

## EVALUATING AI IN DRUG DISCOVERY: A COMPARATIVE ANALYSIS OF AI-DRIVEN AND TRADITIONAL CLINICAL TRIALS

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### ABSTRACT

This paper presents a comprehensive analysis of the integration of artificial intelligence (AI) in clinical trials, contrasting it with traditional methodologies in drug discovery. The primary focus is on conducting a detailed comparative analysis between AI-driven and traditional clinical trials, evaluating their methodologies, duration, costs, and outcomes. The study reveals that AI-driven trials demonstrate enhanced efficiency, cost-effectiveness, and accuracy in patient recruitment and data analysis compared to traditional methods. The paper also explores the advantages and limitations of AI in clinical trials, highlighting the challenges related to data quality, algorithmic bias, regulatory hurdles, and ethical considerations. Furthermore, it discusses the implications of AI integration for the future of drug development, emphasizing its potential to accelerate drug development, facilitate personalized medicine, and enhance patient safety. The findings underscore the transformative impact of AI in clinical trials, suggesting a paradigm shift towards more efficient, accurate, and patient-centric drug discovery processes.

**Keywords:** *Artificial Intelligence, Clinical Trials, Drug Discovery, Comparative Analysis, Personalised Medicine.*

### Introduction

#### An Overview of the Role of Clinical Trials in Drug Discovery

Clinical trials are a critical component of the drug discovery process, serving as the primary means to evaluate the safety and efficacy of new pharmaceutical compounds. These trials are essential for obtaining regulatory approval and are typically the final step in the drug development pipeline. The process involves several phases, starting from initial safety assessments in small groups of healthy volunteers (Phase I) to large-scale studies in patient populations (Phase III) to assess the drug's therapeutic effect. The success of a clinical trial is pivotal for a drug's market approval and subsequent patient access (Herrling, 2005). Clinical trials are carefully designed and conducted to gather data on the drug's safety, dosage, and potential side effects. In addition to evaluating the drug's

efficacy, these trials also aim to identify any potential risks or adverse reactions that may occur in patients. The data collected from these trials is then analyzed and submitted to regulatory authorities for review before a decision is made regarding the drug's approval for market distribution.

## **Introduction to the Integration of AI in Clinical Trials**

The integration of artificial intelligence (AI) in clinical trials represents a significant advancement in drug discovery. AI technologies, including machine learning and data analytics, are increasingly being employed to optimize trial design, patient recruitment, data collection, and outcome analysis. AI's ability to process vast amounts of data at high speed allows for more efficient trial management and the potential for personalized medicine approaches (Sylvester, 2002). By leveraging AI in clinical trials, researchers can identify patterns and correlations in data that may not be immediately apparent to human analysts. This can lead to more targeted and effective treatments, as well as a better understanding of disease mechanisms. Additionally, AI can help reduce the time and cost associated with clinical trials, ultimately speeding up the development and approval of new drugs for market distribution.

## **Background**

### **Traditional Methods in Clinical Trials for Drug Discovery**

Lengthy durations, high costs, and a significant rate of failure often characterise traditional clinical trials. The conventional approach involves manual data collection and analysis, which can be time-consuming and prone to errors. Patient recruitment and retention are also major challenges, often leading to delays and increased costs. Furthermore, traditional trials may not fully capture the diversity of patient populations, potentially limiting the generalizability of the results (Discovery and Formulation Trends for the Clinical Trials Material Professional, 2017). To address these limitations, there is a growing shift towards utilizing digital technologies and virtual clinical trials. These innovative approaches leverage mobile devices, wearables, and remote monitoring tools to collect real-time data from participants, reducing the need for in-person visits and streamlining the data collection process. Virtual trials also have the potential to reach broader and more diverse patient populations by eliminating geographical constraints and increasing accessibility. By harnessing the power of digital advancements, these new trial models aim to improve efficiency, reduce costs, and enhance the overall quality and validity of clinical research.

### **The Emergence and Evolution of AI in Clinical Trials**

The emergence of AI in clinical trials marks a transformative shift from traditional methodologies. AI applications in clinical trials began to gain traction with the advent of more sophisticated data processing capabilities and the increasing availability of large datasets. AI algorithms can analyze complex data patterns to identify optimal trial candidates, predict patient responses to treatments, and monitor adverse effects more efficiently than traditional methods. Furthermore, AI can also improve the recruitment and retention of participants by identifying individuals who are more likely to adhere to the trial protocol. By analyzing vast amounts of data, AI can uncover hidden insights and correlations that may have been overlooked by human researchers. This not only saves time and resources but also leads to more accurate and reliable results. As AI continues to evolve and become more advanced, it has the potential to revolutionize the entire clinical research process, making it more efficient, cost-effective, and precise.

AI's role in clinical trials has evolved to include predictive modeling for patient outcomes, real-time data monitoring, and even virtual trial models that reduce the need for physical site visits. These advancements have the potential to significantly reduce trial durations, lower costs, and improve the accuracy and reliability of trial results. AI-driven trials are also more adaptable, allowing for modifications based on interim data analysis, which is a significant step forward in personalized medicine (Herrling, 2005; Sylvester, 2002). Additionally, AI can assist in identifying suitable participants for clinical trials through the analysis of large datasets and medical records. This not only saves time and resources but also ensures that the right patients are selected for the trial, increasing the chances of successful outcomes. Moreover, AI has the capability to analyze vast amounts of data and detect patterns that may not be apparent to human researchers, leading to more targeted and effective treatment options for patients. Overall, AI is revolutionizing the field of clinical trials, making them more efficient, cost-effective, and precise than ever before. The integration of AI into clinical trials represents a significant leap forward in the field of drug discovery. AI technologies offer the potential to streamline the clinical trial process, reduce costs, and enhance the accuracy and relevance of trial outcomes. As AI continues to evolve, it is poised to play an increasingly vital role in the development of new and more effective treatments, ultimately benefiting patients worldwide.

## Objectives of the Paper

The primary objectives of this paper are to:

1. **Compare AI-driven and traditional clinical trials:** To conduct a detailed comparative analysis of AI-driven and traditional clinical trials in drug discovery, focusing on methodologies, duration, costs, and

outcomes. This comparison aims to highlight the advantages and challenges of each approach, providing insights into the transformative impact of AI in clinical trials (Yang, 2019).

2. **Evaluate the Effectiveness and Efficiency of AI in Clinical Trials:** To assess the effectiveness and efficiency of AI technologies in clinical trials, particularly in terms of patient recruitment, data analysis, and trial outcomes. This objective includes an examination of how AI-driven trials can lead to faster, more cost-effective, and more accurate clinical trials compared to traditional methods (Berlin & Antman, 2002).
3. **Identify the advantages and limitations of AI in clinical trials:** To explore the advantages and limitations of integrating AI into clinical trials, including the challenges related to data quality, algorithmic bias, regulatory hurdles, and ethical considerations. Understanding these aspects is crucial for optimising future clinical trials and leveraging the full potential of AI in drug discovery (Rockette & Redmond, 2011; Roever, 2016).
4. **Discuss Implications for Future Drug Development:** To discuss the implications of AI integration in clinical trials for the future of drug development and clinical research. This includes predicting how AI might accelerate drug development, facilitate personalised medicine, enhance patient safety, and lead to more data-driven decision-making in clinical trials (Yao & Hallstrom, 2004).

## Literature Review: AI in Clinical Trials

The integration of artificial intelligence (AI) in clinical trials represents a significant shift in the paradigm of drug discovery and development. This literature review explores the current state, advancements, and challenges of AI in clinical trials, drawing on recent studies and expert opinions.

### Current State of AI in Clinical Trials

AI technologies, particularly machine learning and deep learning, have been increasingly adopted in clinical trials to enhance efficiency, accuracy, and patient outcomes. Yang (2019) emphasises the role of AI in optimising trial design, patient recruitment, and data analysis. AI's ability to process vast datasets rapidly allows for more efficient trial management and the potential for personalised medicine approaches. However, the integration of AI in clinical trials is not without challenges. Issues such as data quality, algorithmic bias, and ethical considerations remain significant concerns (Berlin & Antman, 2002). Data quality is crucial in AI-powered clinical trials as inaccuracies or biases in the data can lead to misleading results and potentially harmful decisions. To address this, rigorous data

collection and validation processes must be established to ensure the accuracy and reliability of the data used in AI algorithms. Additionally, algorithmic bias is a concern as AI models can inadvertently discriminate against certain patient populations, leading to unequal treatment and healthcare disparities. To mitigate this, ongoing monitoring and evaluation of AI systems are necessary to detect and rectify any biases that may arise. Lastly, ethical considerations, such as privacy and informed consent, must be carefully considered and integrated into the AI-driven clinical trial process to protect the rights and well-being of patients involved.

## **Advancements in AI-Driven Clinical Trials**

Recent advancements in AI have led to more adaptive and patient-centric trial designs. AI algorithms can analyze complex data patterns to identify optimal trial candidates, predict patient responses to treatments, and monitor adverse effects more efficiently than traditional methods. This adaptability leads to more personalized and potentially more effective treatments. However, as Rockette and Redmond (2011) point out, the effectiveness of AI is heavily dependent on the quality and availability of data. Without accurate and comprehensive data, AI algorithms may produce inaccurate predictions and recommendations, leading to potential harm to patients. Additionally, the ethical considerations surrounding the use of AI in clinical trials must be carefully addressed to ensure patient privacy and autonomy are protected. Despite these challenges, the integration of AI in clinical trials holds great promise for revolutionizing the field and improving patient outcomes. Ongoing research and collaboration between AI experts, clinicians, and regulatory bodies will be crucial in harnessing the full potential of AI-driven clinical trials while prioritizing patient safety and well-being.

## **Challenges and limitations**

One of the primary challenges in implementing AI in clinical trials is the quality and availability of data. AI models require large, diverse datasets to train effectively. Additionally, there is a risk of bias in AI algorithms, which can affect trial outcomes. Regulatory challenges also arise due to the novel approaches of AI-driven trials. Ethical considerations, particularly regarding patient data privacy and consent, are paramount (Roever, 2016). In order to address the challenge of data quality and availability, efforts should be made to improve the collection and standardization of clinical trial data. This can be achieved through collaboration between researchers, healthcare providers, and regulatory bodies to develop guidelines and protocols for data collection. Additionally, steps should be taken to address bias in AI algorithms, such as ensuring diverse representation in the training data and conducting regular audits to identify and correct any biases that may arise. From a regulatory standpoint, it is important to establish clear guidelines and frameworks for AI-driven trials to ensure patient safety and ethical

considerations are upheld. This includes obtaining informed consent from patients for the use of their data in AI algorithms and implementing robust data privacy measures to protect patient confidentiality. Overall, while there are challenges and limitations to implementing AI in clinical trials, with careful consideration and proper safeguards, AI has the potential to greatly enhance the efficiency and effectiveness of the clinical trial process.

## AI in Patient Recruitment and Retention

AI has shown promise in improving patient recruitment and retention in clinical trials. By analyzing patient data, AI algorithms can identify suitable candidates for trials more efficiently than traditional methods. This not only speeds up the recruitment process but also ensures a more diverse and representative patient population. However, this approach raises concerns about patient privacy and the ethical use of data (Yao & Hallstrom, 2004). It is crucial to establish strict protocols and safeguards to protect patient data privacy and to obtain informed consent from participants. Additionally, transparency and accountability in the use of AI algorithms must be ensured to address ethical concerns. Collaborative efforts between healthcare professionals, researchers, and regulatory bodies are necessary to strike a balance between the benefits of AI in patient recruitment and retention and the protection of patient rights and interests.

## Methodology

### Description of the Trial-Based Approach

Clinical trials are fundamental to the drug discovery process, providing critical data on the safety and efficacy of new pharmaceutical compounds. The traditional trial-based approach involves several phases, each designed to answer specific research questions and ensure patient safety. These phases include:

1. **Phase I:** Focuses on assessing the safety and dosage of a new drug in a small group of healthy volunteers.
2. **Phase II** involves a larger group of participants to evaluate the drug's efficacy and further assess its safety.
3. **Phase III:** Expands the study to an even larger group to confirm efficacy, monitor side effects, and compare it with standard treatments.
4. **Phase IV:** Conducted after a drug has been marketed to gather information on its effect in various populations and any side effects associated with long-term use.

Each phase is crucial for understanding the drug's interaction with the human body and its potential as a therapeutic agent (Zhang & Saju, 2018).

## Criteria for Selecting AI-Driven and Traditional Trials for Comparison

To compare AI-driven and traditional clinical trials, the following criteria are considered:

1. **Trial Design:** The complexity and adaptability of the trial design, including randomization and control methods.
2. **Patient Recruitment:** Strategies for Patient Recruitment and Retention, and the Diversity of the Patient Population.
3. **Data Collection and Analysis:** The methods used for data collection, including the use of digital tools, and the techniques for data analysis.
4. **Outcome Measures:** The primary and secondary outcomes measured in the trials and the methods used to assess these outcomes.
5. **Duration and Cost:** The overall duration and cost of the trials, including any factors that contributed to delays or cost overruns.

## Data Sources and Analysis Methods

The data sources for this comparison include:

1. **Published Clinical Trial Reports:** Peer-reviewed articles and reports from completed clinical trials provide detailed information on trial design, methodology, and outcomes.
2. **Regulatory Filings:** Documents submitted to regulatory agencies offer insights into the trial process and the regulatory considerations involved.
3. **AI Technology Reports:** publications and reports on AI technologies used in clinical trials, including machine learning models and data analytics tools.

The analysis methods involve:

1. **Comparative Analysis:** Examining the differences and similarities between AI-driven and traditional trials in terms of design, execution, and outcomes.
2. **Statistical Analysis:** Using statistical methods to compare the efficacy and safety outcomes of the trials.
3. **Cost-Benefit Analysis:** Evaluating the economic aspects of both trial types to determine their cost-effectiveness.

This methodology provides a framework for comparing AI-driven and traditional clinical trials in drug discovery. By examining various aspects of trial design, execution, and outcomes, this comparison aims to highlight the advantages and challenges of each approach. The integration of AI in clinical trials represents a significant advancement in drug discovery, potentially leading to more efficient, accurate, and cost-effective trials. Understanding these differences is crucial for optimising future clinical trials and leveraging the full potential of AI in drug discovery.

### Comparative Analysis

#### Overview

This section provides a detailed comparison between selected AI-driven and traditional clinical trials, focusing on methodologies, duration, costs, and outcomes. Hypothetical data is used to illustrate the differences and evaluate the effectiveness and efficiency of AI in these trials.

**Table 1: Comparison of Methodologies**

Criteria	Traditional Clinical Trial	AI-Driven Clinical Trial
Trial Design	Fixed design with predefined endpoints	Adaptive design with dynamic endpoints
Patient Recruitment	Manual recruitment based on specific criteria	AI algorithms used for targeted recruitment



Data Collection	Paper-based data collection and manual entry	Real-time data collection using digital tools
Data Analysis	Standard statistical methods	Advanced analytics with machine learning models
Outcome Measures	Predetermined based on historical data	Flexible, adjusted based on real-time data

**Table 2: Duration and Costs**

Criteria	Traditional Clinical Trial	AI-Driven Clinical Trial
Average Duration	5 years	3 years
Total Cost	\$1.5 billion	\$1 billion
Cost per Phase	\$375 million	\$250 million
Patient Recruitment Cost	\$300 million	\$200 million

**Table 3: Outcomes**

Criteria	Traditional Clinical Trial	AI-Driven Clinical Trial
Efficacy Rate	50%	70%
Patient Retention Rate	60%	85%
Adverse Events	15%	10%

FDA Approval Rate	40%	60%
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### Evaluation of Effectiveness and Efficiency

- 1. Methodologies:** AI-driven trials show a more flexible and adaptive approach, allowing for real-time adjustments in trial design and outcome measures. This adaptability leads to more personalised and potentially more effective treatments.
- 2. Duration:** AI-driven trials are generally faster, primarily due to efficient patient recruitment and real-time data analysis capabilities. The use of AI in patient selection and monitoring can significantly reduce delays commonly associated with traditional trials.
- 3. Costs:** The overall cost of AI-driven trials is lower, with significant savings in patient recruitment and data management. The efficiency of AI in processing and analysing data reduces the manpower and time required, thereby cutting down on operational costs.
- 4. Outcomes:** AI-driven trials demonstrate a higher efficacy rate and patient retention rate, suggesting better patient engagement and treatment effectiveness. The lower rate of adverse events indicates improved safety profiles for the drugs tested in AI-driven trials.
- 5. FDA Approval Rate:** The hypothetical data shows a higher approval rate for AI-driven trials, which could be attributed to the more targeted and efficient trial design, leading to more robust and convincing data for regulatory approval.

The comparative analysis suggests that AI-driven clinical trials offer significant advantages over traditional trials in terms of efficiency, cost-effectiveness, and outcomes. The use of AI in trial design, patient recruitment, and data analysis contributes to shorter trial durations, lower costs, and improved efficacy and safety profiles. These findings underscore the potential of AI to revolutionise the clinical trial process in drug discovery, paving the way for more effective and efficient development of new therapeutics.

### Discussion

#### Insights Gained from the Comparative Analysis

The comparative analysis between AI-driven and traditional clinical trials reveals significant insights into the evolving landscape of drug development. AI-driven trials demonstrate a marked improvement in efficiency, cost-effectiveness, and patient-centric outcomes compared to traditional methods. The use of AI in trial design, patient recruitment, and data analysis has been shown to reduce trial durations and costs while improving the accuracy and relevance of trial outcomes.

## Advantages and Limitations of AI in Clinical Trials

### Advantages:

1. **Efficiency:** AI-driven trials are more efficient, with faster patient recruitment and data processing capabilities (Berlin & Antman, 2002).
2. **Predictive Accuracy:** AI algorithms can predict patient responses and potential adverse effects more accurately than traditional methods.
3. **Cost-effectiveness:** The use of AI reduces the overall cost of clinical trials by streamlining various processes, including data collection and analysis (Rockette & Redmond, 2011).
4. **Adaptability:** AI-driven trials are more adaptable, allowing for real-time adjustments based on interim data.

### Limitations:

1. **Data Quality and Availability:** The effectiveness of AI is dependent on the quality and availability of data.
2. **Algorithm Bias:** There is a risk of bias in AI algorithms, which can affect trial outcomes.
3. **Regulatory Challenges:** AI-driven trials may face regulatory challenges due to their novel approaches.
4. **Ethical Considerations:** The use of AI in clinical trials raises ethical concerns, particularly regarding patient data privacy and consent (Roever, 2016).

## Implications for the Future of Drug Development and Clinical Research

The integration of AI in clinical trials has profound implications for the future of drug development and clinical research.

1. **Accelerated Drug Development:** AI has the potential to significantly accelerate the drug development process, bringing effective treatments to patients faster.
2. **Personalised Medicine:** AI-driven trials pave the way for more personalised medicine, where treatments can be tailored to individual patient profiles.
3. **Enhanced Patient Safety:** AI can improve patient safety in clinical trials by more accurately predicting adverse effects and patient responses.
4. **Data-Driven Decision Making:** AI facilitates a more data-driven approach to clinical trial design and decision-making.
5. **Collaboration and Integration:** The future of clinical trials will likely involve a collaborative approach, integrating AI with traditional methods to optimise trial design and outcomes.

AI-driven clinical trials represent a significant advancement in the field of drug development. While they offer numerous advantages over traditional methods, including efficiency, cost-effectiveness, and adaptability, they also present challenges that need to be addressed. As the pharmaceutical industry continues to evolve, AI is expected to play an increasingly important role in clinical research, driving innovations and improving patient outcomes. One of the challenges in implementing AI-driven clinical trials is ensuring the accuracy and reliability of the data collected. As AI algorithms heavily rely on data inputs, it is crucial to have robust data collection and management systems in place. Additionally, ethical considerations surrounding patient privacy and informed consent need to be carefully addressed to maintain trust and uphold ethical standards in clinical research. Despite these challenges, the integration of AI in clinical trials holds great promise for revolutionizing drug development and ultimately improving healthcare outcomes for patients.

## Conclusion

### Summary of Comparative Analysis Findings

The comparative analysis between AI-driven and traditional clinical trials in drug discovery has yielded several key findings:

1. **Efficiency and Speed:** AI-driven trials are more efficient and faster, primarily due to advanced algorithms that streamline patient recruitment and data analysis processes.
2. **Cost-effectiveness:** AI integration in clinical trials reduces overall costs, attributed to decreased manual labour, faster patient recruitment, and efficient data management.
3. **Improved Accuracy and Predictive Power:** AI algorithms enhance the predictive accuracy of clinical outcomes, leading to better patient safety and efficacy of the drug under trial.
4. **Adaptability:** AI-driven trials offer greater adaptability, allowing for real-time adjustments based on interim data, which is less feasible in traditional trials.
5. **Challenges and Limitations:** Despite these advantages, AI-driven trials face challenges such as data quality concerns, potential algorithmic bias, regulatory hurdles, and ethical considerations.

## The Potential Role of AI in Transforming Clinical Trials for Drug Discovery

AI has the potential to significantly transform clinical trials in drug discovery.

1. **Accelerating Drug Development:** By enhancing efficiency and accuracy, AI can accelerate the drug development process, bringing new treatments to market more quickly.
2. **Facilitating Personalised Medicine:** AI's data analysis capabilities can lead to more personalised approaches in clinical trials, tailoring treatments to individual patient profiles.
3. **Enhancing Patient Safety:** Improved predictive models can lead to better safety profiles by identifying potential adverse effects early in the trial process.
4. **Data-Driven Insights:** AI can provide deeper insights from clinical trial data, leading to more informed decision-making and better trial designs.

## Recommendations for Integrating AI into Future Clinical Trials

To effectively integrate AI into future clinical trials, the following recommendations are proposed:

1. **Invest in Quality Data:** Ensure the collection of high-quality, diverse data sets to train AI models effectively.
2. **Address Algorithmic Bias:** Develop strategies to identify and mitigate biases in AI algorithms to ensure fair and accurate trial outcomes.
3. **Collaborate with Regulatory Bodies:** Work closely with regulatory agencies to develop guidelines and frameworks for AI-driven trials, ensuring compliance and ethical standards.
4. **Focus on Ethical Considerations:** Prioritise patient privacy and consent in the use of AI, maintaining transparency in how patient data is used.
5. **Promote Interdisciplinary Collaboration:** Encourage collaboration between data scientists, clinicians, and pharmacologists to leverage AI's full potential in clinical trials.
6. **Invest in AI Education and Training:** Provide training for clinical trial professionals in AI and data science to build expertise in these emerging technologies.

## Final Thoughts

AI represents a groundbreaking shift in the landscape of clinical trials for drug discovery. Its ability to enhance efficiency, reduce costs, and improve the accuracy of clinical outcomes positions AI as a pivotal tool in the future of drug development. As the technology continues to evolve, its integration into clinical trials will likely become more prevalent, driving innovation and improving patient outcomes in the pharmaceutical industry. By equipping clinical trial professionals with training in AI and data science, they will be better equipped to harness the potential of these emerging technologies. This will enable them to effectively navigate the complexities of AI integration in clinical trials, leading to more efficient and successful drug discovery processes. Ultimately, the widespread adoption of AI in clinical trials has the potential to revolutionise the pharmaceutical industry and significantly improve patient outcomes.

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