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AI Innovation in Clinical Trials: A Game – Changer for Health Care

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ABSTRACT

The most trustworthy way to demonstrate the efficacy and security of a treatment or clinical strategy is through clinical trials, which also offer crucial data that informs health policy and medical practice. Clinical research conducted today require a lot of labour, costly, complicated, and subject to biases such as socioeconomic, racial, and gender bias. Poor patient cohort selection and recruitment strategies, along with ineffective patient monitoring in the course of experiments, two of the primary reasons due to significant trial failure rates. Companies or appropriate healthcare facilities are currently using patient-centric strategies to find and interact with trial subjects. Digital resources (such as social media and mobile apps) and cooperation can be used to build a feasible pattern of patient-centric trials that will increase participant diversity, lessen patient burden enhance the availability of clinical trials, and hasten the approval of ground-breaking treatments. The application of artificial intelligence (Artificial intelligence)-enabled technology and real-world data (RWD), or data scientifically from several sources, in the healthcare industry has begun to change clinical trial methodology in recent years. This has allowed for the redesign of important phases in the clinical trial design process. Here, we talk about how Artificial intelligence might change how clinical trials are conducted in the future.

Keywords: *Artificial intelligence; Clinical trials; Digital resources; Health care.*

1.0 Introduction

Issues with growing costs and diminishing outcomes are plaguing global healthcare systems. This presents a "wicked problem" for those in charge of overseeing healthcare systems; it has multiple roots, is hard to understand and explain, and necessitates a multifaceted solution.

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Drug research requires clinical trials, and AI technology has the potential to revolutionize this field as it has in other areas. Such AI-clinician collaboration, in which AI is utilized to give the clinician thorough, evidence-based clinical decision assistance, may present significant prospects for improving healthcare services. Over the past ten years, artificial intelligence (AI) has gained widespread acceptance in the field of medicine. This is demonstrated by the fact that more and more medical gadgets with inbuilt AI algorithms are now on the market (Kurariya *et al.*, 2023).

AI has the potential to improve clinical trial stages while reducing the strain and expense of clinical development. Therapeutic trials offer crucial evidence to direct medical practice and health policy and are the most reliable method of demonstrating the safety and efficacy of a treatment or therapeutic approach. In an effort to further clinical research, numerous sizable clinical research firms are now starting to invest in AI. Artificial intelligence has the potential to enhance the efficacy of the search for correlations between biomarkers and indications. This could help identify lead compounds with a better chance of success in clinical development. It offers the chance to change crucial stages of conducting clinical trials, like planning, designing, and carrying out the study. To increase recruitment, Machine learning, Deep Learning, Natural Language Processing, and Optical Character Recognition can be used to link huge and diverse datasets, such as clinical trial databases, published medical literature, and electronic medical records (EMRs), by matching patient traits to selection criteria (Pachiappan *et al.*, 2023).

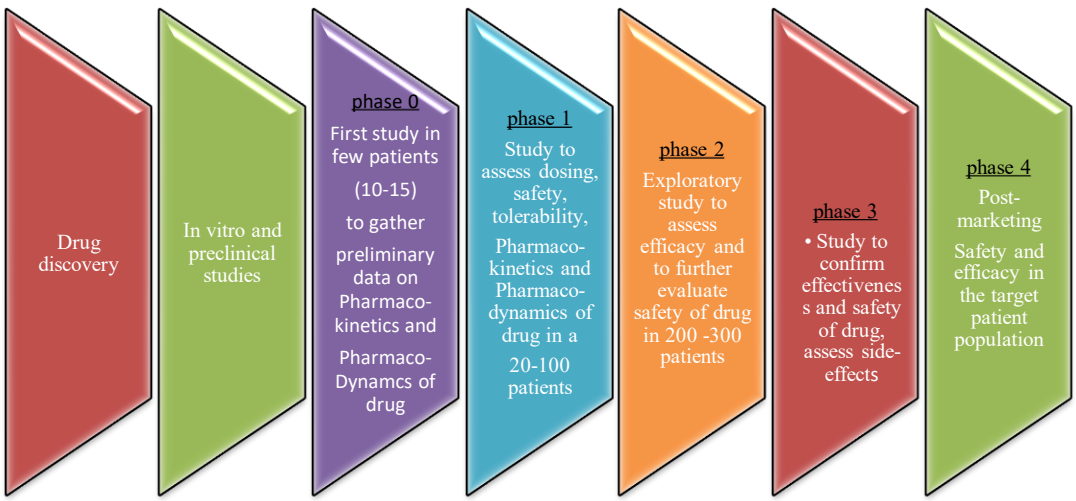
AI seems to provide a novel approach, especially in light of how difficult it is to develop clinical trials. Artificial intelligence plays a significant role in the development, extraction, analysis, and refinement of data used in the healthcare industry's predictive models. Artificial Intelligence) use in enhancing the data-driven methodology in clinical pathway development and execution offers significant proof of its possible integration into clinical trial planning. Therefore, scientists in academia and the pharmaceutical sector are using methods for artificial intelligence such as natural language processing, deep learning, and machine learning to enhance clinical trials (Cascini *et al.*, 2022). The best method to show a treatment's effectiveness and safety is through clinical trials, which also offer crucial data that informs medical practice and public policy. Present-day clinical studies are labour-intensive, costly, complicated, and maybe biased (i.e., based on socioeconomic, racial, or gender identity). Defective patient cohort selection and recruitment procedures, together with inadequate patient monitoring during trials, are two major reasons for high trial failure rates (Zhang *et al.*, 2023). In the past few years, artificial intelligence has become increasingly important in the pharmaceutical sector. The possibilities and promise of artificial intelligence in clinical research are enormous. It's one of the newest and most sophisticated technologies that is changing clinical trials. A strong technological foundation

for artificial intelligence has been provided to the healthcare sector by the swift progress of information technology and the extensive gathering of biomedical data. Researchers are investigating the use of artificial intelligence in applications to enhance the quality of medical services and diagnostic accuracy, while also reducing the risk and complexity of clinical trials. Clinical research done the old-fashioned way takes a long time and has a 10% success rate. Artificial intelligence is currently being used in a number of clinical trial processes.

Artificial Intelligence can assist researchers in carrying out a clinical study, utilizing real-world data analysis to enhance patient classification and forecast outcomes. Artificial intelligence has the potential to enhance the efficacy of the search for correlations between biomarkers and indications. This could help identify lead compounds with a better chance of success during the clinical development phase. It offers the chance to change important stages of conducting clinical trials, like planning, designing, and carrying out the study. Utilizing artificial intelligence -based techniques to execute the first three rounds of clinical trials with a patient recruiting focus.

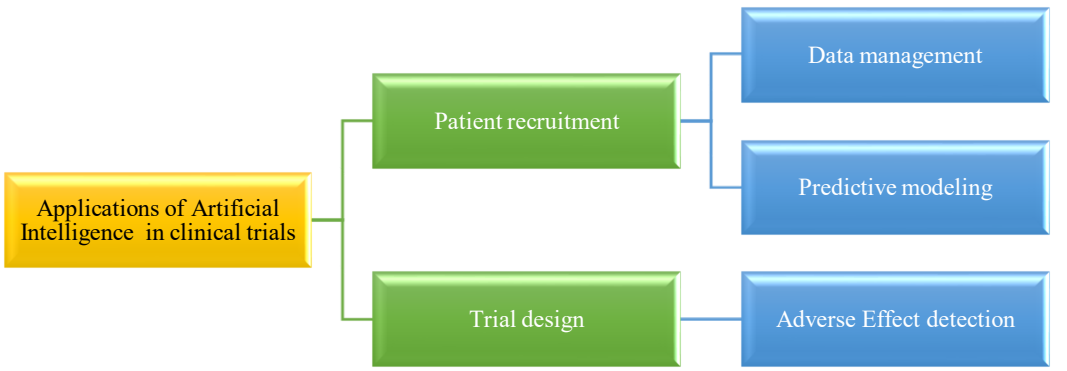
With regard to clinical trial design, we specifically want to draw attention to the most pertinent elements impacted by this breakthrough, as well as the usefulness of these artificial intelligence tools and how they impact the outcome of clinical trials. Furthermore, we sought to ascertain real-world Artificial intelligence application instances (Kurariya *et al.*, 2023; Sollini *et al.*, 2023). Clinical trial research is essential to screening these four phases since developing new drugs for the purpose of screening novel molecules is required as per follows. The steps for developing a new drug a per are as follows:

Figure 1: Phases of Clinical Trials



Artificial intelligence offers several benefits in clinical trials, including faster recruitment, improved data management, predictive analytics, enhanced accuracy, improved efficiency, and cost savings. Artificial intelligence is mostly used in drug development to screen novel compounds for therapeutic applications and those that demonstrate pharmacological effects. Although advantages come with several drawbacks, these are the main ones. Design constraints, problems with integration in healthcare, legal obstacles, and moral ramifications.

Figure 2: Application of Artificial Intelligence in Clinical Trials



In order to improve clinical trial design and foster clinical transformation, this article will offer a thorough overview of the ways in which artificial intelligence (AI) is being used to improve clinical trials and make them safer, more efficient, and more useful (Sollini *et al.*, 2023).

2.0 Importance

Due to a greater dependence on digital technology for data collection the COVID-19 pandemic's implications for clinical trial execution, namely site monitoring, might accelerate the use of Artificial Intelligence in clinical trial execution. Over the past 20 years, Artificial Intelligence has become increasingly sophisticated and widely employed in pre-clinical research, translational research, and medication development; nevertheless, its application Operations and data analysis in clinical trials have been complex. "Clinical trial operations" refers to the tasks linked to carrying out and maintaining the clinical trials, including site selection, patient recruitment, trial tracking, and data gathering. Clinical trial data analysis includes statistical software development, statistical analysis, and data management of participant clinical data from a trial. Patient recruitment has proven to be

very difficult from a trial operations perspective; over 30% of phase 3 trials have terminated early owing to enrolment difficulties, and an estimated 80% of trials have not met enrolment deadlines. Regulators need trial site monitoring, which entails physically visiting the sites, as a significant and costly quality control measure. Clinical trial Because of multi-center international trials, monitoring has also become more costly, time-consuming, and labor-intensive.

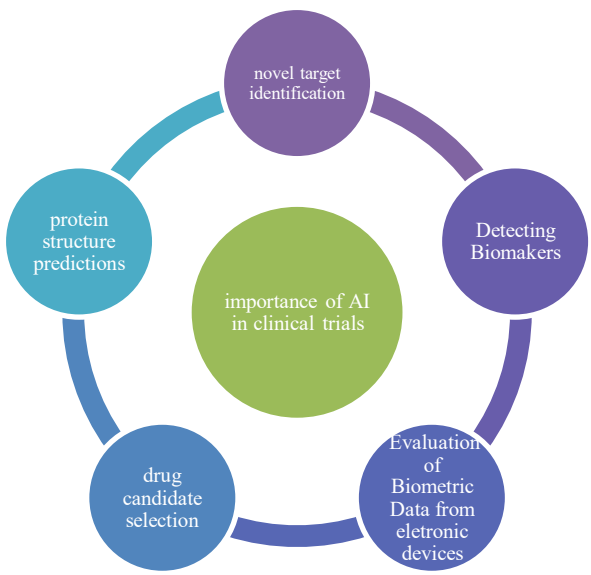
Furthermore, the time span that has been virtually constant over the past 20 years between the "last visit" trial milestone for submitting the data package for regulatory approval and the last phase 3 trial gives Artificial Intelligence a big window of opportunity to revolutionize the industry in a positive way. The utilization of digital technology for patient data collection and the growing trend towards fully or partially virtual (or "decentralized") trials suggest that COVID-19 will hasten the integration of Artificial Intelligence into clinical trial operations. Artificial Intelligence approaches not only provide real-time automated and "smart" monitoring for clinical data quality and trial site performance monitoring, but they may also be used to enhance patient recruitment and project enrollment efficiency. We consider. Artificial Intelligence has the potential to completely transform clinical trial operations and trial data analysis, particularly in the areas of trial data analysis, clinical study report creation, and regulatory submission data packages (Kolluri *et al.*, 2022).

Phase III clinical trials are the most complicated and time-consuming, accounting for around half of the entire cost. A major impediment to the development of novel medications is the high percentage of failures in clinical studies. Phase II compounds progress to Phase III at a rate of slightly less than thirty percent. Up to one-third of Phase III compounds are approved by R&D agencies. Because of the different chances of success for compounds passing through each stage of the trials, only one out of every ten that start clinical trials gets approved by the Food drug administration, Complicating matters, just 10% of these large-scale clinical trials end in success. The most recent field of drug research to recognize and permit the positive effects of Artificial Intelligence is clinical trials. As new opportunities arise, the development of these tools will continue to improve the field of clinical research. Numerous connections that reinforce one another allow artificial intelligence to advance into a more sophisticated future state.

Artificial intelligence can help solve all of these issues with the clinical trial process because it is challenging to mine various data sets for clinical trials and retain data on every patient participating in the trial technique. Clinical trial preparation, execution, and management involve patient recruitment and selection, site selection, monitoring, data gathering, and analysis. Moreover, trial monitoring is a costly and time-consuming procedure for a multi-center worldwide investigation.

The period of time between the "last subject, last visit" and data submission to regulatory agencies, which necessitates time-consuming data collection and processing procedures, is another difficulty with clinical trials. Clinical trial challenges have changed as a result of artificial intelligence and digitization. Information engines, patient stratification, and trail operation are the three primary domains that researchers in this discipline are concentrating on applying AI-based software to. Artificial intelligence has a lot of possibilities and opportunities when it comes to clinical trials. Businesses all over the world use it because of its effectiveness, cost savings, and safety benefits (fewer errors). Artificial Intelligence can help a business achieve its objectives in a variety of areas, including patient selection, trial monitoring, study closeout, and many more areas where it offers advantages like fresh perspectives or the ability to complete quality assurance tasks more quickly and accurately than ever (Morley *et al.*, 2020).

Figure 3: Importance Artificial Intelligence in Clinical Trials



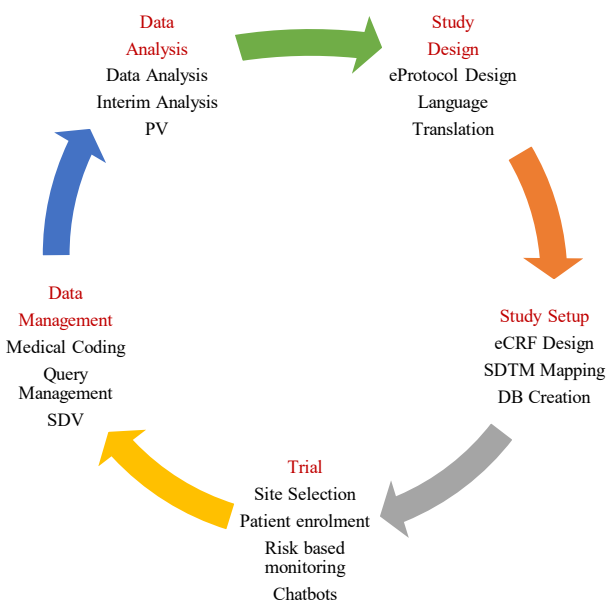
It's true that clinical studies demand a significant financial outlay, and the drug-market approval process takes years. A portion of the problem stems from the clinical trials' frequent failures, which happen very late in the drug's entire development cycle. Only around 10% of medications that start clinical trials go on to be approved by the FDA in the United States. Poor patient cohort selection, ineffective recruiting strategies, and inadequate infrastructure to handle complicated clinical trials are frequently blamed for the 90% of

trials that fail. Artificial Intelligence can be used to speed up the clinical trial process in a number of areas, including patient recruiting, data analysis, pattern recognition, and probable adverse event identification, in such a demanding setting. By accelerating the drug development process, researchers may be able to lower costs and improve patient outcomes. But when using Artificial Intelligence in clinical trials, there are challenges to overcome and disadvantages to consider, just as with any new technology (Glass *et al.*, 2019).

3.0 Conventional Methods of AI in Clinical Trials

Sequential and linear the best way to make sure new medications are safe and effective is through clinical trials. A number of things led to the study's demise, including under enrolment, attrition during the study, unanticipated adverse effects, and inconsistent results. When discovery and preclinical research are finished, there are four phases to a clinical study. Phase I consists of the first testing of a medication or treatment on 20–80 patients in order to determine safety and detect side effects. After beginning this process, about 70% of participants advance to the next level in three to six months. In phases II and III, a larger sample size is used to test the medicine or therapy. (Between 100 and 300 individuals) in order to assess its safety and efficacy.

Figure 4: Process of AI in Clinical Trials



Approximately one year or two later, 33 percent of individuals go to the last stage. Ten times as many people (1000–3000) are involved in Phase III as in Phase II in order to determine efficacy, identify and track side effects, and compare findings to other existing studies. Only between 25% and 33% of participants advance to the next level, and this process might take anywhere from a year to four years. Following Food Drug Association approval and general public availability of a medication, Phase IV takes place. To find the greatest uses for it and guarantee its safety, scientists are still keeping an eye on how it affects the general public. Given the rigorous regulatory review that a drug or therapy must undergo before reaching this stage, it is not surprising that this procedure can take a year or longer and have a success rate of 70–90%.Sub therapeutic dosages are evaluated in various studies' first phase I on a small number of subjects (10–15) (Chopra *et al.*, 2023; Byline, 2023).

3.1 Method of searching

The Cochrane Library electronic databases, Embase, and Pubmed were all searched. The search terms that were used were "hypertension," "randomized," "cancer," "vandetanib," and "ZD6474." Only clinical trials and English-language publications were included in the search parameters. We also manually examined abstracts given utilizing the same keywords, at the annual meetings of the American Society of Clinical Oncology (ASCO) and the European Society of Medical Oncology (ESMO) between March 2001 and March 2012. We also searched the clinical trial registration database for details on the registered randomized controlled trials (RCTs). We also looked through the original and review publications' reference lists to find pertinent research (Morley *et al.*, 2020).

3.2 Study choice

After evaluating the articles and abstracts found by the search independently, two investigators (QWX and SZ) came to a consensus on any differences. Since the Food Drug Association has approved a daily dose of 300 mg of vandetanib, we assessed the risk of hypertension at this dosage to ensure clinical significance. We did not include phase I trials in the analysis because of the restricted sample sizes and dose variability. The only clinical trials that were included were phases II and III, and they only used vandetanib at the prescribed dose.

The following criteria were used to carefully identify the pertinent clinical trials by hand:

- individuals treated with vandetanib alone at a dose of 300 mg day1;
- events or the rate of occurrences and available sample size for hypertension; and
- prospective clinical trials in cancer patients.

There was only one publication included, and it was the most recent and educational. When several publications on the same trial were obtained or when there was a mix of cases in the publications. Extraction of data and evaluation of quality. Data extraction and publication reviews were conducted by two separate investigators, HAN and LF. The publication year, the treatment arm, the first author's name, the number of patients enrolled, the number of patients in the treatment and control groups (if any), and any noteworthy adverse events (hypertension) were taken out of each included paper. Data was taken from the available sources, entered into an electronic database, and documented on a data collection form. Based on how the study's methodology and findings were reported, the quality of the included trials was assessed using a quantitative 5-point Jadad scale. A trial was considered to be of excellent quality if it had a rating of three or more (Chopra *et al.*, 2023; Byline, 2023).

3.3 Clinical outcomes

In every trial, hypertension was taken out of the safety profile. The National Cancer Institute's Common Terminology Criteria for Adverse Events, versions II or III, were followed while recording these clinical outcomes. The classification of hypertension is described in each of the two variants as follows: grade I: no treatment is necessary if there is an asymptomatic, temporary (less than 24 hours) elevation in blood pressure of more than 20 mmHg (diastolic) or more than 150/100 mmHg if it was previously within the normal limit (WNL); Immunotherapy may be necessary in grade II, which is recurrent or persistent (lasting more than 24 hours) or symptomatic elevation of blood pressure of more than 20 mmHg (diastolic) or more than 150/100 mmHg if previously WNL; grade III requires the use of multiple medications or more intensive therapy than before; and grade IV, hypertensive crisis. Our analysis included every case of grade 1 or greater hypertension. (Mann *et al.*, 2022).

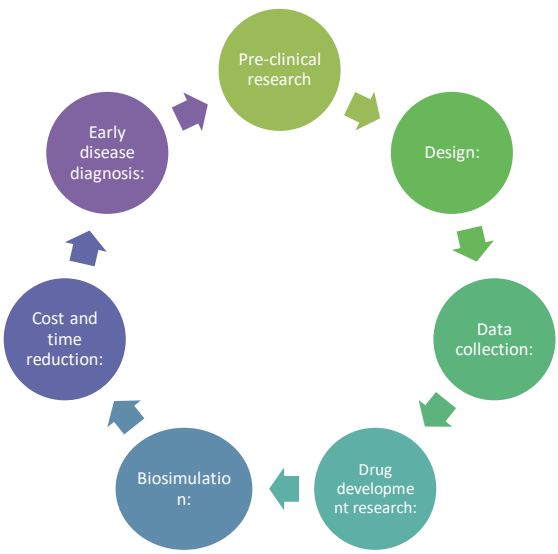
3.4 Data interpretation

An intention-to-treat approach was used for the analysis. Regardless of whether they received the prescribed treatment, patients were evaluated according to how that treatment is distributed. The quantity of individuals with all grades of hypertension and high grades (grades 3 and 4) of hypertension on vandetanib, were taken out of the adverse event results. We calculated the proportion of hypertensive patients and their The 95 percent confidence interval for every research. For studies with a control group in the same trial, we additionally calculated and assessed the relative risk of hypertension. To ascertain, we employed the conventional half-integer adjustment. The Relative Risk and variance for a trial where the control arm had zero occurrences reported. The Q statistic based on $\chi 2$ was

utilized to measure the heterogeneity between studies. If the heterogeneity was less than 0.05 or the I2 was greater than 50%, it was deemed statistically significant. The data was analysed using a random effects model to see whether heterogeneity was present. When heterogeneity was absent, a fixed effects model was applied.

The statistical technique of inverse variance was applied to determine the pooled incidence. A statistical test was deemed important if its P-value was less than 0.05. To assess if publication bias exists, the Begg and Egger tests were employed. The Comprehensive Meta-Analysis program edition 2 and State edition 12.0 software (State Corporation, College Station, Texas, United States of America) were used for all statistical analyses (Qi *et al.*, 2013).

Figure 5: Application of AI in Clinical Trials



4.0 Application of Artificial Intelligence in Clinical Trials (Figure 5)

- Prior to clinical trials: AI is useful for predicting toxicity and finding new molecular targets (Microbioz India, 2023).
- Design: AI is capable of forecasting patient outcomes, trial success rates, and assisting in the formulation and evaluation of hypotheses (Thomas et al., 2021).
- Data collection: AI has the potential to transform creative approaches to data collection (Pandya & Pandya, 2023).
- Bio simulation: Bio simulation can be transformed by AI (Microbioz India 2023; Pandya & Pandya, 2023).

- Early disease diagnosis: Early disease diagnosis could be revolutionized by AI (Thomas *et al.*, 2021; Pandya & Pandya, 2023).
- Cost and time reduction: AI has the potential to save money and time (Pandya & Pandya, 2023).
- Drug development research: AI can enhance research on medication development while reducing the need for rework (Microbioz India (2023), Thomas *et al.*, 2021).

5.0 Advantages of Artificial Intelligence in Clinical Trials

- *Faster recruitment:* Artificial intelligence greatly speeds up the recruitment process by connecting participants to appropriate studies based on genetic profiles and medical histories (Glass *et al.*, 2019; Microbioz India, 2023).
- *Enhanced data management:* AI-driven systems that are able to organize and instantly evaluate vast volumes of data can help ensure data accuracy and integrity throughout the trial (Microbioz India, 2023; Starmind, 2023).

Figure 6: Advantages of AI Clinical Trials

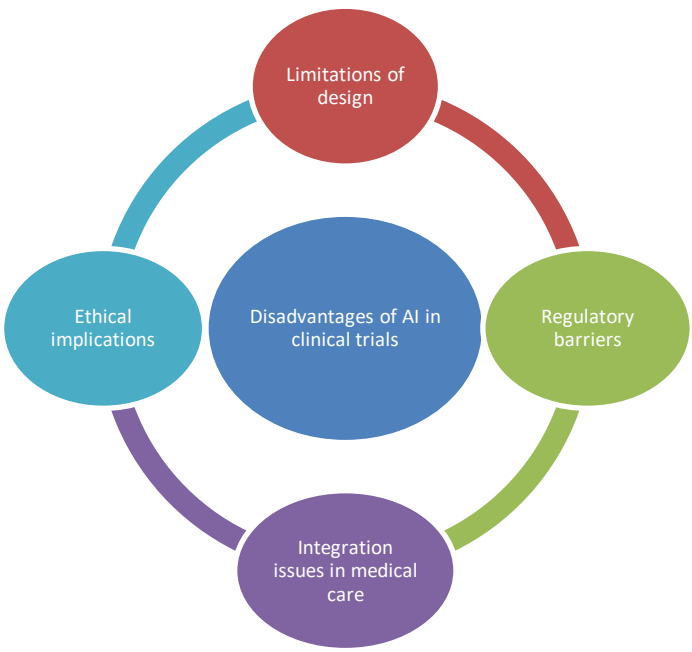
- *Predictive analytics:* Adverse occurrences and patient outcomes can be predicted using AI algorithms. This speeds up the conclusion of the experiment and improves patient safety (Glass *et al.*, 2019; Inside ICON, 2024).

- *Improved efficiency:* This effectiveness leads to faster outcomes and shorter trial times. (Glass *et al.*, 2019; Starmind, 2023)
- *Enhanced accuracy:* This improved precision is essential for determining which treatments have the greatest promise (Glass *et al.*, 2019; Inside ICON, 2024).
- *Cost savings:* Artificial intelligence has the potential to drastically lower the overall cost of clinical trials by streamlining trial design, patient recruiting, and data administration. (Glass *et al.*, 2019; Microbioz India, 2023; Inside ICON, 2024).

6.0 Disadvantages of Artificial Intelligence in Clinical Trials

- *Limitations of design:* Historical data sets have been used to validate the majority of the models and applications of AI in healthcare currently in use (Shen *et al.*, 2019).
- *Integration issues in medical care:* Integrating AI-based diagnosis and treatment recommendations into clinical procedures and electronic health record systems may be challenging. More than any incapacity to offer precise and useful advice, these integration problems have likely been an obstacle to the widespread application of AI (Plana *et al.*, 2022).

Figure 7: Disadvantages of AI in Clinical Trials



- *Regulatory barriers:* A number of the algorithmic and data-related problems stem from underlying national privacy laws and regulatory obstacles. Health care data collection and pooling may be impeded by privacy rules (Bitkina *et al.*, 2023).
- *Ethical implications:* It is nearly impossible to understand or interpret many AI algorithms, especially the deep learning algorithms employed in picture analysis. It could be challenging to hold AI systems accountable if they make mistakes in patient diagnosis and treatment (Yin *et al.*, 2023).

7.0 Future Scope

In the years to come, AI will help medical professionals across the board make better clinical judgments. For the patient's correct care, this technology can offer the most recent knowledge and information. If artificial intelligence is used properly, the future of healthcare will improve. First, unstructured text is converted to machine language, and data is then electronically recorded. Artificial intelligence will be applied to innovation and finance. It can execute a necessary medical task expertly (Starmind 2023; Inside ICON, 2024). Clinical trials are already using artificial intelligence, and as more medications are created, the use of this technology will only grow. More data than ever before is available to researchers, and their analytical tools are more potent than ever. However, many researchers are not taking advantage of the opportunity to optimize their drug development process by having real-time access to international specialists and historical instances. With Starmind's artificial intelligence solution, businesses can efficiently (Starmind, 2023).

Clinical trials must be able to handle the greater quantity of more focused methods that are needed. Global regulators have issued guidelines to entice biopharma businesses to employ RWD tactics. Because they define novel, patient-centered outcomes, innovative trials that use RWD are expected to become more important in the regulatory process. All parties participating in clinical trials will make judgments in the future based on the needs of the patient (Inside ICON, 2024; Haleem *et al.*, 2019).

There is a lot of opportunity for growth and innovation when it comes to AI in clinical research. This will make it possible for scientists and medical practitioners to use AI-driven insights for better patient outcomes, disease prevention, and personalized treatment. Integration of AI with other cutting-edge technologies, such as blockchain and the Internet of Medical Things, is one area of future research.

Clinical research utilizing AI responsibly can be aided by block chain technology, which can improve the security, privacy, and interoperability of medical data. A significant quantity of real-time patient data may also be obtained via the IoMT, which AI algorithms can then use to analyze early warning indicators, forecast the course of diseases, and

improve treatment strategies. These artificial intelligence systems may respond to patient inquiries, make tailored recommendations, and give 24/7 access to medical information. An improved patient experience can result from increased patient participation, self-management, and adherence to treatment regimens (Versel, 2024).

Figure 8: Future Cope of Artificial Intelligence in Clinical Trials

8.0 Conclusion

Artificial intelligence has the potential to support patient monitoring and appropriate care. Doctors, surgeons, and clinicians are not necessary for the assessment of an image or result. Artificial intelligence (AI)-driven solutions offer decision-making capabilities that aid in anticipating medical problems. Using a digital app to deliver medical advice is beneficial. The practical application of this technology is to improve treatment and diagnostic accuracy. It can lower medical expenses and help avoid sickness. By using this technology, unwanted hospital visits can be decreased and patient inquiries can be addressed. AI offers a great resource and detects issues when there is a physician shortage.

In order to provide patients with better care, this technology first determines the biological cause of the illness. It completes the task accurately and can visualize medical images with ease. By analysing patient data, Artificial intelligence supports cancer diagnosis and therapy. The diagnosis of cardiac disease is one of its uses. In order to get a definitive outcome, it expedites the clinical studies. Artificial intelligence builds algorithms

that analyse several aspects of patient data and are helpful in providing details about the patient, the severity of their sickness, and their chances of survival. In the upcoming years, it will be utilised for digital supervision in hospitals to improve patient care.

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