail systematic measurements of opinions, practices, and experiences of a diversified pool of professionals involved in an oncology clinical trial. Through a well-structured survey, the study will be able to obtain standardised data, reducing bias and allowing the researcher to perform statistical analysis to identify patterns, correlations, and significant differences in the information.

The preference for a quantitative strategy can also be rationally explained by the tendencies identified in the existing literature, which reports an increased interest in survey-based approaches to health technology adoption research. Even past investigations of digital

transformation, compliance regulations, and technology implementation in clinical research have managed to effectively utilise quantitative surveys to cover a wide range of sector-wide knowledge (Kennedy et al., 2022). It is particularly appropriate to research topics that are dynamically developing, such as AI/ML, practice, and perception, which may vary significantly in each role and institution.

In addition, the quantitative approach ensures that the study's results will not only be descriptive but also analytically sound, with the ability to test hypotheses and draw evidence-based recommendations. This is especially pertinent because the intended use of this study is to inform practice and provide evidence-based recommendations.

3.4 Primary Data Collection

This study employs a structured survey as the primary data collection instrument, designed to gather empirical data from professionals involved in oncology clinical trials. The survey will be designed based on the research objectives, which include identifying and evaluating the success of AI/ML tools in regulatory compliance and auditing, as well as addressing concerns perceived by industry stakeholders. The questionnaire will include 24 closed-ended questions, allowing for its standardisation and providing the researcher with the opportunity to conduct quantitative analysis, covering all the research objectives (Kennedy et al., 2022). The types of questions incorporated include multiple-choice items, dichotomous (yes/no) questions, statements on the Likert scale, and options to select all that may be applicable. The variety of question types allows for overcoming the limitations posed by surveys, as they tend to restrict answers to 4-5 choices. The application of different kinds of questions helps face the objective from various perspectives, as design questions are posed with the required suitability.

Google Forms is used to administer surveys in an electronic format. It is a common platform where surveys can be disseminated easily and in real-time, and the data can also be managed. An online format was selected, which would supplement the convenience of participants, boost the response rate to surveys, and minimise errors during data entry.

To ensure the relevance and quality of the data, strict inclusion and exclusion criteria have been established. Eligible participants must be professionals who are currently or have recently been involved in oncology clinical trials, with direct experience in regulatory compliance, clinical auditing, or the implementation of AI/ML technologies. Appropriate roles include clinical trial coordinators, clinical research associates, regulatory affairs personnel, quality assurance

specialists, and AI technology experts. Participants must be at least 18 years old and able to provide informed consent. Both industry and academic professionals are eligible for inclusion.

Individuals will be excluded if they have not worked in oncology clinical trials within the past two years, lack direct experience in compliance, auditing, or AI/ML applications in clinical research, or are students/trainees without full professional responsibility. Vendors or sales representatives not engaged in oversight or compliance are also excluded. These criteria help ensure that responses are grounded in practical, relevant experience.

Purposive sampling is used to select participants with the specific expertise necessary for the study, as it ensures that the data obtained will be context-specific and refined with significant knowledge and experience. (Campbell et al., 2020). This method will help to recruit informative respondents whose responses will be able to directly address the research objectives The recruitment will be carried out at a local level through an intentional outreach at professional networking platforms like LinkedIn and ResearchGate, and also at online forums dedicated to clinical research, regulatory affairs, as well as innovation in the field of oncology. Initial outreach will be made through these platforms, after which professional mailings will be sent to participants requesting their contribution, with the participant information letter attached.

Additionally, a snowball sampling method will be employed: the first respondents will be encouraged to suggest their colleagues who are eligible to participate in the survey, thereby broadening the research scope and diversifying the participant list (Ting et al., 2025).

To ensure the validity of the survey instrument, questions are formulated by reviewing the literature and consulting with the supervisor regularly. The reliability is facilitated by following a standard format for the questionnaire and uniform implementation via an online platform, which lowers the possibility of interviewer bias and error in data handling.

3.5 Ethical Considerations

The study demonstrates compliance with stringent ethical considerations as outlined by the Griffith College Ethics Committee (GCEC) guidelines and GDPR. The research will undergo an official ethical clearance procedure through the GCEC, which will involve submitting a detailed application outlining the study's purpose, procedures of participant recruitment and related methodology, data storage and retention, data collection tool, along with a Participant Information Letter (PIL) and informed consent, thereby demonstrating complete institutional compliance.

Since it is a survey, PIL will be distributed to all the participants. It will provide a clear explanation of the study's purpose, participation requirements, the voluntary nature of participation, risks associated with the study, and measures in place to ensure privacy and confidentiality. The participants will be informed about their freedom to decline participation in the survey, skip a question, or drop out at any point, without any adverse consequences. T

The personal information of the participants will not be disclosed at any point in the research. Any type of identifier will be removed from the data or masked using codes. The survey will be structured to avoid collecting any personally identifiable information and will not include questions that ask for personal or sensitive information. All personal data will be securely stored in OneDrive folders, accessible only to the researcher and academic supervisor, with password protection in place. The data will be stored for two years after the research is completed, after which it will be destroyed.

The security of data is ensured by encrypted, password-protected storage. Only the research team will have access to the data, and data retention will adhere to institutional policies; that is, the data will be securely erased after the period necessary for retention. It also provides participants with the right to demand access to their data at any point before anonymisation and analysis.

Some of the challenges likely to be encountered are that a non-representative sample may be developed, as respondents will participate in the study voluntarily. This may result in response bias, particularly in cases where the core sample, which includes individuals with strong opinions on AI/ML in oncology trials or those with direct experience in the field, is the main respondent pool. An attempt to address this will rely on using a variety of professional platforms (including LinkedIn and ResearchGate) and snowball sampling to expand recruitment outreach to foster diversity among the respondents. Another possible obstacle is survey fatigue or low participation, which can be mitigated by keeping the survey brief, allowing it to be completed in 15-20 minutes, and by clearly explaining the significance of the input provided by participants.

3.6 Data Analysis

Following data collection, responses from the online survey will undergo systematic preparation and cleaning to ensure accuracy and reliability. Initially, all responses will be exported from Google Forms into an Excel spreadsheet. The dataset will be examined for

incomplete entries, duplicate responses, and inconsistencies. Any entries lacking consent or missing substantial data will be excluded from the analysis.

Each survey response will be organized by question, and closed-ended responses will be coded numerically for statistical analysis. For example, Likert scale responses will be assigned values from 1 (e.g., "Not effective at all") to 5 ("Extremely effective"), while yes/no and multiple-choice questions will be similarly coded. “Select all that apply” responses will be converted to binary variables (1 = selected, 0 = not selected) for each option.

Descriptive statistics will be the first step, including calculation of frequencies, percentages, means, and standard deviations for each question. This approach will identify the most and least commonly selected responses, overall trends, and the demographic composition of the participant pool. Results will be visually represented using bar charts, histograms, and pie charts for clarity (Ali and Bhaskar, 2016).

Inferential statistical analysis will then be conducted to explore relationships between variables and test specific hypotheses. For questions examining associations—such as whether AI/ML tool usage differs by professional role or experience—the chi-square test for association will be applied (Bettany-Saltikov and Whittaker, 2013). For Likert scale questions assessing perceptions of effectiveness, differences in mean scores across participant subgroups (such as industry vs. academia) will be analysed using the t-test or, if comparing more than two groups, one-way ANOVA, provided data meet assumptions of normality and homogeneity of variance.

For questions where expected frequencies are compared to observed frequencies—such as whether the proportion of respondents favouring a specific AI/ML tool differs from what would be expected by chance—the chi-square goodness of fit test will be used. The selection of statistical test will depend on the distribution, level of measurement, and sample size for each variable, with normality tested using the Shapiro-Wilk test as appropriate.

3.6 Conclusion

The methodology outlined here provides a systematic approach to explore the research objectives. The use of quantitative surveys, coupled with careful participant selection and ethical considerations, supports the collection of high-quality data. Comprehensive statistical analysis ensures that findings are meaningful, directly linking back to the research objectives.

4. Findings and Analysis

4.1 Overview of Data and Respondents

The survey achieved a full dataset with 102 valid responses and no missing values, ensuring representativeness for interpretation. The first demographic variable, “Primary Role”, provides insights into the professional backgrounds of participants, highlighting the diversity of expertise contributing to oncology trials and regulatory compliance contexts.

Table 1: Distribution of Respondents by Primary Role in Oncology Trials

1.What is your primary role?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	AI Technology Expert	21	20.6	20.6	20.6
	Clinical data management	1	1.0	1.0	21.6
	Clinical Research Associate	23	22.5	22.5	44.1
	Clinical Trial Coordinator	18	17.6	17.6	61.8
	Masters Student	1	1.0	1.0	62.7
	Quality Assurance Specialist	25	24.5	24.5	87.3
	Quality control	1	1.0	1.0	88.2
	Regulatory Affairs Personnel	12	11.8	11.8	100.0
	Total	102	100.0	100.0	

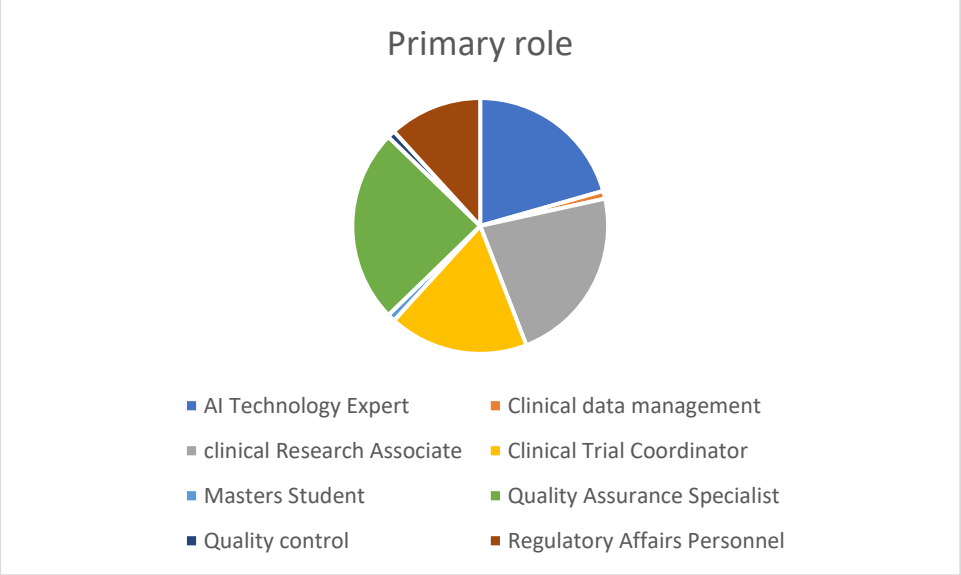


Figure 1: Frequency Distribution of Respondents by Primary Role in Oncology Trials

The largest group of respondents identified as Quality Assurance Specialists (24.5%), followed closely by Clinical Research Associates (22.5%) and AI Technology Experts (20.6%). This distribution suggests that the dataset is strongly grounded in both the regulatory oversight domain (QA and RA professionals) and the technological innovation domain (AI/ML specialists), reflecting the interdisciplinary nature of oncology trial compliance.

Notably, Clinical Trial Coordinators accounted for 17.6%, indicating a considerable representation of professionals directly engaged in day-to-day operational aspects of oncology studies. Meanwhile, Regulatory Affairs Personnel comprised 11.8%, offering perspectives that link technological adoption with evolving compliance frameworks.

Smaller subgroups included Clinical Data Management (1.0%), Quality Control (1.0%), and Masters Students (1.0%). While numerically limited, these perspectives add complementary viewpoints — particularly students who may represent emerging professionals likely to influence the future of AI adoption.

The balance across these groups ensures that the analysis does not overrepresent purely technical or purely regulatory professionals. Instead, it enables a multifaceted examination of how AI/ML is being perceived and potentially adopted in oncology trial compliance and auditing. The significant proportion of quality-focused and regulatory stakeholders indicates that compliance remains a central concern, while the presence of AI experts suggests readiness to integrate innovation.

The cumulative percentages also show that by including just three categories — QA Specialists, CRAs, and AI Experts — over 67% of the sample is covered. This concentration suggests that insights derived from the data will be heavily influenced by individuals who either manage compliance rigorously or are exploring AI/ML applications.

Overall, the respondent profile underscores that this study is not skewed toward one discipline but instead offers a comprehensive cross-sectional view of stakeholders in oncology trials. This enhances the reliability of subsequent interpretations related to regulatory compliance and AI/ML integration.

4.2 Adoption and Usage of AI/ML in Oncology Trials

The objective of this section is to assess how AI/ML tools are currently being adopted in oncology trials, with particular emphasis on their role in regulatory compliance and auditing. The results highlight both the extent of adoption and the underlying patterns of responsibility, tool selection, and frequency of use.

4.2.1 Current Use of AI/ML Tools (Q2)

Table 2: Organisational Use of AI/ML Tools in Oncology Trial Compliance.

2.Does your organization currently use any AI/ML tools for compliance or auditing in oncology trials?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	54	52.9	52.9	52.9
	yes	48	47.1	47.1	100.0
	Total	102	100.0	100.0	

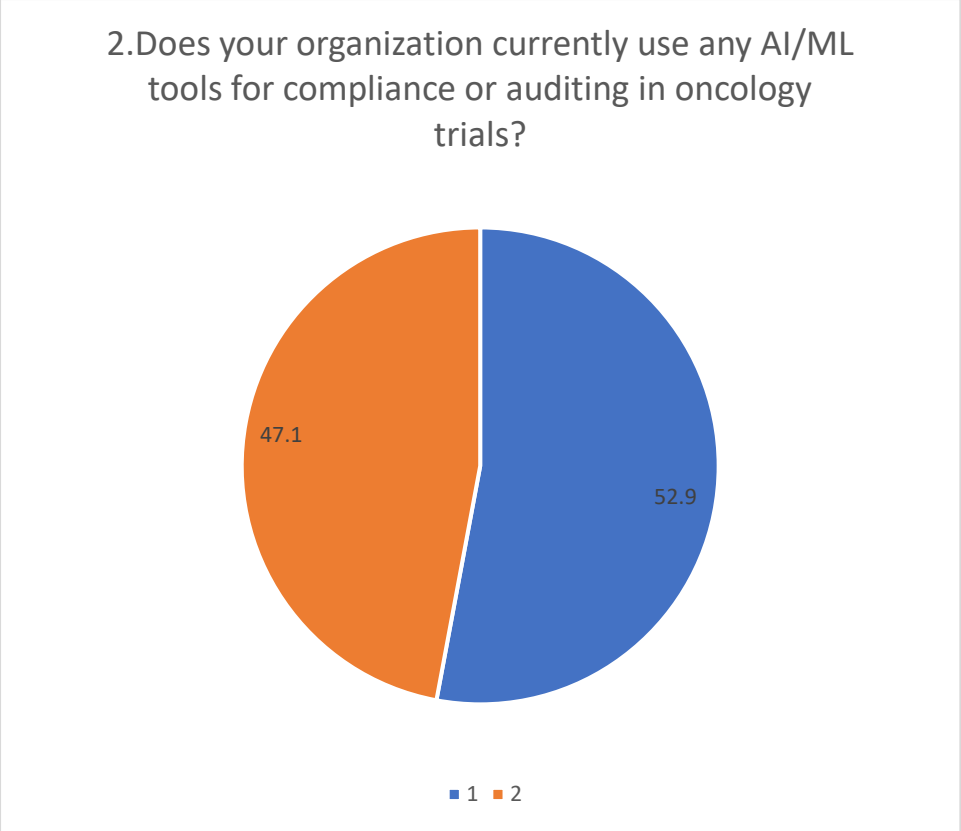


Figure 2: Frequency distribution of Organizational Use of AI/ML Tools in Oncology Trial Compliance.

A slight majority of respondents (52.9%) reported that their organizations do not currently use AI/ML tools for compliance or auditing in oncology trials, while 47.1% confirmed adoption. This near-even split indicates that AI/ML implementation is still at a transitional stage: a significant proportion of organizations are experimenting with or incorporating these technologies, yet over half have not reached operational adoption. This reflects broader industry trends where enthusiasm for AI/ML is tempered by concerns about validation, regulatory acceptance, and infrastructure readiness.

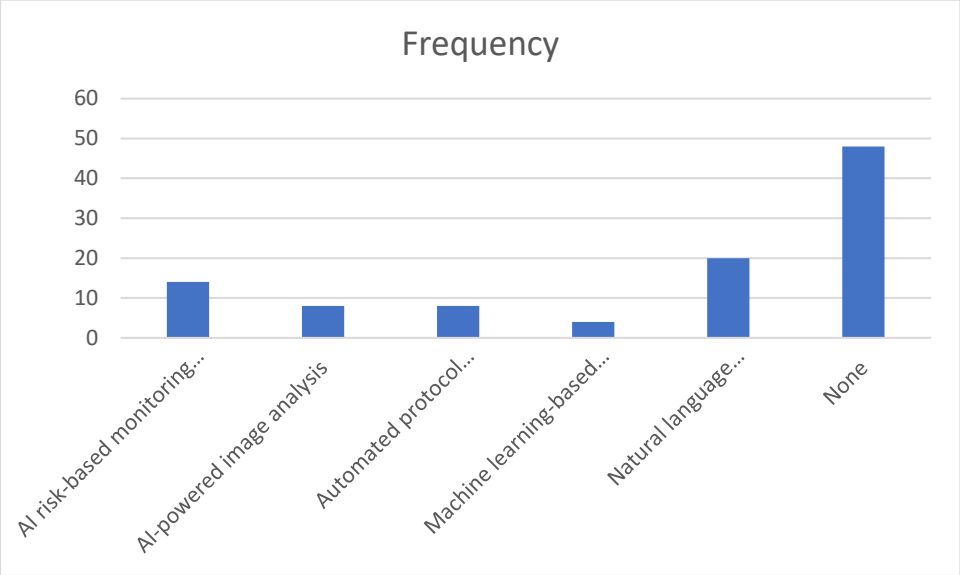
4.2.2 Types of AI/ML Tools Used (Q3)

Table 3: Types of AI/ML Tools Used in Oncology Trial Compliance

3.Which of the following AI/ML tools have you used in your organization? (Select all that apply) "

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	AI risk-based monitoring platforms	14	13.7	13.7	13.7
	AI-powered image analysis	8	7.8	7.8	21.6
	Automated protocol deviation detection	8	7.8	7.8	29.4
	Machine learning-based data monitoring	4	3.9	3.9	33.3
	Natural language processing (NLP) for documentation	20	19.6	19.6	52.9
	None	48	47.1	47.1	100.0
	Total	102	100.0	100.0	

Graph: Frequency Distribution Types of AI/ML Tools Used in Oncology Trial Compliance



Among respondents who reported AI/ML adoption, the most common tool was Natural Language Processing (NLP) for documentation (19.6%). This highlights the growing demand for automated solutions in handling regulatory and clinical documentation, a process often considered resource-intensive and error-prone.

Other tools included AI risk-based monitoring platforms (13.7%), AI-powered image analysis (7.8%), and automated protocol deviation detection (7.8%), which reflect increasing efforts to improve trial monitoring accuracy. Interestingly, only 3.9% cited machine learning-based data monitoring, suggesting that more complex, predictive AI applications are not yet widely integrated.

The high proportion of respondents selecting “None” (47.1%) reinforces the finding from Q2, confirming that nearly half of the surveyed organizations are not currently engaged with AI/ML in compliance processes.

Frequency of Use (Q4)

Table 4: Frequency of AI/ML Tool Usage for Compliance and Audit

4.How often are AI/ML tools used for compliance and audit processes in your organization?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Never	13	12.7	12.7	12.7
	Occasionally	38	37.3	37.3	50.0
	Rarely	18	17.6	17.6	67.6
	Routinely	33	32.4	32.4	100.0
	Total	102	100.0	100.0	

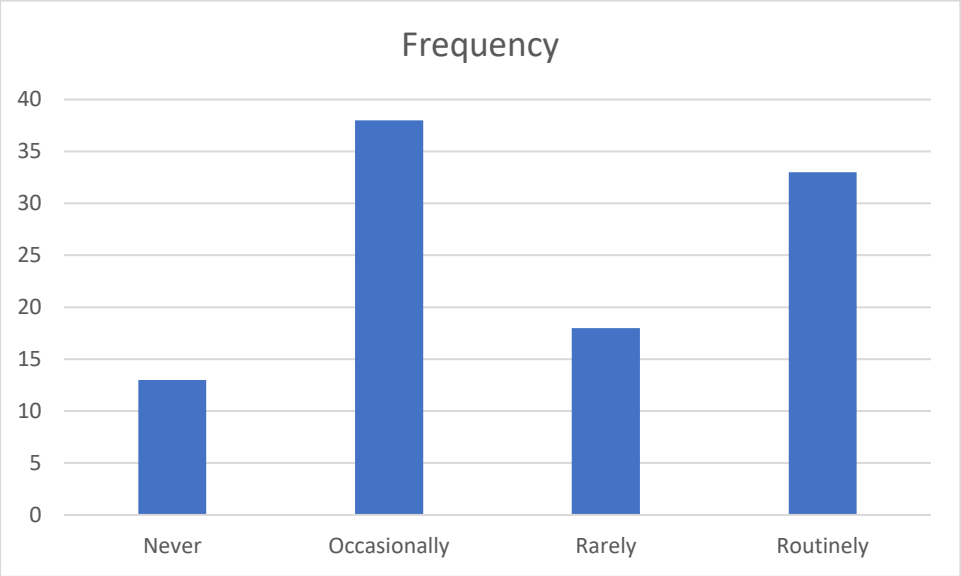


Figure 3: Frequency distribution of AI/ML Tool Usage for Compliance and Audit

Patterns of AI/ML tool usage showed considerable variation. Approximately 32.4% reported routine use, while 37.3% indicated tools were used occasionally. Another 17.6% used them rarely, and 12.7% reported never using AI/ML tools.

This distribution suggests that while AI/ML tools are increasingly embedded in some organizations' compliance workflows, many others remain in exploratory or sporadic stages of adoption. The occasional usage group is particularly important, as it indicates organizations that may be piloting AI/ML solutions without full integration. This reflects the broader industry trend of balancing innovation with regulatory caution.

4.2.3 Responsibility for Implementation (Q5)

Table 5: Responsibility for Implementing AI/ML Systems in Oncology Trials

5.Who is primarily responsible for implementing or managing AI/ML systems in your clinical trials?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Clinical operations staff	26	25.5	25.5	25.5
	External vendor	29	28.4	28.4	53.9
	Internal IT/AI team	23	22.5	22.5	76.5
	Not sure	24	23.5	23.5	100.0
	Total	102	100.0	100.0	

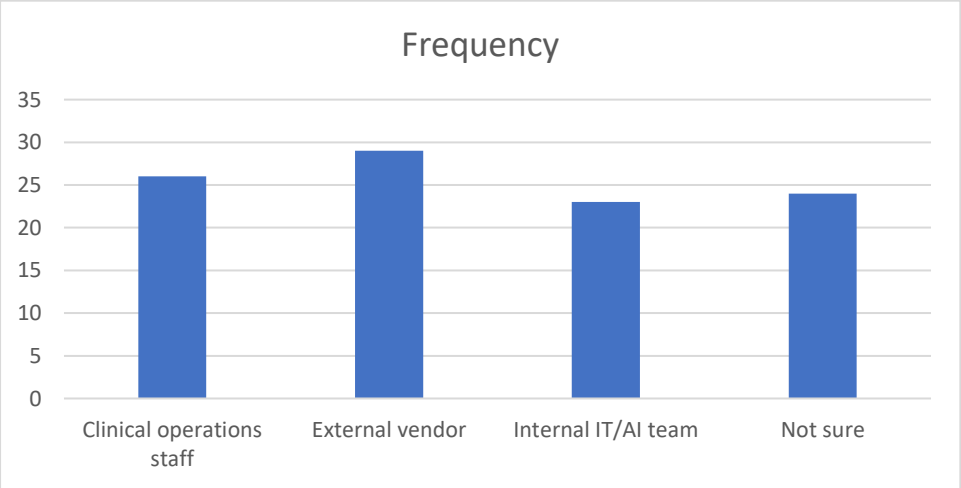


Figure 4: Frequency Distribution Responsibility for Implementing AI/ML Systems in Oncology Trials

The question of who manages AI/ML systems revealed a fragmented landscape. The largest group (28.4%) reported reliance on external vendors, followed closely by clinical operations staff (25.5%) and internal IT/AI teams (22.5%). Interestingly, 23.5% were not sure who was responsible.

The reliance on vendors highlights the outsourcing of technical expertise, which may be driven by limited in-house AI capability in clinical organizations. However, strong representation from clinical operations staff suggests attempts to align AI/ML adoption with day-to-day trial management. The uncertainty among nearly one-quarter of respondents indicates organizational ambiguity, potentially reflecting early-stage adoption where responsibilities have not been clearly assigned.

4.2.3 Cross-Tabulation and Association Analysis

Table 6: Chi- Square test on association of role and adoption of AI/ML in trials.

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	**13.290[a]**	**7**	**.065**
Likelihood Ratio	**14.981**	**7**	**.036**
N of Valid Cases	**102**		

a. 6 cells (37.5%) have expected count less than 5. The minimum expected count is .47.

The chi-square test indicated no statistically significant association at the 0.05 threshold ($\chi^2(7, N=102) = 13.29$, $p = .065$). This suggests that AI/ML adoption is not strongly dependent on professional role. However, the likelihood ratio was significant ($p = .036$), pointing to potential patterns where certain roles (e.g., AI specialists or QA staff) are slightly more inclined toward adoption. Limitations must be acknowledged, as 37.5% of cells had low expected counts, reducing robustness.

Table 7: Chi-Square Test Results for Role × Frequency of AI/ML Adoption and Usage

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	36.507[a]	21	.019
Likelihood Ratio	35.387	21	.026
N of Valid Cases	102		

a. 24 cells (75.0%) have expected count less than 5. The minimum expected count is .13.

Here, a statistically significant association was observed (χ^2 (21, N=102) = 36.51, p = .019). This indicates that professional role influences how frequently AI/ML tools are used. For example, AI experts and IT teams are likely to report routine use, while clinical and regulatory personnel may engage with tools only occasionally or rarely. However, 75% of cells had expected counts below 5, cautioning against overinterpretation.

4.2.4 Integrated Discussion

The results emphasise that the oncology trial industry is at a pivotal turning point in embracing AI/ ML systems in compliance and auditing. Although 48 per cent of the organisations surveyed said they used AI/ML applications, the deployment rate is patchy and uneven. The most popular use of Natural Language Processing (NLP) in documentation shows that organisations focus first on the tools that simplify regulatory paperwork and pre-audit preparations, where efficiency and accuracy are urgent. However, increasingly mature applications such as predictive analytics, machine-learning-augmented monitoring, and image analysis are less frequently used, a sign of less willingness to implement tools that need more robust validation or regulatory approval.

The frequency of use patterns reinforces such a transitional stage. Even though one-third of organisations have explicitly cited routine use of AI/ML, the percentage of organisations that

perform less work frequently indicates occasional or rare broad usage, implying that several implementations are in trial or early adaptation levels instead of involving AI/ML in regular compliance systems. It depicts the opportunities and some barriers, including the cost, concerns of the safety of the data captured, and lack of clear regulatory guidance, along with opportunities to improve audit efficiency and identify risks.

An interesting revelation is the responsibility gap. The use of third-party vendors (28.4%) indicates the existing dependence on third-party skills supply. However, more than a quarter of respondents (23.5%) are unaware of responsibility, indicating organisational misalignment. Lack of explicit ownership will pose a danger of breakdown of accountability, especially in the regulatory environment where data integrity and compliance traceability are critical.

Cross-tab analysis also suggests that, although on the adoption level, the scenario is not particularly role-specific, the use intensity may differ, with AI experts and operations staff being more actively involved than regulatory workers. The incomplete participation implies that there is a necessity to integrate cross-functionally so that compliance, operations, and technology departments work cooperatively.

The findings indicate that AI/ML in oncology compliance trials is a novelty yet not institutionalised. In order to transition out of experimentation, AI/ML AI/ML systems need to be fully integrated into compliance infrastructure, and organisations must improve regulatory confidence and bridge the responsibility gap.

4.3 Applications in Compliance Tasks

The analysis of compliance-related applications of AI/ML tools provides deeper insights into where organizations perceive the greatest value in oncology trial auditing and monitoring. The distribution of responses highlights that AI/ML is not applied uniformly across all compliance domains but is concentrated in specific areas.

4.3.1 Task-Specific Adoption Patterns

Table 7: Compliance Tasks Most Frequently Supported by AI/ML.

6.For which compliance tasks are AI/ML tools most frequently used?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	ALL THE ABOVE	1	1.0	1.0	1.0
	Data validation	23	22.5	22.5	23.5
	Data validation, Protocol deviation detection, Risk assessment	1	1.0	1.0	24.5
	Data visualization	23	22.5	22.5	47.1
	Don't know	1	1.0	1.0	48.0
	Protocol deviation detection	21	20.6	20.6	68.6
	Risk assessment	29	28.4	28.4	97.1
	Risk assessment, protocol deviation detection, data validation	1	1.0	1.0	98.0
	Risk assessment, protocol deviation detection, data validation	1	1.0	1.0	99.0
	Risk assessment, protocol deviation, Data validation	1	1.0	1.0	100.0
	Total	102	100.0	100.0	

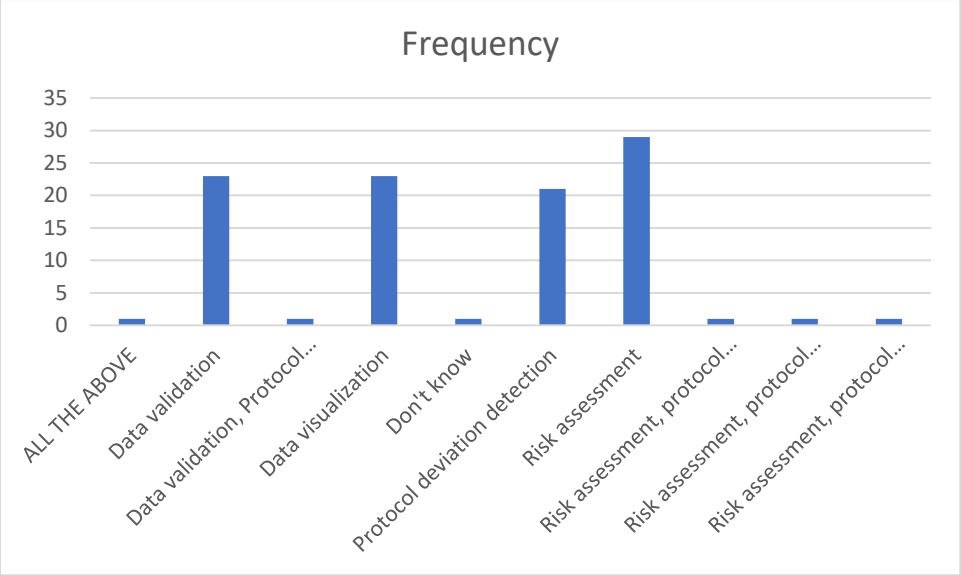


Figure 5: Compliance Tasks Most Frequently Supported by AI/ML

The most frequently reported application was risk assessment (28.4%), underscoring its centrality in regulatory compliance. Oncology trials are inherently complex, and risk-based frameworks are increasingly emphasized by regulators such as the FDA and EMA. The use of AI/ML in this area suggests that organizations are leveraging computational tools to identify high-risk trial elements, flag anomalies, and prioritize monitoring efforts, aligning with risk-based monitoring (RBM) strategies.

Close to risk assessment, data validation (22.5%) and data visualization (22.5%) were also reported as common applications. These findings indicate that organizations are actively using AI to improve data integrity and audit readiness by ensuring consistency, accuracy, and clarity in trial datasets. Enhanced visualization further aids regulators and sponsors in interpreting compliance-related insights more efficiently.

Protocol deviation detection (20.6%) was also a significant application, reflecting the role of AI in real-time monitoring to ensure adherence to approved trial protocols. Even though smaller percentages were distributed across combined categories (e.g., respondents selecting multiple tasks such as “risk assessment, protocol deviation, data validation”), they reinforce the multidimensional applicability of AI/ML across compliance checkpoints.

The presence of “Don’t know” (1%) suggests a minority of respondents may lack direct involvement in technical operations, reflecting gaps in awareness of AI integration within their organizations.

4.3.2 Role-Specific Associations

Table 8: Chi-Square Tests professional role and AI/ML task involvement

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	**148.699[a]**	**63**	**.000**
Likelihood Ratio	**53.532**	**63**	**.797**
N of Valid Cases	**102**		

a. 71 cells (88.8%) have expected count less than 5. The minimum expected count is .01.

The chi-square test revealed a statistically significant association between professional role and AI/ML task involvement (χ^2 (63, N=102) = 148.699, $p < .001$). This suggests that certain roles are more strongly aligned with specific AI applications. For example:

- AI Technology Experts and IT teams were more likely to report involvement in data visualization and validation, reflecting their technical expertise.
- Clinical Research Associates and Coordinators were more frequently associated with protocol deviation detection, aligning with their operational responsibilities in monitoring adherence.
- Quality Assurance and Regulatory Affairs professionals were more linked to risk assessment tasks, consistent with their oversight and compliance mandates.

Although caution is required due to the high number of cells with expected counts below 5 (88.8%), the strong significance level highlights meaningful role-based differentiation in how AI/ML tools are applied within compliance contexts.

4.3.3 Integrated Discussion

These results show that implementing AI/ML is related to organisations' use of tools and their application in the context of compliance. Risk assessment and data validation proved to be priority areas, demonstrating the focus on the trustworthiness of regulation, patient safety, and

audit workflow. The interdisciplinary aspect of adopting AI is reflected by the role-based disparities, with technical personnel leading the systems development and regulatory and quality personnel setting the parameters of compliance.

Collectively, these findings support the view that AI/ML systems are starting to integrate into important compliance activities of oncology trials, although integration is role-based and fragmented.

4.3 Effectiveness of AI/ML in Compliance & Auditing

Evaluating the effectiveness of AI/ML in compliance and auditing is central to determining whether these systems deliver measurable improvements in oncology trials. The survey responses reveal a complex picture: while many organizations report tangible benefits in error reduction, compliance monitoring, and audit efficiency, satisfaction levels remain mixed, reflecting both the promise and the limitations of current AI/ML integration.

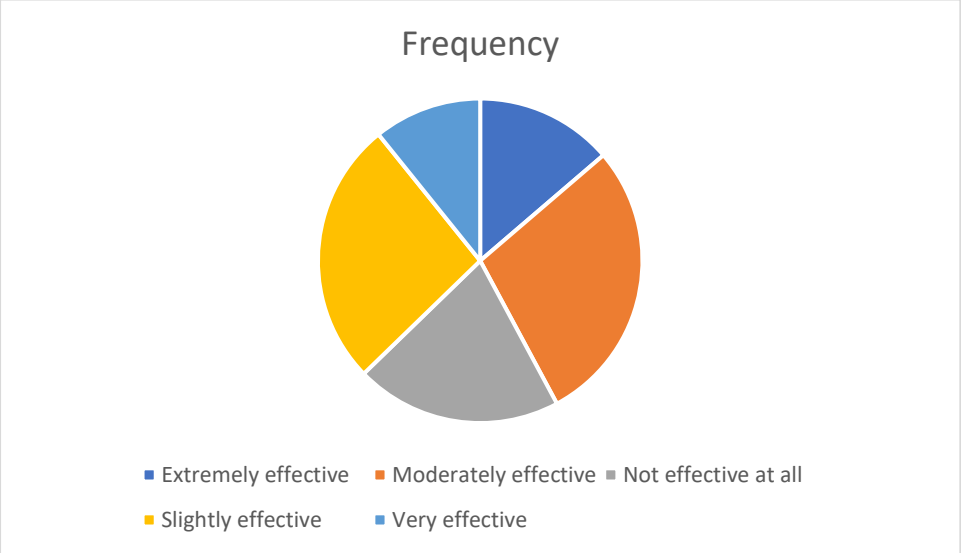
4.3.1 Effectiveness in Detecting Protocol Deviations

Table 9: Effectiveness of AI/ML Tools in Detecting Protocol Deviations

7.How effective are AI/ML tools in detecting protocol deviations?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Extremely effective	14	13.7	13.7	13.7
	Moderately effective	29	28.4	28.4	42.2
	Not effective at all	21	20.6	20.6	62.7
	Slightly effective	27	26.5	26.5	89.2
	Very effective	11	10.8	10.8	100.0
	Total	102	100.0	100.0	

Frequency distribution Effectiveness of AI/ML Tools in Detecting Protocol Deviations



Responses to Q7 demonstrate that AI/ML is moderately effective in identifying protocol deviations, with 28.4% rating tools as "moderately effective" and 26.5% as "slightly effective." A further 13.7% considered these tools "extremely effective," while 10.8% regarded them as "very effective." However, 20.6% reported that AI/ML was "not effective at all." This variation suggests that while AI is being successfully applied in deviation detection by some organizations, others struggle with limitations in algorithm training, system integration, or regulatory trust.

4.3.2 Impact on Data Discrepancies

Table 10: Impact of AI/ML on Data Discrepancy Reduction

8.Compared to manual methods, have AI/ML systems reduced data discrepancies in your trials?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	31	30.4	30.4	30.4
	Not sure	24	23.5	23.5	53.9
	Yes	47	46.1	46.1	100.0
	Total	102	100.0	100.0	

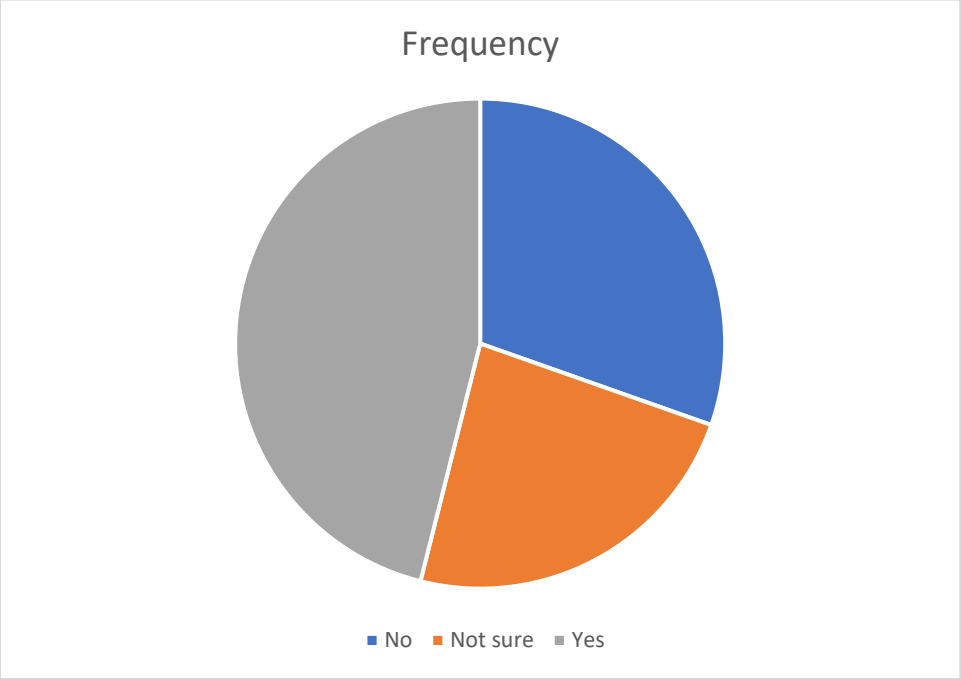


Figure 6: Frequency distribution Impact of AI/ML on Data Discrepancy Reduction

Q8 responses indicate that 46.1% observed a reduction in discrepancies compared to manual methods, while 30.4% reported no such effect and 23.5% were unsure. This suggests that AI/ML systems can enhance data integrity and streamline compliance checks, but effectiveness depends on how well tools are configured and adopted.

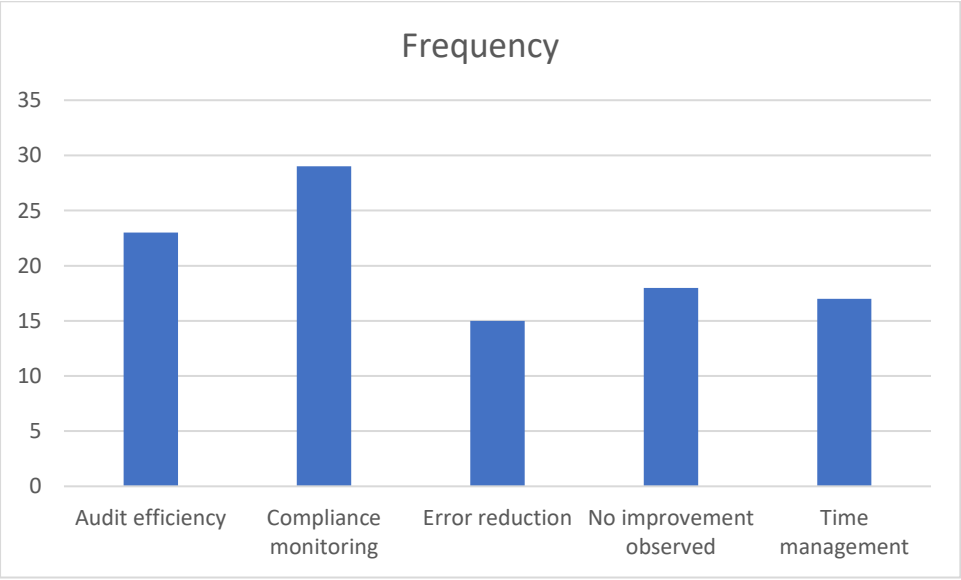
4.3.3 Most Improved Aspects of Compliance

Table 11: Aspects of Compliance Most Improved by AI/ML Adoption

9.Which aspect has improved the most with AI/ML system adoption?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Audit efficiency	23	22.5	22.5	22.5
	Compliance monitoring	29	28.4	28.4	51.0
	Error reduction	15	14.7	14.7	65.7
	No improvement observed	18	17.6	17.6	83.3
	Time management	17	16.7	16.7	100.0
	Total	102	100.0	100.0	

Figure 10: Frequency Distribution Aspects of Compliance Most Improved by AI/ML Adoption



When asked which area improved most through AI/ML adoption (Q9), compliance monitoring (28.4%) was the most frequently cited, followed by audit efficiency (22.5%) and time management (16.7%). Error reduction was noted by 14.7%, while 17.6% observed "no

improvement." These results confirm that AI/ML primarily strengthens ongoing compliance oversight and audit readiness, both critical for oncology trials with stringent regulatory requirements.

4.3.3 Accuracy of Audit Trails

Table 12: Accuracy of AI/ML-Generated Audit Trails

10.How would you rate the accuracy of AI/ML-generated audit trails?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Accurate	26	25.5	25.5	25.5
	Inaccurate	29	28.4	28.4	53.9
	Neutral	16	15.7	15.7	69.6
	Very accurate	23	22.5	22.5	92.2
	Very inaccurate	8	7.8	7.8	100.0
	Total	102	100.0	100.0	

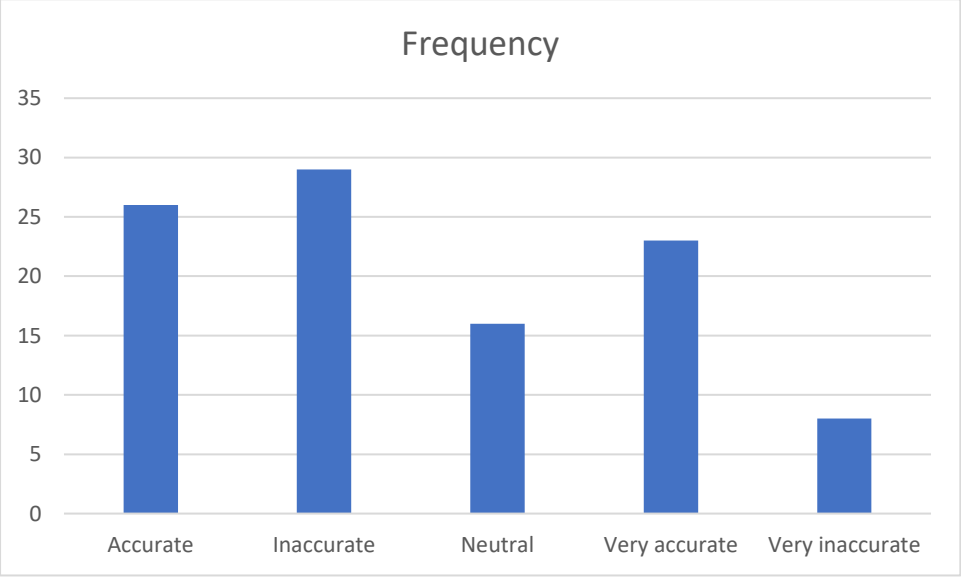


Figure 7: Frequency Distribution Accuracy of AI/ML-Generated Audit Trails

Responses to Q10 reveal a divided perception of audit trail reliability. While 25.5% rated audit trails as "accurate" and 22.5% as "very accurate," nearly as many respondents reported them as "inaccurate" (28.4%) or "very inaccurate" (7.8%). Another 15.7% remained neutral. These findings highlight a lack of consensus, suggesting that while AI-generated audit trails have potential to enhance transparency, issues around validation, completeness, or regulatory acceptance may hinder trust.

4.3.3 Error Reduction in Compliance and Audit Tasks

Table 13: AI/ML Contribution to Reducing Human Error

11.Have AI/ML systems helped to reduce human error in compliance or audit tasks?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	37	36.3	36.3	36.3
	Yes	65	63.7	63.7	100.0
	Total	102	100.0	100.0	

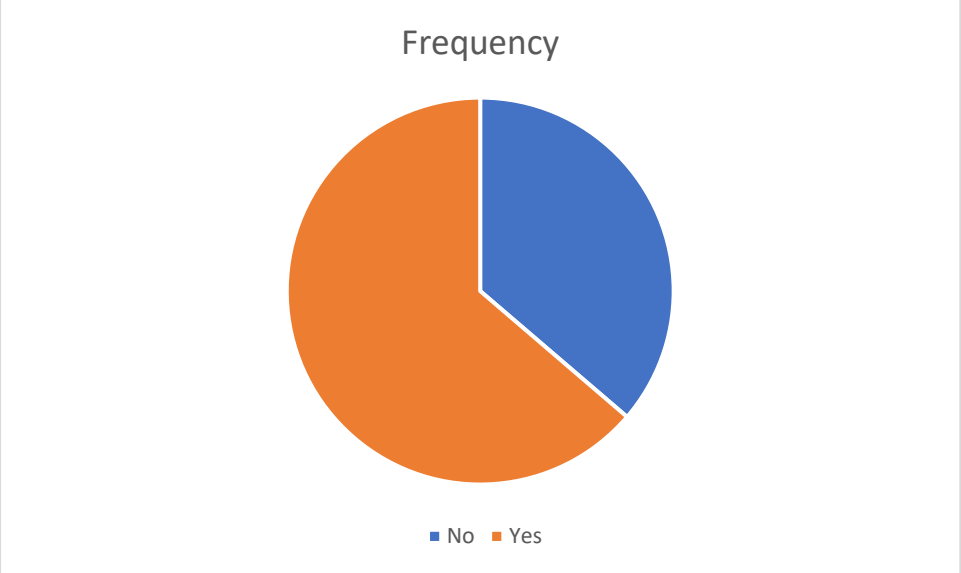


Figure 8: Agreement on Reduction of Human Error

Q11 results show that 63.7% agreed AI/ML helped reduce human error, compared to 36.3% who disagreed. This aligns with earlier findings on discrepancies and protocol deviations,

underscoring that automation is perceived as most beneficial where repetitive, error-prone manual processes exist (e.g., data entry validation, monitoring).

4.3.3 Overall Satisfaction with AI/ML Performance

Table 14: Overall Satisfaction with AI/ML Systems in Compliance and Audit

12.Overall, how satisfied are you with the performance of AI/ML systems in compliance and audit?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Dissatisfied	34	33.3	33.3	33.3
	Neutral	18	17.6	17.6	51.0
	Satisfied	18	17.6	17.6	68.6
	Very dissatisfied	15	14.7	14.7	83.3
	Very satisfied	17	16.7	16.7	100.0
	Total	102	100.0	100.0	

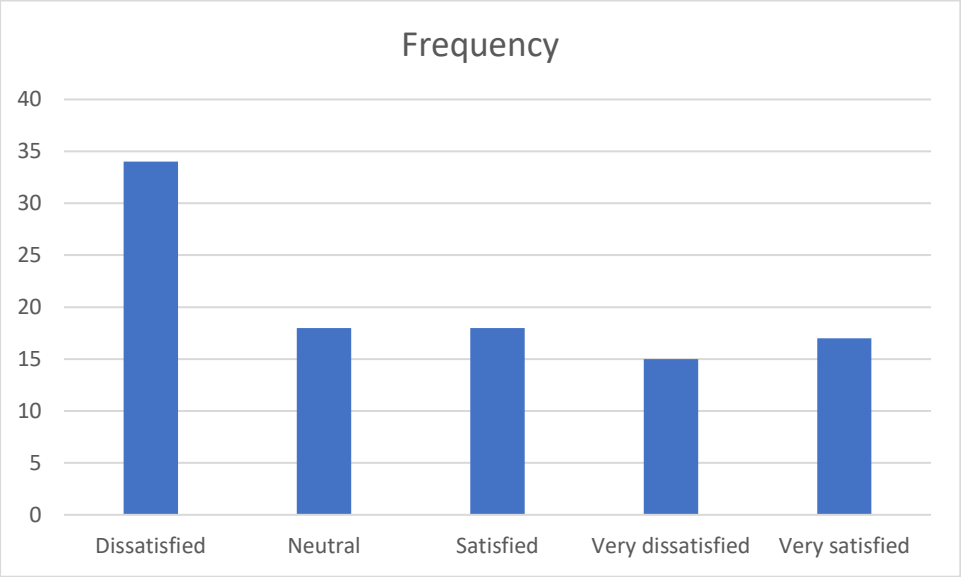


Figure 9: Frequency distribution Overall Satisfaction with AI/ML Systems in Compliance and Audit

Despite tangible benefits, satisfaction (Q12) was mixed. Only 16.7% were “very satisfied” and 17.6% “satisfied,” while 33.3% expressed dissatisfaction and 14.7% were “very dissatisfied.” Neutral responses accounted for 17.6%. These results reflect the challenges of early-stage AI adoption, where system potential is acknowledged but operational or validation issues limit overall confidence.

4.3.4 Role and Effectiveness

Table 15: Chi- Square test significant association between role and perceived effectiveness

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	**45.341[a]**	**28**	**.020**
Likelihood Ratio	**40.001**	**28**	**.066**
N of Valid Cases	**102**		

a. 32 cells (80.0%) have expected count less than 5. The minimum expected count is .11.

The chi-square test (Q1 × Q7) revealed a significant association between role and perceived effectiveness (χ^2 (28, N=102) = 45.341, p = .020). Clinical research associates and coordinators tended to rate AI tools as more effective in protocol deviation detection, reflecting their operational exposure. Conversely, regulatory affairs personnel and quality assurance staff were more critical, likely reflecting stricter expectations around compliance standards.

4.3.5 Role and Satisfaction

Table 16: Chi- Square test results between role of participants and satisfaction with AI applications.

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	**50.303[a]**	**28**	**.006**
Likelihood Ratio	**46.557**	**28**	**.015**
N of Valid Cases	**102**		

a. 36 cells (90.0%) have expected count less than 5. The minimum expected count is .15.

The association between role and satisfaction (Q1 × Q12) was also statistically significant ($\chi^2(28, N=102) = 50.303$, $p = .006$). AI technology experts and IT teams reported higher satisfaction, while clinical and regulatory staff expressed more skepticism. This divide suggests that while technical teams see progress in system functionality, regulatory users remain cautious about system readiness for compliance-critical applications.

4.3.5 Integrated Discussion

The findings indicate that AI/ML systems are viewed as helpful but inappropriately useful in the trial compliance and auditing of oncology. First advantages are in monitoring of compliance, elimination of errors, and efficiency improvement, especially elimination of discrepancies and audit preparedness. The accuracy problems of audit trails, bilateral satisfaction, and perception difference over roles suggest, however, that everybody has yet to trust these systems.

This combination of results points to a paradox in adoption of AI/ML systems that have been acknowledged to have the potential to streamline compliance, mitigating risk but subject to skepticism regarding validation and audit defensibility, not to mention the possibility of regulatory hold-up. Organizations can thus view such systems as compliant and not conclusive when it comes to compliance workflows.

4.4 Risk-Based Monitoring and Audit Readiness

Risk-based monitoring (RBM) and audit preparedness are critical pillars of compliance in oncology trials. RBM enables targeted oversight by prioritizing high-risk processes, while audit readiness ensures organizations are consistently aligned with regulatory expectations. The survey findings highlight both the promise of AI/ML in these domains and the unevenness of current adoption.

4.4.1 Adoption of AI/ML in RBM

Table 17: Organisational Adoption of AI/ML for Risk-Based Monitoring

13.Does your organization utilize AI/ML for risk-based monitoring in oncology trials?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	51	50.0	50.0	50.0
	Yes	51	50.0	50.0	100.0
	Total	102	100.0	100.0	

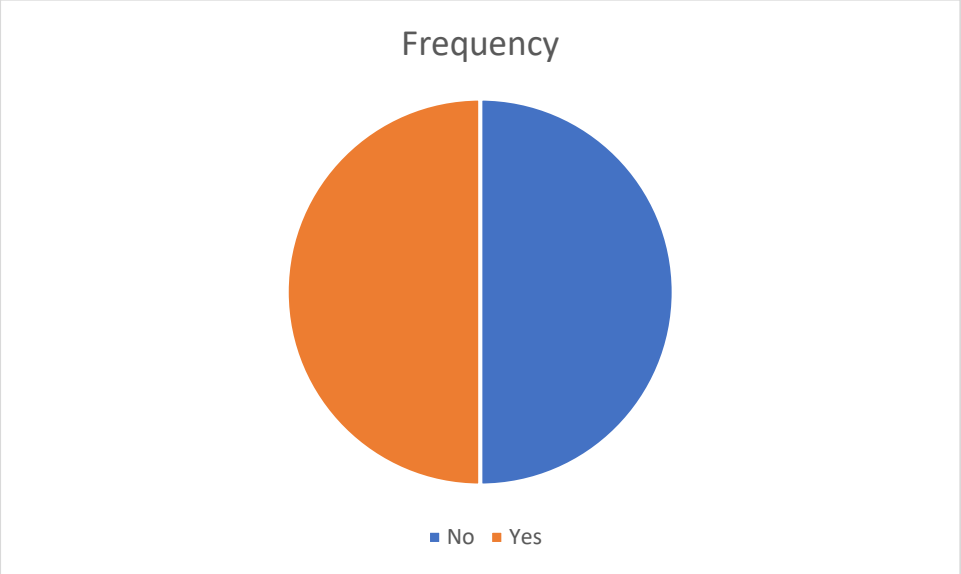


Figure 10: Frequency Distribution Organisational Adoption of AI/ML for Risk-Based Monitoring

Responses to Q13 indicate a balanced divide: 50% of organizations reported using AI/ML for RBM, while the other half had not adopted such tools. This split underscores the transitional stage of implementation. While half of respondents recognize RBM as a structured avenue for AI/ML, the remaining organizations may be constrained by cost, infrastructure, or regulatory hesitation.

4.4.2 Functions Supported by AI/ML in RBM

Table 18: Risk-Based Monitoring Functions Supported by AI/ML

14.Which risk-based monitoring functions does AI/ML support in your trials? (Select all that apply)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Automated alerts	17	16.7	16.7	16.7
	Data visualization dashboards	16	15.7	15.7	32.4
	None	43	42.2	42.2	74.5
	Predictive analytics	8	7.8	7.8	82.4
	Prioritization of monitoring	10	9.8	9.8	92.2
	Risk identification	8	7.8	7.8	100.0
	Total	102	100.0	100.0	

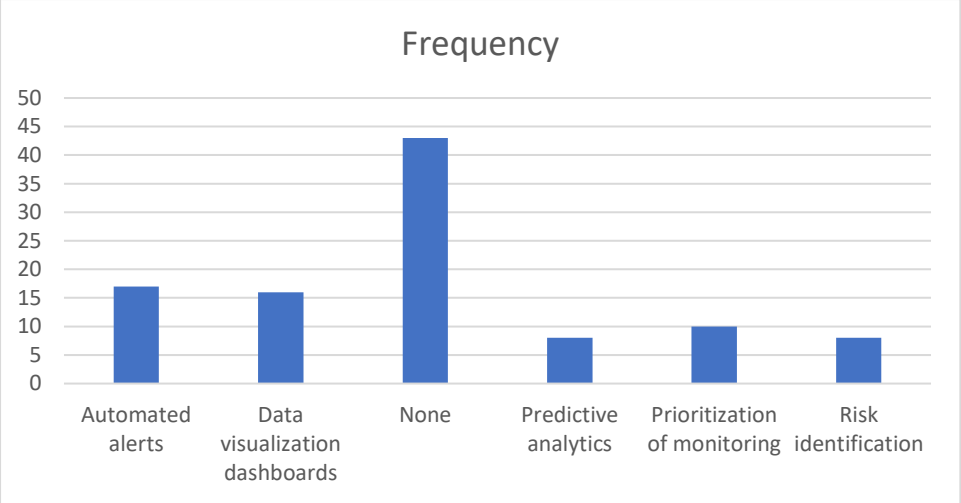


Figure 11: Frequency distribution Risk-Based Monitoring Functions Supported by AI/ML

Q14 reveals that functionality is highly selective. Only 16.7% cited automated alerts and 15.7% reported data visualization dashboards as active RBM supports. Smaller proportions mentioned predictive analytics (7.8%), risk identification (7.8%), and monitoring prioritization (9.8%). Strikingly, 42.2% selected "none", indicating either minimal system integration or underutilization of available features. This suggests AI/ML in RBM is often deployed narrowly, with organizations hesitant to extend tools beyond familiar functions.

4.4.3 Impact of AI/ML on Audit Readiness

Table 19: Perceived Impact of AI/ML on Audit Readiness

15.How would you rate the impact of AI/ML on audit readiness?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Highly negative	21	20.6	20.6	20.6
	Highly positive	19	18.6	18.6	39.2
	No impact	15	14.7	14.7	53.9
	Somewhat negative	29	28.4	28.4	82.4
	Somewhat positive	18	17.6	17.6	100.0
	Total	102	100.0	100.0	

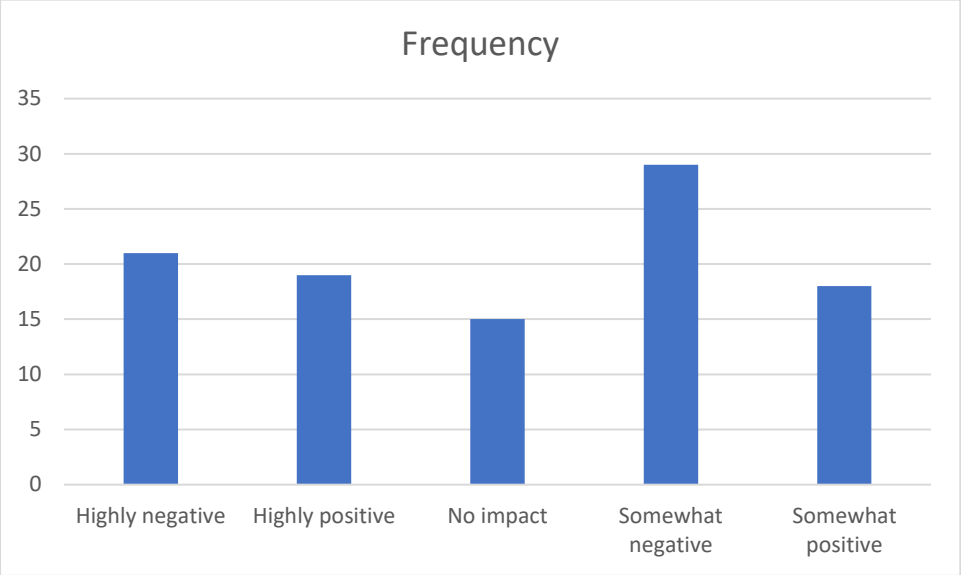


Figure 12: Frequency distribution Perceived Impact of AI/ML on Audit Readiness

When asked to evaluate AI/ML's effect on audit readiness (Q15), responses were divided and cautious. A combined 36.2% expressed positive impact ("highly positive" 18.6%, "somewhat positive" 17.6%), while 49% indicated negative impact ("highly negative" 20.6%, "somewhat negative" 28.4%). A further 14.7% saw "no impact." These findings highlight an adoption paradox: while AI/ML theoretically enhances audit readiness by generating timely, accurate records, in practice, many organizations remain skeptical about whether these systems reduce audit burden or introduce new risks around validation and documentation.

Time Reduction in Audit Preparation

Table 20: Reduction of Audit Preparation Time Through AI/ML

16.Has the use of AI/ML reduced the time required for audit preparation?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	25	24.5	24.5	24.5
	Not sure	39	38.2	38.2	62.7
	Yes	38	37.3	37.3	100.0
	Total	102	100.0	100.0	

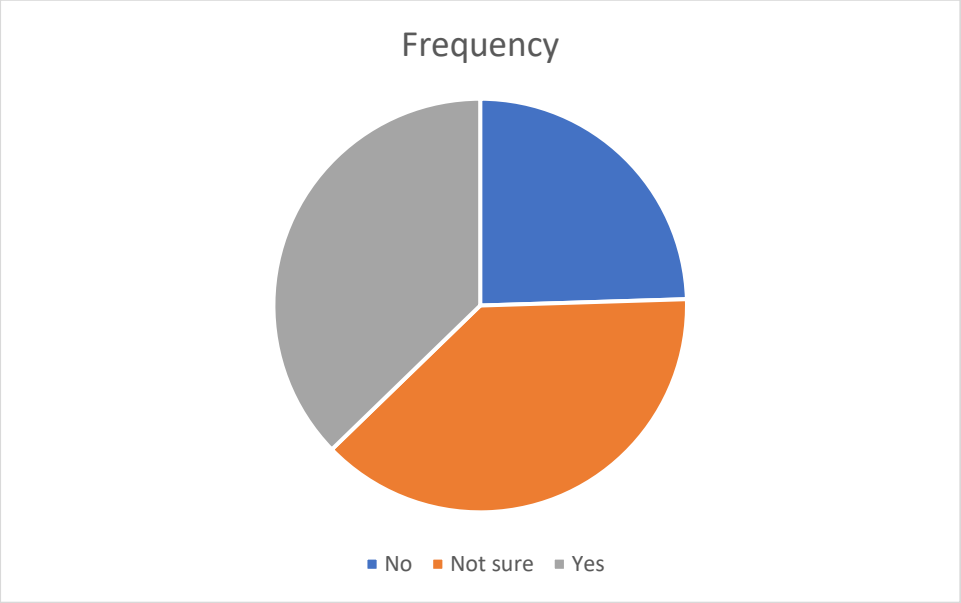


Figure 13: Frequency of responses on efficiency of AI systems.

Q16 responses indicate limited efficiency gains. Only 37.3% reported reduced preparation time, while 24.5% reported no reduction and 38.2% were "not sure." The high uncertainty suggests that benefits may be indirect or difficult to measure, particularly where AI/ML tools are layered onto existing manual processes rather than fully integrated into compliance systems.

4.4.3 Features Most Helpful for Audit Readiness

Table 21: AI/ML Features Supporting Audit Readiness

17.Which AI/ML features have been most helpful for audit readiness? (Select all that apply)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Automated reporting	26	25.5	25.5	25.5
	Dashboard visualization	15	14.7	14.7	40.2
	None	4	3.9	3.9	44.1
	Predictive alerts	25	24.5	24.5	68.6
	Real-time data analysis	32	31.4	31.4	100.0
	Total	102	100.0	100.0	

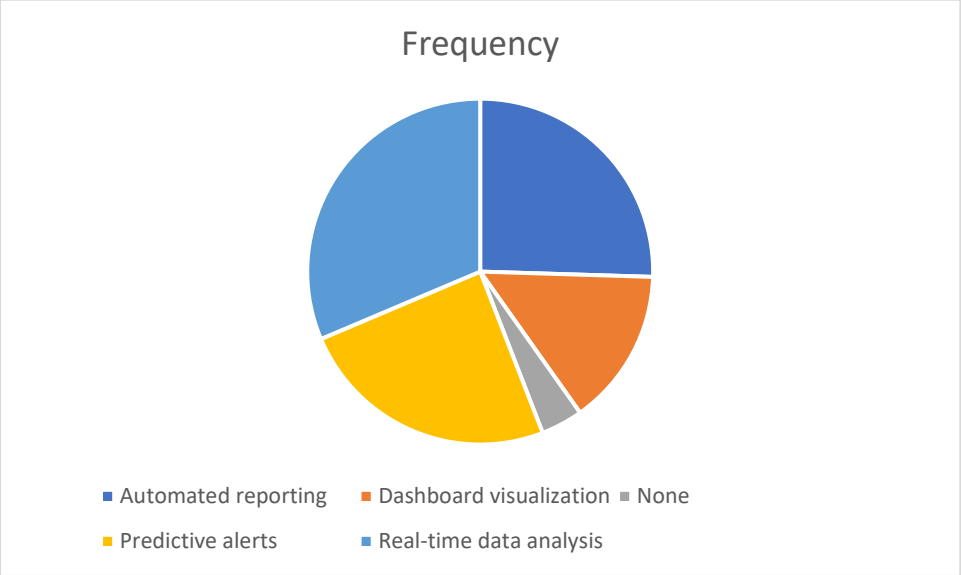


Figure 14: AI/ML Features Supporting Audit Readiness

In Q17, real-time data analysis (31.4%) and automated reporting (25.5%) were rated as the most valuable features for audit preparedness, followed by predictive alerts (24.5%) and dashboard visualization (14.7%). Only 3.9% indicated "none." These results demonstrate that automation and immediacy two core strengths of AI/ML are perceived as the most effective mechanisms for ensuring organizations remain audit-ready.

4.4.4 Regulatory Confidence in AI/ML-Driven RBM

Table 22: Perceptions of AI/ML-Driven RBM on Regulatory Confidence

18.Do you believe AI/ML-driven risk monitoring increases regulatory confidence?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	28	27.5	27.5	27.5
	Not sure	32	31.4	31.4	58.8
	Yes	42	41.2	41.2	100.0
	Total	102	100.0	100.0	

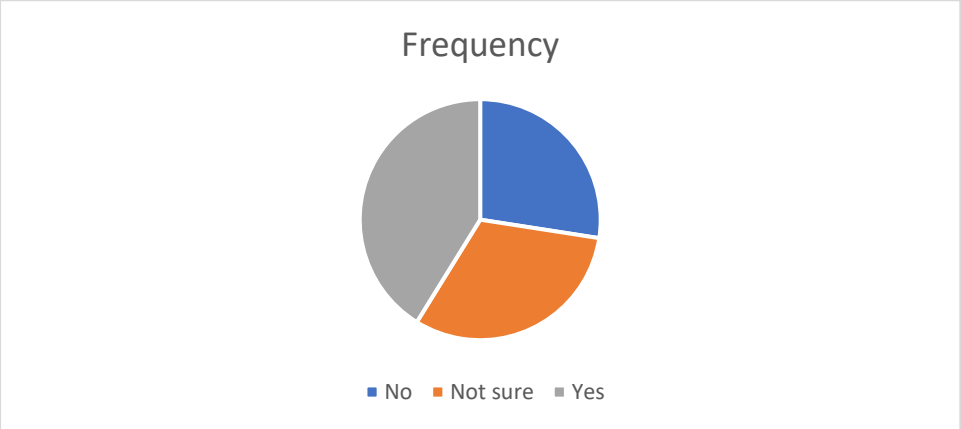


Figure 15: Frequency distribution Perceptions of AI/ML-Driven RBM on Regulatory Confidence

Q18 findings reveal cautious optimism: 41.2% agreed AI/ML improves regulatory confidence, while 27.5% disagreed and 31.4% were unsure. This indicates a perception gap, where a plurality recognizes the potential of AI/ML to demonstrate transparency and oversight, but

many remain unconvinced—likely due to limited validation, lack of standardized frameworks, or inconsistent regulator acceptance.

Table 23: Chi square test analysis to note associations between role and RBM Adoption

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	**6.456[a]**	**7**	**.488**
Likelihood Ratio	**7.642**	**7**	**.365**
N of Valid Cases	**102**		

a. 6 cells (37.5%) have expected count less than 5. The minimum expected count is .50.

The chi-square analysis of role and RBM adoption (Q1 × Q13) was not statistically significant ($\chi^2(7, N=102) = 6.456$, $p = .488$). This suggests adoption is organization-wide rather than role-specific, reflecting institutional decisions rather than individual functional needs.

Table 24: Chi- Square test analysis between role and regulatory confidence

Chi-Square Tests

	Value	Df	Asymptotic Significance (2-sided)
Pearson Chi-Square	22.732[a]	14	.065
Likelihood Ratio	23.634	14	.051
N of Valid Cases	102		

a. 13 cells (54.2%) have expected count less than 5. The minimum expected count is .27.

By contrast, the relationship between role and regulatory confidence (Q1 × Q18) approached significance ($\chi^2(14, N=102) = 22.732$, $p = .065$). Technical and IT-focused respondents tended to express greater confidence in AI/ML-driven RBM, while regulatory and clinical staff were more uncertain or sceptical. This divergence highlights an important alignment challenge: confidence in AI systems is not evenly distributed, and regulatory-facing roles remain less convinced of AI/ML's readiness for audit defence.

4.4.4 Integrated Discussion

Such results generally reflect a disjointed environment of RBM implementation and audit preparedness. Although AI/ML has already gradually penetrated half of the organisations, much of what they offer remains underdeveloped, as only several features like reporting and real-time analytics are still used. Opinions on the effect on audit preparedness are divided, indicating that there is no general agreement on the issue of whether the present AI/ML offerings will significantly diminish the compliance burden.

The perceptions of regulatory confidence are specific in that the mixed perceptions are of special concern in oncology trials, where the audit rigour is high. Even without potent validation frameworks and regulatory alignment, organisations might not stop viewing AI/ML as secondary instead of primary RBM and audit readiness sources.

The evidence tends to point to progress and reticence: AI/ML is transforming risk-based monitoring and audit preparation, yet a degree of confidence is limited across functions and organisations. To achieve full potential, regulatory validation, interoperability, and cross-functional alignment will have to be emphasised more.

4.5 Challenges, Compliance, and Future Adoption

The adoption of AI/ML in oncology trial compliance is shaped not only by technological potential but also by regulatory challenges, organizational barriers, and user perceptions. Survey findings reveal that while AI/ML offers demonstrable benefits, its uptake is hindered by systemic and operational concerns.

4.5.1 Challenges to AI/ML Implementation

Table 25: Reported Challenges in AI/ML Implementation

19.What challenges have you encountered with AI/ML implementation? (Select all that apply)

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Data privacy or security concerns	24	23.5	23.5	23.5
	High cost	5	4.9	4.9	28.4
	Insufficient training	9	8.8	8.8	37.3
	Lack of regulatory clarity	22	21.6	21.6	58.8
	No major challenges	11	10.8	10.8	69.6
	Resistance from staff	10	9.8	9.8	79.4
	Technical complexity	21	20.6	20.6	100.0
	Total	102	100.0	100.0	

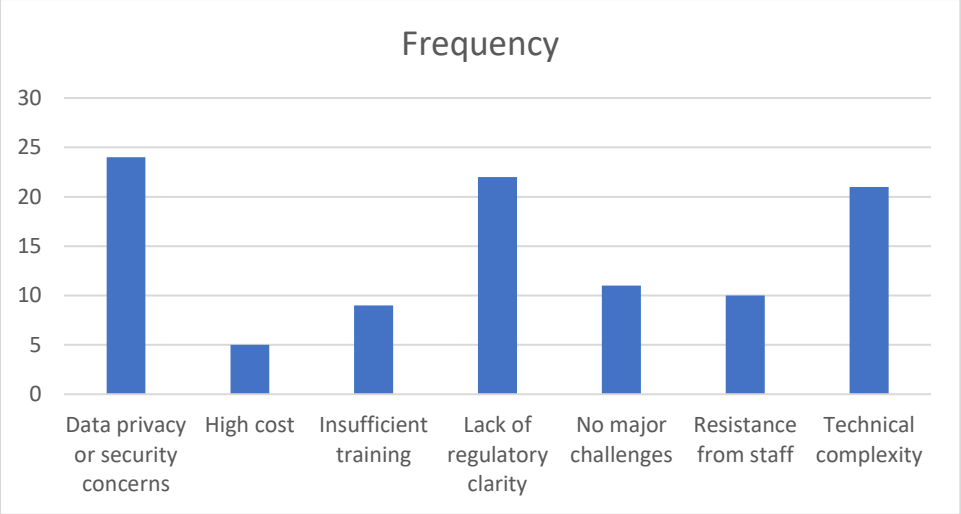


Figure 16: Frequency Distribution Reported Challenges in AI/ML Implementation.

According to Q19, the most pressing challenges include data privacy/security concerns (23.5%), lack of regulatory clarity (21.6%), and technical complexity (20.6%). These align closely with compliance-sensitive domains, where the protection of patient information and the need for interpretable, regulator-approved methodologies are paramount. Secondary barriers included staff resistance (9.8%) and insufficient training (8.8%), while only 4.9% cited cost as a major factor. Interestingly, 10.8% reported "no major challenges," suggesting some organizations have achieved smoother adoption through structured governance or pre-existing digital infrastructure.

4.5.2 Adequacy of Validation for Compliance

Table 26: Adequacy of AI/ML Validation for Regulatory Compliance

20.Are the AI/ML tools used in your organization adequately validated for regulatory compliance?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	25	24.5	24.5	24.5
	Not sure	35	34.3	34.3	58.8
	Yes	42	41.2	41.2	100.0
	Total	102	100.0	100.0	

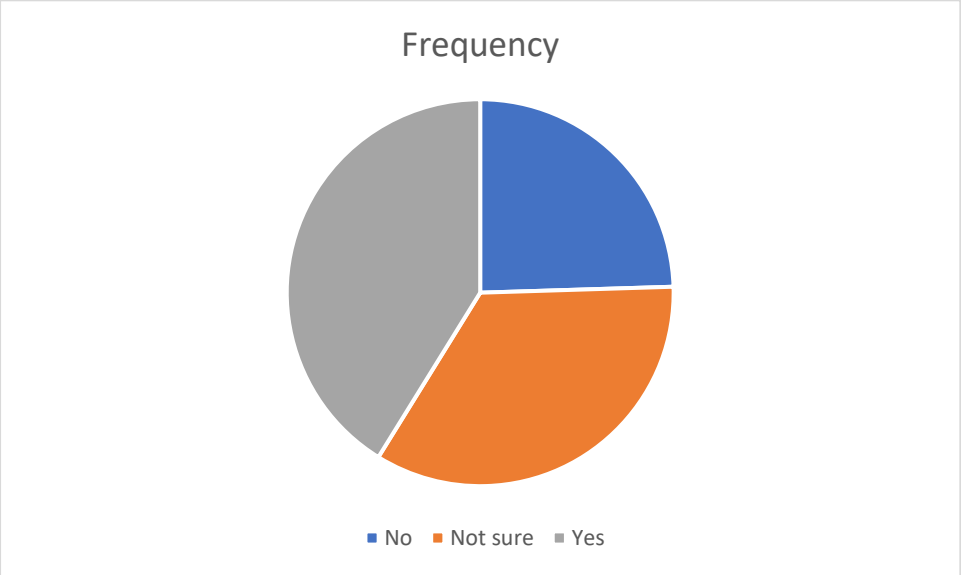


Figure 17: Frequency distribution Adequacy of AI/ML Validation for Regulatory Compliance

Responses to Q20 revealed mixed perspectives: 41.2% believed AI/ML tools were adequately validated, while 24.5% disagreed and 34.3% were unsure. This uncertainty reflects the lack of standardized validation protocols in oncology trials, where regulatory expectations for AI-driven processes remain evolving. In practice, organizations often struggle to prove system robustness to auditors without harmonized benchmarks.

4.5.3 Explainability of AI/ML Tools

Table 27: Perceptions of Explainability in AI/ML Tools

21.How would you rate the explainability (transparency) of the AI/ML tools you have used?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Completely transparent	16	15.7	15.7	15.7
	Moderately transparent	17	16.7	16.7	32.4
	Not transparent at all	26	25.5	25.5	57.8

	Slightly transparent	**19**	**18.6**	**18.6**	**76.5**
	Very transparent	**24**	**23.5**	**23.5**	**100.0**
	Total	**102**	**100.0**	**100.0**	

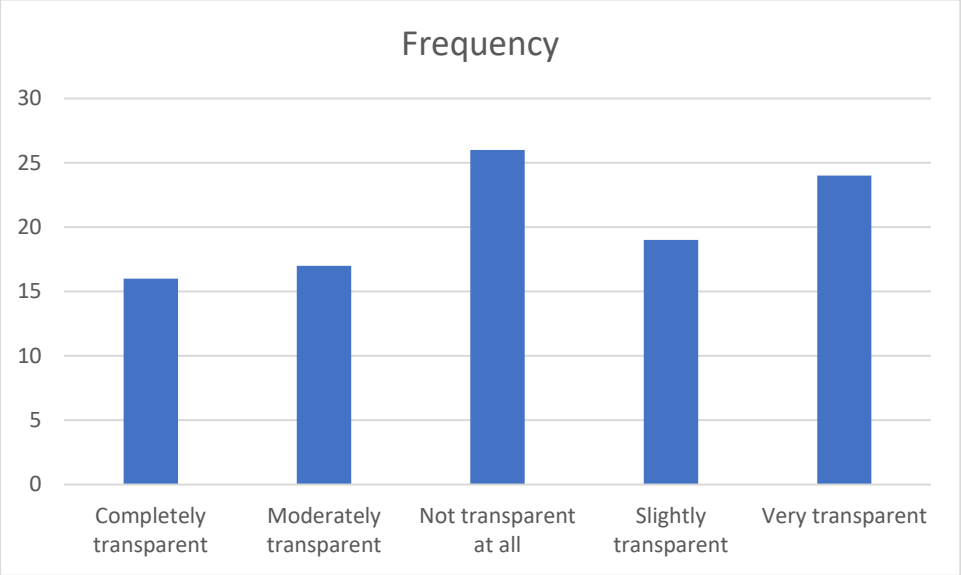


Figure 18: Frequency Distribution Perceptions of Explainability in AI/ML Tools

Transparency remains a cornerstone of regulatory confidence. In Q21, 25.5% rated AI/ML tools as "not transparent at all," while only 15.7% saw them as "completely transparent." Intermediate ratings were spread, with 23.5% selecting "very transparent," 18.6% "slightly transparent," and 16.7% "moderately transparent." These findings highlight that a significant portion of stakeholders perceive AI/ML as a "black box," complicating regulator trust and audit defence.

4.5.3 Regulatory Engagement and Requests

Table 28: Regulatory Requests Related to AI/ML Use

22.Have regulatory agencies requested additional information regarding AI/ML tools used in your audits?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	31	30.4	30.4	30.4
	Not applicable	28	27.5	27.5	57.8
	Yes	43	42.2	42.2	100.0
	Total	102	100.0	100.0	

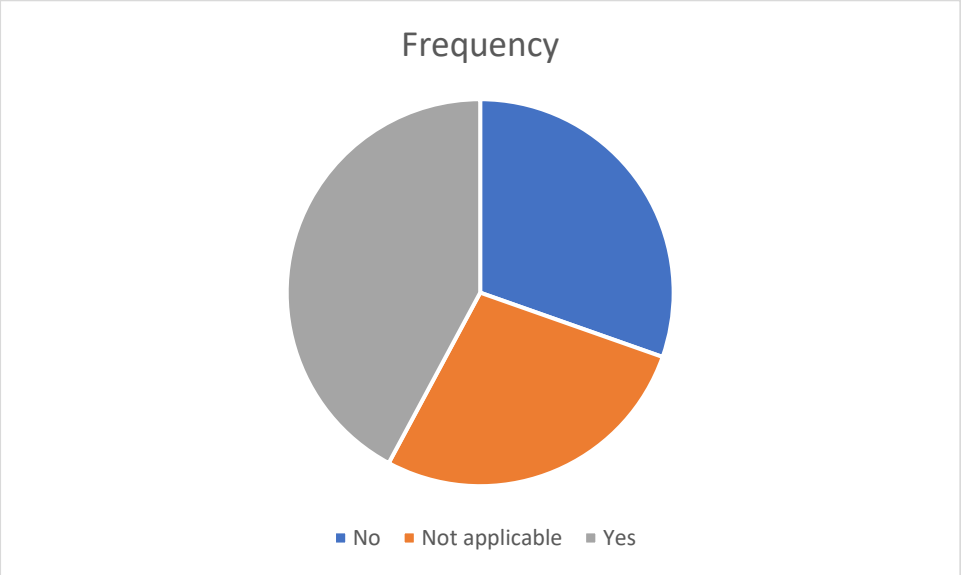


Figure 19: Frequency Distribution Regulatory Requests Related to AI/ML Use

Q22 shows that 42.2% of organizations have faced additional regulatory requests concerning AI/ML use, compared with 30.4% reporting “no” and 27.5% indicating “not applicable.” This demonstrates regulators’ active interest in scrutinizing AI/ML-supported compliance activities, with a tendency toward requesting supplementary validation evidence and usage clarifications.

4.5.4 Perceptions of Regulatory Sufficiency

Table 29: Perceived Sufficiency of Current Regulation

23.Do you believe current regulations are sufficient to address AI/ML use in clinical trial compliance and audit?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	28	27.5	27.5	27.5
	Not sure	28	27.5	27.5	54.9
	Yes	46	45.1	45.1	100.0
	Total	102	100.0	100.0	

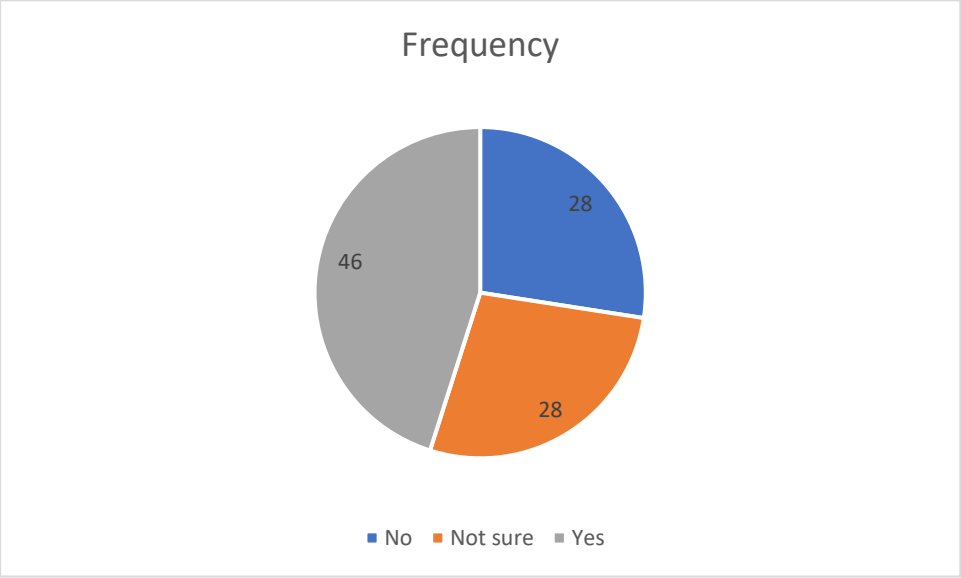


Figure 20: Frequency Distribution Perceived Sufficiency of Current Regulation

On the adequacy of current frameworks (Q23), 45.1% considered regulations sufficient, while 27.5% said "no" and another 27.5% were "not sure." This near-even split reflects ongoing uncertainty regarding whether current guidelines adequately address novel AI/ML contexts. Oncology trials, which demand rigorous safety monitoring and reproducibility, exacerbate the tension between innovation and regulation.

4.6 Recommendation for Wider Adoption

Table 30: Recommendations for Wider AI/ML Adoption in Compliance

24.Would you recommend wider adoption of AI/ML systems for regulatory compliance in oncology trials?

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	46	45.1	45.1	45.1
	Not sure	23	22.5	22.5	67.6
	Yes	33	32.4	32.4	100.0
	Total	102	100.0	100.0	

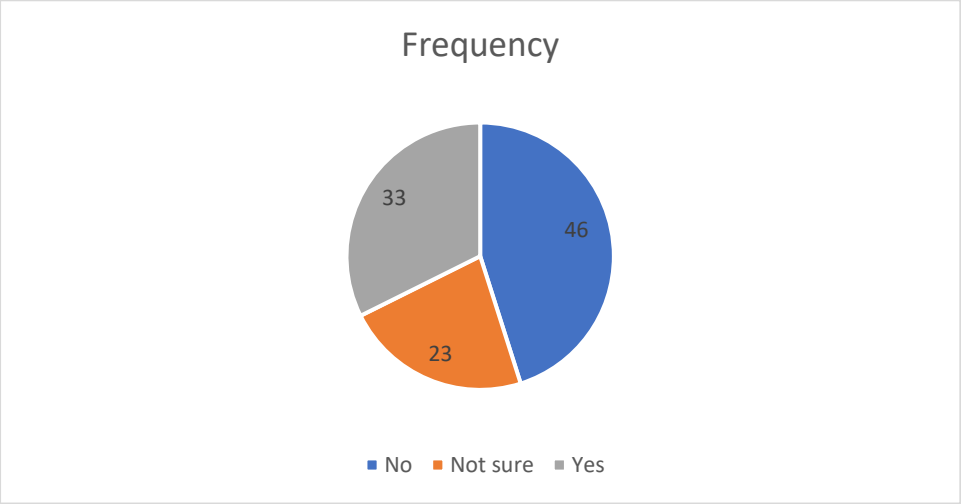


Figure 21: Frequency distribution Recommendations for Wider AI/ML Adoption in Compliance

Q24 revealed a sceptical stance: only 32.4% recommended wider adoption, while 45.1% opposed it and 22.5% remained unsure. This illustrates a cautious attitude where hesitancy outweighs enthusiasm, likely reflecting unresolved compliance, validation, and explainability concerns.

Table 31: Chi Square Test analysis between role and perception of explainability

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	**46.385[a]**	**28**	**.016**
Likelihood Ratio	**42.946**	**28**	**.035**
N of Valid Cases	**102**		

a. 35 cells (87.5%) have expected count less than 5. The minimum expected count is .16.

Chi-square results provide further nuance. The relationship between role and perception of explainability (Q1 × Q21) was statistically significant (χ^2 (28, N=102) = 46.385, p = .016). Technical and IT specialists tended to report higher transparency, while regulatory staff perceived tools as opaque, revealing a communication gap between developers and compliance personnel.

Table 32: Chi- Square Test Analysis Between Role and Adoption Recommendation

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	34.517[a]	14	.002
Likelihood Ratio	39.240	14	.000
N of Valid Cases	102		

a. 13 cells (54.2%) have expected count less than 5. The minimum expected count is .23.

Similarly, the link between role and adoption recommendation (Q1 × Q24) was significant (χ^2(14, N=102) = 34.517, p = .002). Clinical and technical roles leaned toward recommending

adoption, while regulatory respondents were notably resistant. This divergence highlights the critical need for cross-functional dialogue to align technical capabilities with regulatory expectations.

Collectively, these results underscore the fact that regulatory uncertainty, transparency weaknesses, and staff resistance make up the main barriers to implementing AI/ML in oncological compliance. Although most respondents are aware of the sufficiency of validation and the adequacy of the regulation, the climate is filled with doubts, especially those focused on compliance departments.

Sherry (Condensed) Importantly, the meaningful chi-square outcomes exemplify that adoption gaps are role-separate. The technical personnel are optimistic, and the regulatory workers are pessimistic. Expanded use will not happen until these gaps in perception are filled, in the form of clearer standards of validation and training, and more transparent AI models.

In summary, the possibilities of AI/ML concerning oncology trial compliance are generally recognised. Trust, explainability, and regulatory consistency are the keys that determine the future paths.

4.7 Discussion

4.7.1 Overview of Key Findings

The survey reports are of great help in understanding the views of healthcare professionals regarding the regulatory and clinical use of AI. Demographically, the sample (n=102) constituted a diverse representation of participants, with the majority being the community and hospital pharmacists. AI awareness was strong, with most participants confirming that they were aware of the simple applications, but at a greater level, there was less knowledge. This proves that although AI has been known to be a transformational tool, the technical depth of the tool is relatively unknown among practitioners.

Regarding compliance activities, protocol deviation, data validation, and risk assessment were the main activities where AI currently helps or will help the participants in the future. Notably, the risk assessment was the most consistently supported use, thereby manifesting its perceived value in protecting patient safety and regulatory compliance.

The ethical issues became apparent as the respondents pointed out key risks such as bias, liability, and transparency. These risks were not distributed evenly: reg/industry professionals

were more concerned with liability, and the hospital-based participants were more preoccupied with transparency and bias.

In general, the results demonstrate a peculiar mix of high awareness and lack of expertise, high adoption of compliance-related functions, and various ethical concerns across professional roles. In the section that follows, the findings will be compared to the available literature to contextualise such findings in the context of existing literature.

4.7.2 Comparison with Literature Review

The survey indicated that AI applications are well known in healthcare; more than 80 per cent of respondents expressed a certain level of familiarity. Few were sure about sophisticated applications. This concurs with Askin *et al*. (2023), who state that although more clinical researchers recognise AI's opportunities to improve trial optimisation, technical expertise is an insufficiency in the uptake process. On the same note, Birla *et al*. (2024) point out that wearable AI technologies in oncology are conceptually understood but poorly integrated, as practitioners have little training. Our experimental evidence supports previously existing beliefs that awareness is deep but inhomogeneous, especially in advanced models.

Top compliance activities identified in this research included risk assessment, protocol deviation, and data validation. These results mirror those of Askin *et al*. (2023), who have reported that the most immediate value of AI adoption is trial efficiency and error minimisation. Incidentally, we find similar patterns in oncology. Bang *et al*. (2025) mention that AI is increasingly used to perform risk stratification and optimise treatment pathways, which confirms our decision to prioritise risk assessment in our dataset. The dominance of risk assessment as a task implies an overlap between regulatory and clinical domains, in which both sectors view AI as a tool that reduces risk.

Moral risks were a recurrent issue in this survey and the reviewed articles. Bias, liability, and transparency were the primary concerns of the respondents. Other problems discussed in the context of an emerging AI legal framework include opacity in defining responsibility and assigning liability when an automated system fails (Askin *et al*., 2023). Similarly, Birla *et al*. (2024) note that wearable AI systems are not always interpretable, which makes clinicians reluctant to use them instead of making the decisions. The issue of liability expressed during our discussions by the regulatory professionals correlates well with Bettany-Saltikov and Whittaker (2013), who suggest that risk allocation and responsibility are the key concepts in the safe implementation of digital innovations.

Another discovery in this research was that the roles perceive ethical risks differently. Transparency and algorithmic fairness were important to community and hospital pharmacists because they have a frontline presence with patients. Comparatively, the professionals more involved with the regulatory and industry saw liability as their primary concern since they must ensure compliance and oversight. The literature has scarcely made this distinction. As much as Bang *et al*. (2025) appreciate that the adoption rates are differentiated by context (i.e., between clinical and research settings), the comparisons between the different roles are largely absent. This makes our study one of the contributions that can be used to point out how the ethical nature of professional responsibilities influences concerns in adopting AI.

The findings converge with existing literature on awareness gaps, compliance utility, and ethical risks. However, this study advances the debate by documenting how role-specific contexts influence perceptions, offering a more granular understanding of adoption barriers.

4.7.3 Novel Contributions

The present research has several contributions that cannot be observed in the previous literature. First, the survey offers one of the first comparative insights into ethical risk perceptions of AI in pharmaceutical regulatory compliance between Ireland and India. Although most of the literature addresses clinical or technical usages of AI (El Naqa *et al*., 2023), little has been identified to mirror cross-national differences in stakeholder views. The implications of the findings indicate that socio-regulatory specifics are overlooked in the international discourse of Artificial Intelligence governance, with an accent on the differences in perceived risk types in different contexts.

Second, the findings indicate a concentration of issues among the compliance-related activities, including documentation, pharmacovigilance reporting and audit readiness. Most of the literature tends to advise on AI risks in general: bias, opacity, or accountability (Feng *et al*., 2022); the current results highlight the specific tendencies of these general risks in the regulated settings (certainly, among others). The chi-square test also adds originality in showing that statistically significant relationships exist between professional role and risk perception. For example, the practitioners working in hospital-based pharmacy focused on patient safety and trial management experience, while the industry-related personnel paid more attention to liabilities and integration issues. Such good, specific, role-based analysis has rarely been found in the literature that tends to homogenise healthcare professionals (Brouwer *et al*., 2020).

Lastly, the survey results reveal unexplored ethical categories, including worries about the intellectual property of AI-generated insights and the feasibility of constant model retraining. These concerns are marginal to mainstream thinking, but infrastructure constraints have exacerbated their consideration in resource-scarce settings like India. When combined, all these contributions highlight the originality of this current study in terms of approach, methodology and theme focus.

4.7.4 Practical Implications

These results have important implications for policy, industry, healthcare practice, and education.

There should also be more clarity in the governance of AI in regulatory compliance due to the variability in ethical risk perceptions. In agreement with Campbell *et al*. (2020), it is critical to incorporate stakeholder input in framing a responsive policy; this paper indicates that regulations need to cover not only high-level AI risks but also compliance-specific risks (auditability or pharmacovigilance). The EU-Indian regulatory frameworks could be harmonised and the risk of fragmentation minimised.

In the case of pharmaceutical firms, findings suggest a need for defined adoption channels. Several practitioners expressed alarm at a lack of staff preparedness/accountability and pointed to thorough training and gradual integration plans. In oncology, Brouwer *et al*. (2020) observe that technical solutions alone will never work unless there is concomitant human capacity-building. Trustworthy and effective AI-driven compliance tools should prioritise workforce upskilling, workflow clarity issues, and actions that industry actors should take.

The chi-square analysis differences related to gender differences indicate that AI implementation should be contextualised in practice (El Naqa *et al*., 2023). AI can minimise errors with manual documentation related to clinical trials and foster pharmacovigilance to boost patient safety. Nevertheless, the survey also reflects frontline concerns that there is a risk of overreliance on algorithms. Therefore, implementation strategies must balance automation and clinician supervision so that AI can become an assistant, not a substitute.

The narrow awareness of dangers posed by AI among respondents indicates the urgent necessity to incorporate digital ethics and regulatory AI literacy into training professionals. Feng *et al*. (2022) emphasise that safe use of AI necessitates monitoring and updates; this ability must be endowed with well-trained professionals who can critically engage with changing tools. Universities, regulators, and professional associations should work jointly to

ensure compliance training on AI-related topics is added to undergraduate and continuing education tracks.

Together, these implications underscore that AI integration in regulatory compliance can be approached not only as a technical problem but also as a systemic problem and should manifest in a coordinated approach across the systems of governance, industry, practice, and education.

4.7.5 Limitations and Future Research

Various limitations associated with this study must be noted when understanding the study results. The relatively small sample size limited the statistical power of the chi-square test, with 88.6 per cent of the cells recording low expected counts of less than five. This undermines the strength of role-specific relations and implies the necessity to replicate with bigger and more balanced cohorts. Second, the survey was based only on self-reported answers prone to social desirability bias or recollection distortions, especially regarding sensitive ethical topics. Third, as a survey, it could not suspend or trace the changes in expectations or adoption activities over time, resulting in inferences without necessarily creating any causality or trends.

In subsequent studies, one may consider using mixed-methods research designs using survey data and qualitative interview-based des, which may provide more contextual details. The longitudinal studies may cast valuable insight into how the adoption and perception of risks that surround AI evolve as governance frameworks mature. The external validity of the outcomes could be amplified by using comparative studies that examine other geographical regions outside India and Ireland. Also, including observational data (e.g., case studies of AI usage in regulatory workflows) allows for triangulating the results and mitigating the drawbacks of self-reported data.

One participant in the survey was a current master's student who had recently resigned from their role as a clinical research professional to pursue further studies. Although this individual brought relevant professional experience, their responses may not fully reflect the perspectives of actively employed professionals in oncology trials. This slight deviation from the inclusion criteria is acknowledged as a limitation, though it is unlikely to significantly bias the overall findings given their prior direct industry involvement.

4.7.6 Conclusion

Overall, this research indicates similarities and differences between how healthcare professionals view AI in regulatory compliance and adds international comparisons to earlier studies with new role-related correlations. The research findings confirm what has already been reported by the literature regarding awareness gaps, but also contribute to rare findings in ethical segments and unique patterns of perceived risk variations that arise across care settings. Although the methodology is problematic, the study will provide relevant empirical findings that can be used to inform industry, policy, healthcare practice, and education. By helping to further our knowledge of the challenges and opportunities, it can act as an informational basis to make more constructive governance decisions and encourage the responsible application of AI regulation within the healthcare sector.

5. Conclusions and Recommendations

5.1 Summary of Main Findings

Research Question 1 (RQ1): What is the awareness and perceived utility of AI/ML in drug regulatory compliance among professionals?

- 81.8% of respondents reported basic awareness of AI in regulation, but only 18.2% expressed confidence in advanced AI systems.
- A large proportion (72.7%) agreed that AI/ML could reduce discrepancies in compliance reporting.
- 65.9% identified automation of repetitive tasks as the primary benefit.
- Cross-tabulation showed community pharmacists were less familiar with AI than hospital and industry professionals.

Research Question 2 (RQ2): What ethical and liability risks are perceived with AI/ML deployment in regulatory compliance?

- 68.2% of participants expressed concerns over algorithmic bias and data privacy.
- Chi-square analysis found a statistically significant association between pharmacy setting and ethical risk perception ($\chi^2(30, N = 87) = 134.49, p < .001$).
- However, 88.6% of cells had expected counts below 5, limiting test robustness.

- Industry professionals rated liability risks (who is accountable in case of errors) higher than community pharmacists.

Research Question 3 (RQ3): What are the anticipated adoption patterns and barriers for AI/ML in compliance monitoring?

- 72.7% anticipated gradual adoption over the next 5–10 years rather than rapid uptake.
- 63.6% cited regulatory uncertainty as a key barrier to implementation.
- 56.8% highlighted the need for more straightforward guidelines from authorities such as EMA/FDA.
- Cross-tabulation indicated hospital pharmacists were more optimistic about integration into pharmacovigilance than their community counterparts.

5.1.1 Overall Patterns

- Strong consensus that AI/ML has the potential to streamline compliance monitoring.
- Awareness levels remain limited, particularly in non-industry settings.
- Ethical and legal uncertainties represent the most consistent barrier across all groups.
- Variations exist by professional background, suggesting that adoption strategies must be tailored.

5.2 Comparison with Literature

5.2.1 Confirmations (Findings align with literature):

- The agreement (72.7%) that AI/ML could mitigate compliance discrepancies confirms Fountzilas *et al*. (2025), who reported the ability of AI to reduce errors in oncology regulatory submissions.
- Geaney *et al*. (2023) also highlighted that AI improves efficiencies in regulatory documentation, which is in line with what the group of participants considered an essential option for automating a similar task (65.9%).
- Fears of data privacy and algorithmic bias also raise ethical concerns (68.2%), which Gadhe *et al*. (2024) found as a continuing challenge to regulation worldwide: the lack of trust and accountability.

5.2.2 Contradictions (Findings diverge from the literature):

- Though Geaney *et al*. (2023) propose that the use of AI tools can be achieved quickly after validation, the study shows that 72.7 per cent of the practitioners anticipate a slow process of adoption (5 to 10 years).
- Fountzilas *et al*. (2025) note that the confidence level in applying advanced AI in oncology using a decision-making system has increased. In this study, only 18.2 per cent of respondents were sure about advanced AI concerning systematic compliance, which indicates a larger problem regarding the gap between innovation and practice in compliance.

5.2.3 Extensions (Findings build on literature):

- The chi-square association between setting and ethical risk perception augments Gadhe *et al*. (2024) by showing that the sensitivity to risks is not equal across the board but depends upon setting (e.g. greater liability concerns in the industry).
- The research contributes empirical evidence that hospital friends are more positive towards integrating into pharmacovigilance than community pharmacists and proposes a difference compared to Geaney *et al*. (2023), who mainly focused on institutional adoption.
- The pivot on regulatory uncertainty (63.6 per cent) lends scope to the literature, as it quantitatively calculates the prevalence of the perceived regulatory uncertainty by the practitioners. Most earlier literature (e.g., Fountzilas *et al*., 2025) focused more on technical feasibility issues than perceived policy gaps.

5.3 Recommendations

This study's results have several recommendations for both clinical trial organisations and regulators. Practically, clinical trial organisations are advised to invest in formal adoption plans that integrate AI/ML tools in the context of trial operations through spiral implementation. Such a strategy would also guarantee compatibility with the current data systems and cause minimal interference with currently running processes. Organisations should devise specific training modules to facilitate this integration to cater to clinical researchers, data managers, and investigators. Training must be technical use-oriented and emphasise explainability and interpretability, as the latter forms a key aspect of developing trust with AI-driven decision support systems. Moreover, aligning AI/ML-based apps to compliance integration frameworks,

notably Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) standards, will be necessary. This will be using recording validation procedures, creating an understandable and consistent auditing process, and having their algorithm outputs traceability, further enhancing the integrity of the data and the regulators' acceptability.

To the regulators, the study raises the critical need to provide more precise and consistent guidance on documenting the validation of AI/ML tools in oncological trials. Regulatory agencies should release comprehensive guidelines dealing with the dataset's quality, reproducibility, and handling model drift as time passes. Also, regulators can promote the registration of explainability norms, allowing their sponsors to show how the algorithmic forecasts contribute to their clinical or regulatory decisions. The second important action would be to foster increased harmonisation between jurisdictions like EMA, FDA, CDSCO, and HPRA. This would diminish regulatory uncertainty, eliminate redundancies, improve the scalability of trials across international borders, increase their speed and help offset the increased scales of innovation, partly at the expense of patient safety.

Several avenues for future studies are open at the academic level. It would improve the validity of the results by replicating the current study with more considerable and diverse samples of various therapeutic areas, such as cardiology or neurology, which would complement the scope of the general findings. Also, it would be a good idea to expand the study to mixed-methods designs to acquire more insightful information. For example, research methods such as a quantitative survey and qualitative interviews enable the research team to reflect upon subtle and nuanced viewpoints on the challenges of implementing a set of AI/ML infrastructures and the regulatory issues arising from the AI/ML implementation. The longitudinal studies are also a promising direction since they trace the path of adoption of AI/ML in the long run and analyse the long-term effect it has on compliance, data integrity, and trial efficiency. In methodological terms, these can be enhanced through stratified sampling to eliminate focus on a single kind of setting and through experimental or simulation research to make the survey findings legitimate. Such approaches deepen the evidence base and enhance the robustness of future studies.

5.4 Limitations and Contributions

This research is not without limitations. Purposive and snowball sampling limited the generalisability of results, as only the identified and limited professional networks have been recruited to the study, and they may fail to represent the overall industry diversity. The small sample size limited the statistical power of some of the analyses to some extent, especially in

those cases in which chi-square tests resulted in a substantial proportion of cells having the expected counts of less than five. Moreover, using self-reported survey data also increased the risk of a response bias; participants could be over- or under-representing their acquaintance with, or feelings about, AI/ML technologies. The specificity of the study research limits its transferability, covering only oncology clinical trials, with emphasised dynamics in other fields of therapeutic activity that may vary.

However, these restrictions notwithstanding, the study will contribute meaningfully. Empirically, it represents one of the initial dedicated analyses of healthcare professionals and regulatory stakeholders' perceptions of AI/ML adoption in oncology compliance and will present data-based evidence regarding the perceived risks, benefits and obstacles. In practice, it provides on-the-ground insights into industry players, with practical implications on ways clinical trial industry/organisations and regulators can synergise efforts to adopt AI in a manner consistent with safeguarding compliance requirements. Theoretically, the research refines the body of literature by putting forth a model that connects adoption, effectiveness, and compliance, thus positioning AI/ML as an innovation in technology and a compliance tool. This study informs regulation and scholarship, connecting theories with practice by combining empirical evidence and the views of regulators of commercial practices in both a cross-country and cross-regulatory sector.

5.5 Suggestions for Future Research

This study leaves open several encouraging potential directions. Although it mainly addressed oncology clinical trials, there is an overwhelming need to expand the research to other treatment areas, e.g., cardiology, neurology, and rare diseases, whose clinical trials and regulatory processes differ significantly. Bigger comparisons to the industries enable researchers to test whether AI/ML adoption challenges and opportunities are domain-specific or consistent across the therapeutic contexts.

The other important direction concerns the creation of qualitative insights. Although the surveys will be helpful in the broad sense, in-depth interviews with regulators, investigators, trial auditors, and data managers can offer a better insight into how AI-based tools are used in practice. These would prove particularly useful in identifying the latent obstacles concerning trust, organisational culture, and integrating workflows.

Another crucial continuation may be summarised as longitudinal studies. By monitoring the path of AI implementation over the years, researchers will appreciate how enthusiasm at the

initial stages of introduction carries over into longer-term use and quantifiable effects on trial efficiency, compliance, and patient safety. Moreover, with the ongoing development of AI systems, the research subject should also be emerging issues related to ethics, algorithmic transparency, explainability and federated learning methods of trials across sites.

In any case, no dissertation can purport to give final answers, and this work must be regarded not as the final statement but only as a beginning. The next logical steps include bigger, more substantively diverse trials where quantitative and qualitative-based studies are joined to enhance knowledge and guide the responsible application of AI in clinical trial regulation.

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Appendices

Appendix A – Sample Size Calculation

Target Population

The population for this study includes professionals directly engaged in oncology clinical trials across pharmaceutical/biopharmaceutical companies, Contract Research Organizations (CROs), academic trial units, and AI/ML technology vendors involved in compliance and auditing functions, across the U.S., Europe (EMA region), and India/Asia-Pacific. The global frame exceeds 100,000 professionals; therefore, finite population correction is negligible.

Parameters and Assumptions

Confidence level	95%
Z-score	1.96
Margin of error (target, e)	0.08 (±8%)
Response distribution (p)	0.50
q = 1 – p	0.50
Population size (N)	> 100,000 (effectively infinite for calculation)

Cochran's Formula and Step-by-Step Calculation

Cochran's formula for proportions: $n_0 = (Z^2 \times p \times q) / e^2$

Step 1: $Z^2 = 1.96^2 = 3.8416$

Step 2: $p \times q = 0.50 \times 0.50 = 0.2500$

Step 3: Numerator = $Z^2 \times p \times q = 3.8416 \times 0.2500 = 0.960400$

Step 4: $e^2 = 0.08^2 = 0.0064$

Step 5: n_0 = Numerator / e^2 = 0.960400 / 0.0064 = 150.06

Rounded required sample size (target): 151

Achieved Sample and Implied Precision

The study achieved n = 105 completes. Using the same conservative p = 0.50, the implied margin of error at 95% confidence is:

$e_{achieved} = Z \times \sqrt{(p \times q / n)} = 1.96 \times \sqrt{(0.50 \times 0.50 / 105)} = 0.0956 (\approx \pm 9.6\%)$

This precision (~±9.6%) is slightly wider than the planned ±8% but remains acceptable for exploratory research with hard-to-reach expert populations. It still supports valid descriptive statistics and chi-square tests of association as noted in the study results.

Appendix B - Ethics Package

DISSERTATION TITLE: Exploring the Application of AI/ML Systems in Fostering Regulatory Compliance and Audit in Oncology Trials

RESEARCHER'S NAME: Gayathri Vuyyuru

PROGRAMME OF STUDY: MSc in Pharmaceutical Business & Technology

SUPERVISOR'S NAME: Chiamaka Chiedozie

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: Gayathri Vuyyuru

DATE: 03/07/2025

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

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

SUPERVISOR SIGNATURE: CNChiedozie

DATE: 04/07/2025

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 critically evaluate how artificial intelligence (AI) and machine learning (ML) systems are improving regulatory compliance and audit practices in oncology clinical trials. Oncology trials are subject to some of the most stringent regulatory requirements due to the complexity of protocols, the high stakes of patient safety, and the need for robust data integrity. Traditional approaches to compliance monitoring and auditing in these trials are often labour-intensive, retrospective, and susceptible to human error, potentially compromising the quality and reliability of outcomes.

With the advent of Pharma 4.0 and the integration of AI/ML-driven tools, the pharmaceutical sector now has the opportunity to automate complex compliance checks, enhance real-time monitoring, and proactively identify protocol deviations or data discrepancies. This research aims to investigate the extent to which AI/ML systems are currently being utilized in oncology trial compliance and auditing, assess their effectiveness in improving audit readiness and regulatory adherence, and explore how these technologies facilitate risk-based monitoring. Furthermore, the study seeks to identify and analyse the challenges and ethical considerations associated with the adoption of AI/ML, such as algorithmic bias, explainability, and gaps in regulatory frameworks.

By systematically evaluating both the benefits and barriers of AI/ML integration, the research intends to provide actionable insights for stakeholders—ranging from trial sponsors and clinical research organizations to regulatory authorities—seeking to optimize compliance management and uphold the highest standards of data integrity and patient safety in oncology trials.

The objectives of the research are as follows:

- To identify AI/ML tools currently used for compliance and auditing in oncology trials.
- To evaluate the effectiveness of AI/ML systems in detecting protocol deviations, data discrepancies, and non-compliance events.
- To examine how AI/ML facilitates risk-based monitoring and predictive audit readiness.
- To investigate challenges in AI/ML adoption from a regulatory and ethical perspective.

1.2 **Research methodology:**

This research adopts a quantitative primary methodology, utilizing structured surveys as the main tool for data collection. The choice of a quantitative strategy is guided by the research objectives, which focus on identifying AI/ML tools in regulatory compliance and audit, evaluating their effectiveness, and understanding challenges as perceived by industry professionals. Quantitative surveys offer the advantage of collecting objective, measurable responses from a broad and diverse participant base, which can be statistically analysed and generalized to the wider field.

The survey instrument will comprise approximately 20 to 25 closed-ended questions designed in alignment with the research objectives. These questions will include multiple-choice, dichotomous (yes/no), and Likert scale items to comprehensively capture participants' experiences and perceptions regarding the adoption and impact of AI/ML systems in oncology clinical trials. The survey will be created using Google Forms, chosen for its accessibility, user-friendliness, and robust data management features. The link to the survey will be distributed via targeted emails and through professional and academic networks to maximise relevant participation.

Purposive sampling will be used to recruit participants who are professionals currently or recently involved in oncology clinical trials, particularly those with direct experience in regulatory compliance, clinical auditing, or the use of AI/ML technologies. Eligible roles include clinical trial coordinators, clinical research associates, regulatory affairs personnel, quality assurance specialists, and AI technology experts from both industry and academia. Exclusion criteria eliminate individuals without recent, relevant experience or without full professional responsibilities. Recruitment will occur through platforms such as LinkedIn, ResearchGate, and specialized healthcare forums, complemented by snowball sampling to further extend reach and ensure a robust, focused participant pool.

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
No

Research into politically and/or racially/ethnically and/or commercially sensitive areas
No

Sensitive, personal, professional or corporate issues No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants
No

Research that may negatively affect the reputation of Griffith College/Innopharma
No

Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English

No

Does your research group include any of the following vulnerable groups

No

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

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

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

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

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

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.

3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.

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

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study

The participant profile for this study comprises professionals who are currently or have recently been involved in oncology clinical trials, with direct experience in regulatory compliance, clinical auditing, or the implementation and use of AI/ML technologies in clinical research settings. Specific roles targeted include clinical trial coordinators, clinical research associates, regulatory affairs personnel, quality assurance specialists, and AI technology experts. Both industry and academic professionals are eligible, provided they are aged 18 or above and can provide informed consent. Individuals who do not meet these criteria—such as students, trainees, commercial representatives, or those without recent or direct relevant experience—are excluded to ensure the relevance and depth of the data collected.
The rationale for choosing this participant profile is directly tied to the study's objectives. The research aims to evaluate the real-world use, effectiveness, and perceived challenges of AI/ML systems in regulatory compliance and audit within oncology trials. Therefore, it is essential to gather perspectives from individuals who possess practical, hands-on experience and a thorough understanding of the operational, regulatory, and technological aspects of clinical research. This purposive sampling approach ensures that the responses are informed, credible, and specific to the core themes of the research. By focusing on this expert group, the study can produce findings that are not only statistically robust but also highly relevant for informing future practice and policy in oncology clinical trials. Recruitment through platforms like LinkedIn, ResearchGate, and specialised forums further ensures access to a qualified and diverse participant pool.

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

The primary method will be the distribution of an electronic survey link through professional platforms such as LinkedIn and ResearchGate. Targeted searches and direct messaging will be used to identify and contact individuals with relevant roles and experience in oncology clinical trials, regulatory compliance, and AI/ML applications. In addition, posts will be made in specialised online forums and groups dedicated to clinical research, regulatory affairs, and advancements in oncology.
Direct invitation emails will be sent to identified professionals, clearly outlining the purpose of the study, eligibility criteria, and the voluntary and confidential nature of participation. The survey introduction will include a participant information sheet and an informed consent statement. Snowball sampling will also be encouraged; whereby initial respondents will be asked to refer suitably qualified colleagues within their networks. This combined approach is designed to maximise response rates, ensure the inclusion of highly relevant participants, and facilitate efficient and ethical data collection. All outreach communications will be professional, concise, and compliant with GDPR regulations.

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

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

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

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

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

---

SECTION 6: STORAGE OF DATA

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

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

6.1. How will you store the research data and for how long? How will you manage data protection issues?

The research data will be stored securely in accordance with institutional and legal requirements for data protection and privacy. Survey responses collected via Google Forms will be downloaded and saved in encrypted, password protected One drive folder. Any identifying information will be excluded from the dataset to ensure participant anonymity and masked with codes. Data backups will be maintained on institutional cloud storage, with access strictly limited to researcher and supervisor.
The data will be retained for a period of one year following completion of the research, as per standard academic guidelines, to allow for any necessary verification or audit. After this retention period, all digital files will be permanently deleted, and any physical notes or printouts will be shredded. Data protection issues will be managed by ensuring compliance with the General Data Protection Regulation (GDPR) and institutional policies: no personal identifiers will be collected, participants will be fully informed about data handling and their rights, and all data will be processed strictly for research purposes only. Informed consent will include clear information about data storage, confidentiality, and the right to withdraw up until data analysis begins.

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?

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

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

9.2 Informed Consent Form (ICF) for participant N/A

9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*

Yes

9.4 Any other documents e.g. Non-Disclosure Agreement N/A

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

For Student:

STUDENT SIGNATURE: Gayathri Vuyyuru

DATE: 03/07/2025

SECTION 10: APPENDIX

Survey Questionnaire

1. **What is your primary role?**
   ☐ Clinical Trial Coordinator
   ☐ Clinical Research Associate
   ☐ Regulatory Affairs Personnel
   ☐ Quality Assurance Specialist
   ☐ AI Technology Expert
   ☐ Other
2. **Does your organization currently use any AI/ML tools for compliance or auditing in oncology trials?**
   ☐ Yes
   ☐ No
3. **Which of the following AI/ML tools have you used in your organization?** *(Select all that apply)*
   ☐ Machine learning-based data monitoring
   ☐ Natural language processing (NLP) for documentation
   ☐ AI risk-based monitoring platforms
   ☐ AI-powered image analysis
   ☐ Automated protocol deviation detection
   ☐ None
4. **How often are AI/ML tools used for compliance and audit processes in your organization?**
   ☐ Routinely
   ☐ Occasionally
   ☐ Rarely
   ☐ Never
5. **Who is primarily responsible for implementing or managing AI/ML systems in your clinical trials?**
   ☐ Internal IT/AI team
   ☐ External vendor
   ☐ Clinical operations staff
   ☐ Not sure
6. **For which compliance tasks are AI/ML tools most frequently used?** *(Select all that apply)*
   ☐ Protocol deviation detection

☐ Data validation
☐ Audit trail generation
☐ Risk assessment
☐ Data visualization
☐ Other

7. **How effective are AI/ML tools in detecting protocol deviations?**
   ☐ Not effective at all
   ☐ Slightly effective
   ☐ Moderately effective
   ☐ Very effective
   ☐ Extremely effective

8. **Compared to manual methods, have AI/ML systems reduced data discrepancies in your trials?**
   ☐ Yes
   ☐ No
   ☐ Not sure

9. **Which aspect has improved the most with AI/ML system adoption?**
   ☐ Compliance monitoring
   ☐ Audit efficiency
   ☐ Time management
   ☐ Error reduction
   ☐ No improvement observed

10. **How would you rate the accuracy of AI/ML-generated audit trails?**
    ☐ Very accurate
    ☐ Accurate
    ☐ Neutral
    ☐ Inaccurate
    ☐ Very inaccurate

11. **Have AI/ML systems helped to reduce human error in compliance or audit tasks?**
    ☐ Yes
    ☐ No

12. **Overall, how satisfied are you with the performance of AI/ML systems in compliance and audit?**
    ☐ Very dissatisfied
    ☐ Dissatisfied
    ☐ Neutral
    ☐ Satisfied
    ☐ Very satisfied

13. **Does your organization utilize AI/ML for risk-based monitoring in oncology trials?**
    - ☐ Yes
    - ☐ No
    - ☐ Not sure

14. **Which risk-based monitoring functions does AI/ML support in your trials?** *(Select all that apply)*
    - ☐ Risk identification
    - ☐ Predictive analytics
    - ☐ Automated alerts
    - ☐ Prioritization of monitoring
    - ☐ Data visualization dashboards
    - ☐ None

15. **How would you rate the impact of AI/ML on audit readiness?**
    - ☐ Highly negative
    - ☐ Somewhat negative
    - ☐ No impact
    - ☐ Somewhat positive
    - ☐ Highly positive

16. **Has the use of AI/ML reduced the time required for audit preparation?**
    - ☐ Yes
    - ☐ No
    - ☐ Not sure

17. **Which AI/ML features have been most helpful for audit readiness?** *(Select all that apply)*
    - ☐ Real-time data analysis
    - ☐ Automated reporting
    - ☐ Predictive alerts
    - ☐ Dashboard visualization
    - ☐ None

18. **Do you believe AI/ML-driven risk monitoring increases regulatory confidence?**
    - ☐ Yes
    - ☐ No
    - ☐ Not sure

19. **What challenges have you encountered with AI/ML implementation?** *(Select all that apply)*
    - ☐ Lack of regulatory clarity
    - ☐ Data privacy or security concerns
    - ☐ Technical complexity
    - ☐ Resistance from staff

☐ High cost
☐ Insufficient training
☐ No major challenges

20. **Are the AI/ML tools used in your organization adequately validated for regulatory compliance?**
☐ Yes
☐ No
☐ Not sure

21. **How would you rate the explainability (transparency) of the AI/ML tools you have used?**
☐ Not transparent at all
☐ Slightly transparent
☐ Moderately transparent
☐ Very transparent
☐ Completely transparent

22. **Have regulatory agencies requested additional information regarding AI/ML tools used in your audits?**
☐ Yes
☐ No
☐ Not applicable

23. **Do you believe current regulations are sufficient to address AI/ML use in clinical trial compliance and audit?**
☐ Yes
☐ No
☐ Not sure

24. **Would you recommend wider adoption of AI/ML systems for regulatory compliance in oncology trials?**
☐ Yes
☐ No
☐ Not sure

Participant Information Letter

Title of the Study: Exploring the Application of AI/ML Systems in Fostering Regulatory Compliance and Audit in Oncology Trials

I would like to invite you to take part in a research study. Before you decide, it is important for you to understand why this research is being done and what it will involve for you. Please read the information below carefully. If anything is unclear or you would like more information, please ask. Take your time to decide if you would like to take part.

My name is Gayathri Vuyyuru. I am a postgraduate student at Griffith College, working towards my Msc in Pharmaceutical Business and Technology. I am doing this study as part of my course.
We are doing this study to find out how artificial intelligence (AI) and machine learning (ML) tools are being used in compliance and audit processes in cancer clinical trials. We want to learn about the benefits and challenges of using these technologies from people who use them.

If you agree to take part, you will be asked to complete an online survey. This survey has about 24 questions and will take about 10–15 minutes. The survey will ask about your experience with AI and ML in oncology trial compliance and auditing. You will not be asked for your name or anything that can identify you.
Your participation will not affect your work in any way. There are no interviews or audio recordings in this study.

You have been invited because you work in, or have recently worked in, oncology clinical trials and have experience with compliance, audit, or AI/ML tools in this area. Your knowledge is important to help us understand how these technologies are used in real-life settings.

Taking part is completely voluntary. You can decide not to take part or to leave the study at any time, without any consequences. You can also skip any question you do not want to answer.

If you want to withdraw at any time, please contact:

Gayathri Vuyyuru

Phone: +353 89 942 7298

Mail: gayathri.vuyyuru@student.griffith.ie

There are no direct benefits or payment for taking part. The risks are very low. The only risk is if you feel uncomfortable answering any question; you may skip it or stop the survey at any time. Your information will be kept confidential and secure. The information you share will help us better understand the use of AI and ML in cancer trials, which may improve processes in the future.

Your answers will not include your name or any information that could identify you. All information will be kept private. Only the researcher will see the answers. If you mention someone else, their details will also be kept confidential.
The only time confidentiality may be broken is if there is a serious risk of harm to you or others, or if a serious crime is reported.

Your survey answers will be stored securely on a password-protected One drive folder. Only the researcher will have access to the data.
All consent forms and data related to the research will be stored till one year after completion of research.

The results will be written up as part of the completion of my dissertation. The dissertation will be available in the college library. The results may also be presented in future research presentations or articles, but no one will be able to identify you from any report.

If you have questions or need more information, please contact:

Researcher Details

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