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Hazim Abdul Rahman Alhiti *

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Review Article

AI Improves Clinical Trials

Hazim Abdul Rahman Alhiti *

General Surgeon Specialist M.D,Al-Ramadi Teaching Hospital

***Correspondence Author:** Hazim Abdul Rahman Alhiti, General surgeon specialist in Alrahma private Hospital- Baghdad

Received Date: Jun 20, 2023 | Accepted Date: July 10, 2023 | Published Date: July 22, 2023

Citation: Rahman Alhiti HA, (2023), AI Improves Clinical Trials, *Clinical Trials and Case Studies*, 2(4); **DOI:**10.31579/2835-835X/033

Abstract

Background: AI has the capability to do tasks that require humans, like problem-solving, and decision-making.

Aim of the work: This is a mini-review of the effect of AI in clinical trials.

Methods: The author searches deeply for AI definition uses and limitations in clinical trials over their historical development in the academic search engine Google Scholar.

Conclusion: AI greatly enhances clinical trials but has many limitations. It is an excellent tool in the hand of medical researchers.

Keywords: ai; artificial intelligence; improve; clinical trials

Introduction

Clinical trials are research studies that involve human participants to evaluate the safety and effectiveness of new medical treatments, therapies, and interventions. The main aim of a clinical trial is to gather information about the potential benefits and risks of a medical intervention under controlled conditions, with the ultimate goal of providing evidence to support or reject its use in clinical practice. Clinical trials are governed by strict ethical and scientific standards, and can only be conducted with the informed consent of participants. The results of clinical trials are carefully evaluated by regulatory agencies, such as the FDA in the United States before new treatments or interventions are approved for use in the general population (Gaudino M., 2020) Clinical trials are critical in determining the safety and efficacy of new drugs, vaccines, and medical devices before they are released to the general public. They help to evaluate the potential benefits and risks of medical interventions and guide healthcare professionals in making evidence-based treatment decisions. Clinical trials play a vital role in advancing medical science, promoting innovation in medicine, and creating new treatment options for individuals with existing medical conditions. They provide significant opportunities to assess the effectiveness of new treatments, identify potential side effects, and improve current therapies. Clinical trials advance public health by providing data on the safety and efficacy of new treatments that can be used to inform healthcare policy and clinical practice. They shape healthcare policies and guidelines by providing evidence-
based information that can improve patient outcomes and reduce healthcare costs (Lambden S., 2019). This is a mini-review of the effect of AI in clinical trials. Participation in clinical trials allows individuals to play an active role in their own
healthcare and contribute to the development of new treatments that can benefit future generations. Clinical trials provide access to potentially life-saving treatments that may not yet be widely available (Mark D., 2019). There are many kinds of clinical trials like prevention trials, treatment trials, screening trials, supportive care trials, diagnostic trials, genetics trials, and behavioural trials (Campbell B., 2023). Clinical trials have evolved over time to become the gold standard for evaluating the safety and efficacy of new medical treatments. Clinical trials have undergone significant development over time, with an increasing emphasis on standardization, transparency, and evidence-based practice (DeVito N., 2020).

There is a step-ladder historical development in the evolution of clinical trials:

1. Ancient primitive trials: these trials of ancient civilizations all over the world like in Iraq, Egypt, Chinese, and Greece. They based on their observations and simple design.
2. Islamic heritage: Many Islamic researchers utilized medical trials on them patients by herbal medicine or acupuncture, even by surgical procedures like Abu al-Qasim Al- Zahrawi, a medieval surgeon from the Andalusian region.
3. Early Observational Trials: The earliest medical studies date back to the 1700s when James Lind conducted a trial to test the efficacy of different treatments for scurvy.
4. Observational trials in the 1800s and early 1900s also helped to lay the foundation for modern clinical trials.
5. Controlled Trials: In the mid-1900s, controlled clinical trials became more common, with randomized allocation of participants to control groups and experimental groups that received the treatment being studied.
6. Double-Blind Trials: In the 1940s, double-blind trials were introduced, where neither the participants nor the researchers knew which group was receiving the experimental treatment or the placebo.
7. Standardization of Clinical Trials: In the 1960s, the World Health Organization (WHO) and other organizations developed guidelines and standardized protocols for clinical trials, which helped to improve the quality and consistency of trials worldwide.
8. The Rise of Evidence-Based Medicine: In the 1990s, evidence-based medicine emerged as a new paradigm for medical practice, with clinical trial data being used to inform medical decisions.

9. Advancements in Technology: More recently, advancements in technology have allowed for faster and more efficient data collection and analysis, as well as the use of telemedicine to enable remote monitoring of patients in clinical trials (Özdemir V., 2021).

Clinical trials are complex and challenging, and there are several difficulties that can arise during the trial process. Clinical trials require careful planning, attention to detail, and a significant investment of time and resources to overcome these challenges. There are common challenges encountered in clinical trials like adherence to protocol, recruitment of participants, ethical issues, cost and funding, data management, subjectivity of endpoints, and regulatory compliance which can create additional complexities and delays in the trial process (Clark L., 2019). Clinical trials can take several years to complete and can involve several thousand patients. They are conducted under strict guidelines and regulations to ensure the safety of participants and the integrity of the data collected. They are typically in four phases, each of which are specific for a study design (Laursen D., 2019). The World Health Organization (WHO) provides ethical and scientific guidelines for conducting clinical trials. These guidelines are intended to ensure that the rights, safety, and well-being of trial participants are protected and that the trial results are reliable and credible. These guidelines are regularly updated by WHO to ensure that they reflect the latest developments in clinical research, and to ensure that they continue to provide comprehensive and relevant guidance for regulators. The WHO guidelines include: ethical considerations, scientific considerations, regulatory requirements, monitoring and

oversight, transparency and dissemination of results, adherence to clinical practice, and scientific community (Kendall T., 2021). There are several types of clinical trials, each designed to answer different research questions and to evaluate different aspects of a treatment or intervention. The specific type of trial used depends on the research question being asked, the goals of the trial, and the characteristics of the treatment or intervention being studied. The principal kinds of clinical trials include randomized controlled trials (RCTs), observational trials, cross-over trials. These are some of the main types of clinical trials, but there are others as well (Brown D., 2022). Clinical trials are complex endeavors, and despite the best efforts of researchers, errors can occur. It is important for clinical trials to be designed and conducted in a way that minimizes the errors, and for researchers to be transparent about any limitations or shortcomings in their research. This helps to ensure that the results of clinical trials are

accurate, and reliable for clinical practice. The common errors in clinical trials include: selection bias, measurement bias, confounding variables bias, type I and type II errors, publication bias, adverse events bias, and addressing bias is critical bias (Wang H., 2023). Artificial Intelligence or AI signifies the capability of computers to carry out tasks that typically require human intelligence, such as learning, problem-solving, decision-making, and understanding natural language. It involves the development of logical algorithms and computerized programs to analyze data, recognize intended patterns, and make suggestions. The aim of AI is to utilize intelligent computers to think and innovate as humans, with the ultimate objective of making machines that can operate autonomously and improve themselves over time (Gillath O., 2021).

AI possesses many uses, such as home services, personal aid, financial aspects, educational purposes, customer aid, and manufacturing assistance. AI has a wide range of applications that can improve efficiency, productivity, and decision-making across many industries and sectors (Borges A., 2021).AI has different utilizations in medicine, such as personalized medicine, medical image analysis, virtual assistants, drug discovery, surgical assistance, remote monitoring, and clinical decision-making. AI has the potential to make healthcare more efficient, effective, and personalized, ultimately improving patient outcomes and transforming the way healthcare is delivered (Paul D., 2021). AI has the ability to revolutionize research by making it faster, more precise, and logically accurate. AI-enabled research has the potential to significantly reduce the time and cost involved in conducting research and to produce more precise and accurate results. There are many uses of AI in research such as image and signal analysis, drug discovery, Robotic uses, natural language processing, intelligent systems, and predicting outcomes (Harrer S., 2019).

There are several advantages of using AI for clinical trial design, including:

1. Better data analysis: AI can analyze large amounts of data quickly and accurately, enabling researchers to identify trends and relationships that may be missed using traditional methods.
2. Improved patient selection: AI algorithms can analyze vast amounts of data to identify patients who are most likely to benefit from a particular treatment. This helps to ensure that clinical trials are more efficient and effective.
3. Speeding up the process: AI can automate many of the steps involved in clinical trial design, including patient recruitment, data analysis, and adverse event detection. This can significantly reduce the time it takes to complete clinical trials and bring new treatments to market.
4. Improved accuracy and reliability: AI algorithms can help to eliminate human error and bias, which can improve the accuracy and reliability of clinical trial results.
5. Cost savings: By reducing the time and resources required for clinical trials, AI can help to reduce costs and improve the overall efficiency of the drug development process (Park S., 2022). There are certain limitations of AI in clinical trials that should be considered, like:

1. Exclusion of Certain Populations: AI models can only provide recommendations based on the available data, which may not capture the nuances of certain populations or conditions which may be underrepresented in clinical trial data.
2. Limited Data Availability: One of the primary limitations of AI in clinical trials is the lack of access to reliable and comprehensive data. The quality and quantity of data available to AI models can significantly impact the accuracy of their predictions and recommendations.
3. Data Privacy and Security Concerns: Since clinical trial data often contains sensitive information about patients, there are concerns about data privacy and security. There is a potential risk of data breaches and cyberattacks that can compromise patient data, which could impact the ethical implications of clinical trials.
4. Bias: AI models are only as good as the data that they are trained on, and if the data is biased, the AI model can generate biased predictions. There is a risk that AI models trained on historical data could replicate past biases and inequalities.
5. Regulatory Challenges: The use of AI in clinical trials is still considered an evolving field, and there are regulatory challenges that need to be addressed in terms of validating AI models and ensuring their suitability for clinical use.
6. Limited Human Expertise: AI models in clinical trials can only provide recommendations based on data analysis. The interpretation and decision-making based on the recommendations still require human expertise (Desai A., 2020).

Conclusions:

AI can be a valuable tool in clinical trials, but its limitations should be considered, and more research is needed to develop effective AI models that can support clinical trial research.

Results: AI is an excellent tool that helps medical researchers to think, choose, design, and arrange the data statistically and overcome difficulties in clinical trials.

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