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REVIEW PAPER

AI-powered clinical trials and the imperative for regulatory transparency and accountability

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Abstract

Purpose The transformative impact of Artificial intelligence (AI) on clinical trials is explored. To identify the potential benefits of AI in enhancing both the efficiency and effectiveness of clinical research, while also examining the challenges associated with its implementation.

Methods Through an analysis of research literature, case studies, and relevant regulatory frameworks, which highlights the potential of AI in clinical research. This includes improvements in patient recruitment, streamlined data analysis, and optimized clinical trial design. Case studies are presented to showcase the effectiveness of AI in achieving better trial outcomes.

Results Challenges that come with implementing AI such as issues regarding accountability and transparency due to increased reliance on AI-driven insights. Additionally, regulatory uncertainties around approving and overseeing AI-powered clinical trials, and ethical considerations concerning data privacy and potential biases within AI algorithms, are identified. Despite these challenges, the research emphasizes AI's potential to transform drug development by making clinical trials more efficient and insightful.

Conclusion The paper concludes by suggesting future research directions that explore the ethical, legal, and regulatory implications of AI in clinical trials, while further investigating its potential benefits for medical advancements.

Keywords Artificial intelligence · Clinical trials · Drug development · Machine learning · Deep learning

1 Introduction

Initially defined in 1955, artificial intelligence (AI) is the source of technological advancement in creating intelligent computer programs. Artificial intelligence (AI) aims to replicate human decision-making processes by the mechanization of human intelligence processes such as logical reasoning based on self-learning and self-correction [1]. Artificial intelligence has significantly expanded healthcare in drug development and clinical design by exhibiting human-level intelligence in performing complex tasks [2]. The change is driven by AI's ability to study and analyze vast datasets, identify different patterns, and make data-driven predictions, all of which are invaluable in the complex world of clinical research. Currently, AI is being increasingly utilized in clinical trials for maintaining electronic health records and identifying eligible participants for clinical trials more efficiently [3]. Further study protocols made using AI for designing the trials can increase the success rate of clinical trials significantly [4]. A clear difference between the traditional method of conducting clinical trials and the use of AI for clinical trials is visualized in Fig. 1. Data analysis and interpretation can be more streamlined and evident for AI-based drug development and understanding the trends in a patient-centric approach [5]. The use of AI in clinical trials is subject to regulatory oversight to ensure patient safety and data integrity; many regulatory bodies have issued guidelines for it. FDA is working on a flexible risk-based regulatory framework for AI/ML in drug development [6]. The Indian Council of Medical Research (ICMR) has issued "Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare, 2023" to offer ethics steerage for stakeholders on the use of AI in healthcare [7]. FDA also released an "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as Medical Devices (SaMD) Action Plan" that outlines five actions FDA intends to address challenges posed by adaptive AI and machine learning

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Fig. 1 Traditional method compared to the use of AI in clinical trials

Technologies in Medical Devices the solution of. Regulators around the world are taking steps to tighten guidelines and promote innovation that protects patient welfare [8].

1.1 The possibilities of AI in transforming the drug development process

AI assists drug discovery by designing new d rugs that target specific proteins and predicting drug interactions within the body, which allows researchers to identify promising candidates and avoid failure early on [9]. By monitoring patient reactions to therapy, selecting and enrolling those who could profit from new medicine, and designing trials more effectively, AI can revolutionize the industry. This innovation can decrease cost and time spent on identifying therapeutic targets and introducing new medications. As pharmaceuticals inevitably interact with the human body, AI has the capability to enhance their efficacy [10]. AI can be used to identify, design, and predict how drugs are likely to interact with the human body [11]. This can speed up the development and release of novel medications by researchers. A firm called Benevolent AI uses artificial intelligence (AI) to evaluate enormous biological data sets to find novel targeted medications and forecast their efficacy and safety. Verily is a company that is using AI to develop new tools for clinical trials [12]. For example, Verily is developing a wearable device that can monitor patients' responses to treatment in real-time real time. Many regulation bodies are regulating AI and how AI is used in clinical trials a comparison of different nations is shown in Table 1.

2 Evolving role of AI in clinical trials

AI can help recruit patients for trials by analyzing the patients' data and identifying the eligible patients or volunteers faster and more accurately, reducing the burden on the sponsors [4]. The design of the trials would be more patient-centric by studying the historical data to have relevant endpoints in the population [8]. The vast datasets, ensuring data quality, real-time anomaly detection, and identifying potential adverse events early AI will reduce errors and patient safety by optimizing patient dosage and treatment plans. Patient engagements using AI tools like chatbots will enhance the patient experience and provide a more comprehensive understanding of treatment impact in real-world settings [13]. Artificial intelligence can oversee informed consent procedures, protocol adherence, ethical compliance, and trial conduct integrity. It can also help with regulatory submissions by automating document creation and guaranteeing rules are followed, which speeds up the approval process [14].

2.1 The impact of AI in drug development

AI-powered algorithms that can analyze massive databases, making the identification of possible medications more precise and efficient [15]. Also, by reducing drug failures and costs, researchers can measure the safety and efficacy of drugs due to AI's predictive knowledge, freeing up time to focus on optimal medicine AI enables personalized medicine to optimize treatment regimens based on clinical and genetic information [12]. Furthermore, AI streamlines affected person recruitment, records evaluation, and clinical trial design, main to swifter and more price-effective studies, as shown in Fig. 2. Artificial Intelligence drastically lowers costs by way of reducing the time and resources needed for remedy research [15]. AI also improves drug safety by lowering patient risks via early detection of possible toxicity and adverse effects. AI's capacity to assess patient data from real-world settings enhances the findings of clinical trials by offering a thorough grasp of how well drugs work in a range of patient groups [16, 17].

Table 1 Checklist table outlining the use of AI in clinical trials in different regions

Sr No.	Aspects	USFDA	EMA (European Medicines Agency)	CHINA	INDIA (CDSCO)	TGA (Therapeutic Goods Administration)
1.	Regulatory Framework	FDA has guided the use of AI in clinical trials, emphasising data integrity and security.	EMA has guidelines regarding AI use in clinical trials, emphasising a human-centric approach.	China's regulatory framework for AI in clinical trials is evolving, with a focus on data quality.	India's regulatory landscape is developing, with considerations for AI use in trials.	TGA follows a risk-based approach and evolving guidelines for AI in clinical trials.
2.	Data Privacy & Security	Comply with HIPAA and other data privacy laws	Compliance with GDPR for data privacy	Data security regulations apply	Follow Indian data protection laws	Comply with Australian data privacy laws
3.	AI Applications	AI is used for patient recruitment, drug discovery, and data analysis.	AI is used in patient recruitment, safety monitoring, and decision support.	China utilises AI for patient screening, predictive analytics, and outcome assessment.	India explores AI for participant enrolment, data analysis, and safety monitoring.	AI is used for data analysis and patient recruitment.
4.	Benefits	Accelerated trials, reduced costs, improved patient outcomes, and data-driven decision-making.	Enhanced efficiency, improved data quality, and better patient safety.	Faster patient enrollment, predictive modelling, and early identification of issues.	Streamlined processes, better data analysis, and more efficient trials.	Improved data quality, quicker recruitment, and cost reduction.

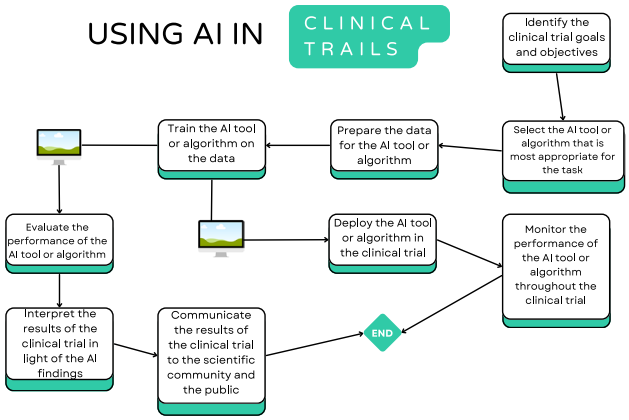

Fig. 2 Schematic representation of probable applications of AI in clinical trial setup

3 AI in clinical trial design, conduct, and analysis

Deep Learning and machine learning are AI techniques used in the pharma industry where machine learning analyses data to build models for decision-making. It comes in two categories, Supervised learning for predication and unsupervised learning for extracting patterns from unlabelled data. Deep learning uses complex models to process large amounts of data [18]. Another field used in drug research is natural language processing (NLP), used for interpreting textual or natural language data. Optical character recognition (OCR) aims to electronically convert images of handwritten human text/printed or typed text into machine-encoded text using pattern recognition and computational vision [9, 19].

AI has transformed drug delivery across all stages, from target identification to clinical trials, making the traditionally expensive and failing process more efficient [20]. AI can assist in choosing parent compounds that might have a better chance of success throughout the development phase and which may increase the effectiveness of the search for showing the association between indications and biomarkers [21]. AI has the significant potential for making plans, designing, and carrying out clinical studies. To increase recruitment by matching affected person functions to choice criteria, massive and numerous datasets, including digital medical facts (EMRs), published clinical literature, and scientific trial databases, may be connected collectively using ML, DL, NLP, and OCR [22]. AI can improve patient selection for clinical trials by analyzing vast amounts of medical records (EMRs). This reduces variability and allows researchers to identify patients with a higher chance of responding to treatment (predictive enrichment). Machine learning helps in this process, by using algorithms to identify patients likely to develop Alzheimer's (AD). This approach was tested with

a tool simulating drugs, the disease, and its course for early AD, even undergoing regulatory evaluation [23].

AI systems have the potential to automatically analyse digital eligibility databases for clinical trials and EMRs and then match those results with clinical trials that are recruiting participants through social media, trial announcements, or registries. Patients can contact investigator sites to have their eligibility assessed and become more aware of clinical studies that interest them sooner. There has been a 58.4% increase in enrolment for lung cancer thanks to AI-based clinical trial matching [20]. A wearable device is not connected to any other nonwearable device. However, it fully functions when connected to the user/patient body either directly or indirectly through clothing, which can perform measurements or data processing tasks. Wearable technology and machine learning models have been used to monitor trial participants for Parkinson's disease, automatically identify cognitive and emotional states, and evaluate sleep quality in neurology trials [24].

AI in drug development faces data hurdles, including digitizing and accessing medical records (EMR). Standardizing data formats across wearables and EMRs is a challenge. Mining large, scattered datasets (genes, trials, articles) is complex. Privacy regulations limit data access, adding to legal hurdles. Data privacy regulations limit access to specific patient data. Similar legal hurdles about data security and impact clinical trial matching [1, 25]. The Food and Drug Administration (FDA) [23] considers software with an AI or ML component a medical device. For technical certification, clinical, quality systems, sophisticated machine learning research, safety and efficacy assurance, transparency, and real-world performance management, the FDA wants AI developers with any new technology that claims artificial intelligence (AI) compliance with these standards in order to enhance the efficiency of clinical design and execution, additive testing intended should be as addition or replacement should be certified [26].

4 AI technologies in clinical research

AI helps to find the right patient for research studies, analyse data, and plan studies better. This improves the research faster and helps find better results, which makes it more efficient and outcomes more precise [27]. One such use is in Patient Recruitment using AI, which is a critical phase in clinical trials and AI has brought innovation in this area and has shown to be a game changer for solving the problem of patient recruitment [5]. Natural Language Processing (NLP) and Text Mining NLP and text mining technology extract precious insights from scientific literature, electronic health statistics (EHRs), and scientific reports. They permit researchers to get entry to a wealth of unstructured statistics, facilitating literature opinions, unfavourable event tracking, and the identification of relevant patient cohorts. NLP-powered tools like IBM Watson aid in fact extraction and interpretation [28].

5 Real-world examples of successful AI-driven clinical trials

AI is advancing clinical trials by identifying ideal patients, optimizing designs, and predicting treatment responses, leading to faster development and improved patient outcomes.

5.1 Use of AI in oncology clinical trials

Data-driven algorithms combined with real-world patient data have potentially improved many areas of clinical trials [29]. Clinical trials for cancer have been transformed in recent years by AI technology, making research more productive and successful trials [30]. AI-based early detection and diagnostic systems have been used for the analysis of CT scans, X-ray, and other medical imaging data. For example, research by Hamamoto et al. indicates that using AI in radiography to identify cancer has led to faster and more accurate results in clinical trials [31, 32]. Individualised Care Artificial intelligence is used to analyse patient data and create plans. These plans take into account the patient's current health status, past treatment outcomes, and genetic profiles. Studies have demonstrated how AI might enhance anti-cancer medication design, leading to more individualised treatment [20]. Artificial intelligence has improved the accessibility of clinical trial patient monitoring and recruitment. Analysing relevant databases and electronic health information can help find potential candidates. Real-time patient data provided by AI-powered technologies also guarantees a greater adherence to trial protocols. The ability of AI models to predict patient reactions to diverse treatments is essential for improving clinical trial designs. By selecting the most promising therapies, these predictive powers increase the possibility that clinical trials will be successful [20]. AI applications in cancer clinical trials create ethical issues and must adhere to regulatory requirements. To guarantee that AI algorithms are open, objective, and respectful of patient privacy, safeguards are required [30].

5.2 Use of AI in *Glaucoma* trials

Automated systems such as Artificial Intelligence (AI) could be used to identify diseases in a large population. However, several issues may arise throughout the AI

pipeline, including inappropriate bias, health disparities, and decreased equity. AI applications in ophthalmology have primarily focused on conditions affecting the posterior portion of the eye [33, 34]. AI has demonstrated the potential to help diagnose illness and predict its progression, such as identifying changes in photoreceptors in choroideremia and retinitis pigmentosa, as well as Retinal Nerve Fiber Layer (RNFL) loss in multiple sclerosis. Optical Coherence Tomography (OCT) AI systems have also employed technology to connect structural and functional changes in glaucoma, with the retinal ganglion cell axonal complex optimised approach showing good predictive value in predicting Visual Field (VF) thresholds using OCT images [35]. To help treat glaucoma, AI must be able to determine the possibility of glaucoma and track the disease's progression. An objective, verified, and standardised definition of glaucoma is needed to act as a ground truth for cases used to train the system. The automated detection of intermediate glaucoma, when patients start to exhibit VF anomalies or functional changes and are more likely to develop visual impairment over their lifespan, should be the primary focus of AI research [36, 37].

Parameters for diagnosis include the Optic Nerve Head (ONH) cup-to-disc ratio, Retinal Nerve Fiber Layer (RNFL) thickness, and Ganglion Cell-Inner Plexiform Layer (GCIPL) thickness. Fundus photography and quantitative OCT image processing are significant choices for AI-assisted glaucoma diagnosis, as they help identify retinal abnormalities and test for eye illness. Patient's eyes can be imaged in community settings and primary care offices using portable fundus cameras. Extensive, diverse training and validation sets that have been clinically validated against outcome or other prognostic standards are required [33]. Support from numerous centers worldwide is required, and cost savings must be shown for AI to become a popular tool for managing glaucoma. By identifying glaucoma early on, patients can avoid more involved and expensive operations, lowering expenses both personally and globally [37].

6 Regulatory challenges in AI-driven clinical trials

Regulatory concerns around AI in clinical trials have proven to be challenging for all the global regulators, which need to be identified and understand the issues causing it. A few of the regulatory challenges are discussed further:

7 Lack of regulatory guidance

Artificial Intelligence in medical trials lacks complete regulatory development due to several elements. Firstly, the rapid evolution of AI technologies makes it hard for regulators to maintain pace with new packages and algorithms. Additionally, the range of AI technologies utilised in medical trials, including system studying and natural language processing, necessitates unique pointers for each, in addition to complicating the regulatory panorama [5]. AI in trials faces data privacy, security, and ethical concerns (bias, transparency). International harmonization is crucial due to transnational research. Limited data on AI safety and efficacy hinders comprehensive guidelines. Regulators are working on frameworks to address these challenges [8].

8 Data availability and standards

For artificial intelligence (AI) to be applied ethically and successfully in clinical trials and healthcare, it is imperative that data-related issues and ethical challenges be addressed. Legislators, data scientists, and medical experts must collaborate across fields to solve ethical issues within the use of AI, including biases among the patients, justice, and benefits [38]. The integrity of clinical trial data should be preserved by regulators by establishing criteria for data security and quality of the data. This comprises procedures for data purification to get rid of mistakes and inconsistencies [39, 40]. Additionally, data sharing and interoperability standards are essential, enabling effortless communication between various healthcare systems and AI tools [41]. These process protects patient data and encourage ethical considerations of AI applications in healthcare, which will eventually improve patient results [16].

9 Ethical considerations

The rapid advancement of AI in healthcare demands ethical guidelines to ensure its responsible use. These guidelines act as a framework to maximize the benefits of AI while minimizing potential risks. They typically focus on core principles like patient autonomy, safety, inclusivity, risk minimization, reliability, and accountability [27]. For instance, the Indian Council of Medical Research (ICMR) placed a strong focus on fairness, validity, and reliability in its ethical guidelines for artificial intelligence (AI) in healthcare. These suggestions address all of the important aspects of AI, such as the requirement for informed consent, data security, and preventing bias in algorithms [42]. Ensuring AI technology

conforms with ethical and legal criteria is the aim, since it promotes safety, trust, and equitable healthcare results. As AI's role in healthcare and research grows, adherence to such ethical guidelines is becoming more and more crucial to safeguard patients and the integrity of medical procedures [40].

10 Evaluation criteria

Medical device management poses a distinct problem, encompassing machine learning and artificial intelligence (AI). AI-based medical devices must comply with dynamic and changing rules that call for specialist evaluation criteria, in contrast to traditional medical devices that are subject to a regulatory framework centered on safety and efficacy [43]. While specific laws are lacking, best practices are emerging to govern AI in healthcare. Organizations worldwide recognize the need for ethical, inclusive, transparent, and efficient AI development and assessment criteria [44]. Given the dynamic nature of AI technology and its potential to impact patient safety and healthcare results, it is imperative to broaden the scope of the requirements in order to guarantee its responsible application in the medical field [13]. These ongoing efforts aim to balance innovation and patient safety in the rapidly advancing field of AI in medical devices.

11 Regulatory initiatives

11.1 FDA's flexible framework

The FDA is aggressively developing a flexible, chance-based regulatory framework to leverage artificial intelligence and machine learning (AI/ML) capabilities inside the pharmaceutical industry. This framework is intended to promote the safe and reliable integration of AI-powered equipment during the phases of drug development and scientific trials [43]. The FDA's strategy acknowledges that the use of AI and ML technologies can significantly speed up the discovery of new drugs and enhance the efficacy and stability of existing ones. The hazards of applying AI/ML in healthcare are taken into account in the FDA policy. It aims to offer suitable oversight based on possible advantages and hazards, allowing for the acceleration of low-risk technology while upholding thorough evaluations for high-risk applications [45]. To determine if AI-powered tools are as safe and effective as conventional medications, the FDA is dedicated to making sure that these tools are extensively studied. Establishing norms and regulations for creating and utilising AI/ML in healthcare is part of this [46]. The framework's goals are to lower obstacles, streamline the regulatory procedure for AI/ML applications, and improve industry uptake. In general, the FDA's accommodating stance on AI/ML in medicine shows a progressive mindset that maximizes the technology's potential while protecting patient safety and treatment options [47].

11.2 European medicines agency (EMA)

The EMA is focused investigating the use of artificial intelligence (AI) in clinical trials. In July 2023, the EMA released a reflection paper outlining current thinking on using AI to develop safe and effective medicines. This paper reflects EMA's recognition of AI's potential for medicine and the tests that are effective [48]. EMA's interest in AI extends to clinical trial design, where AI can transform key steps in study preparation and execution, ultimately increasing trial success rates and reducing costs [49]. Regulatory guidance on AI in medicine and its application in medicine is being developed, focusing on areas such as data generation. In summary, the EMA has been involved in the research and planning of using AI in clinical trials in recognition of its transformative potential in pharmaceutical and clinical research [50, 13].

11.3 The national medical product administration (NMPA)

Regarding the application of artificial intelligence (AI) in clinical trials, China has been actively adopting rules and standards. One of the key elements of Chinese regulation is the requirement for careful planning and design of research projects. In order to obtain reliable and valid trial results, careful consideration is given to choosing an appropriate sample size, establishing control groups, and using the right procedures [51]. Recruitment and patient retention are also covered by Chinese policies. It is advised to use strategies including expanding the reach of recruitment websites, integrating patient advocacy groups, and making use of electronic health data. China places a high value on observing moral standards and obtaining informed agreement before enforcing regulations. Protecting patient privacy and maintaining data integrity are crucial. Increasing openness and simplifying procedures for regulation are two more important aspects to take into account [52]. China has implemented regulations and procedures that govern the use of AI in clinical studies [53].

11.4 The central drugs standard control organization (CDSCO)

The potential of AI to revolutionize clinical trials has been welcomed by the Indian Council of Medical Research (ICMR). There are various advantages of employing AI in clinical trials in India. AI can, among other things, make

it simpler to identify patients for clinical trials by looking through patient data and electronic health records [54]. This increases recruitment efficacy by enabling researchers to identify candidates more quickly. In addition, massive datasets may be analysed by AI-driven algorithms to identify potential safety concerns and unfavourable occurrences, ensuring study participant safety. AI can also enhance trial techniques, leading to less costly and time-consuming research. The promise of AI in clinical trials has prompted the ICMR and CDSCO to take the lead [55]. With a range of stakeholders, they have developed frameworks and rules to regulate the use of AI in clinical studies. The need of data protection, transparency, and ethical considerations while utilising AI in medical research is emphasised by these proposals. Furthermore, the ICMR and CDSCO have launched pilot programmed to assess the practicality and effectiveness of AI in clinical trials. Although there is a lot of promise for using AI in clinical trials in India, there are a few challenges that need to be solved. Interoperability, standardisation, and the availability and quality of data are major challenges [7]. It is also important to carefully consider the ethical and legal implications of using AI in clinical research. The use of AI in clinical trials by the ICMR and CDSCO demonstrates India's dedication to use cutting-edge technology to enhance medical research [56]. Through the use of AI, they want to accelerate the creation of novel therapies, lower expenses, and increase patient safety—all of which will help the worldwide endeavour to improve healthcare outcomes [57]. This progressive approach underscores India's position as a burgeoning hub for clinical research and innovation in the pharmaceutical sector [58].

12 Specific regulatory considerations for the use of AI in clinical trials

Guidelines for Good Clinical Practice (GCP) are essential for integrating AI and machine learning in clinical studies. The conduct of these studies will be ethically sound and prioritise patient safety and data integrity if GCP guidelines are followed [59]. Regarding AI uses in clinical trials, regulatory scrutiny by organisations like the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) has increased. These organisations assess the application of AI and machine learning in several trial-related areas, including patient selection, dosage, and product design. The FDA's proposed risk-based regulatory framework intends to evaluate the degree of risk connected to AI uses in medication development. With the help of this framework, it is possible to adjust the regulatory requirements following the perceived risk [60]. Transparency and comprehensibility are crucial components when using AI models in clinical trials. Regulatory bodies emphasise the requirement for sponsors to provide evidence of the decision-making processes used by AI algorithms to protect the integrity and openness of the trial. Clinical studies must include thorough and accurate documentation of AI-related activities. The use of AI in trial design, data analysis, and decision-making must be fully documented by sponsors [61].

13 The future of AI in clinical trials

A significant role for generative AI is being played in patient eligibility and recruiting. AI systems can analyse enormous volumes of data to identify the best applicants, cutting down on hiring-related expenses and delays. Another useful use is predictive analytics, where AI analyses past test data to forecast results and assist researchers in making defensible choices [40]. Real-time analytics using AI-powered sensors and wearables enable continuous data collection, ensure faster discovery of problems, and improve data quality. Moreover, AI-driven drug discovery accelerates the development of new therapies by identifying and optimizing potential drugs [13]. Finally, AI facilitates adaptive test design, adjusting test parameters based on emerging data to increase performance. Some emerging trends in AI applications for clinical trials, are summarized in Table 2.

13.1 Recruitment optimization

AI is increasingly being used to identify suitable candidates for clinical trials, reducing recruitment time and costs. It has shown remarkable results in clinical trials. Researchers are increasingly turning to AI to improve recruitment, especially by finding the right people for these trials [62]. AI uses patient profiles, medical records, and social media data to screen potential participants better and compare them to the most appropriate clinical trials; if this approach is for professionals, the hiring process will be faster and reduce associated time and costs [63]. The use of AI technology in clinical trial recruitment improves enrollment rates, ultimately resulting in more successful trial outcomes. Scientific journals have recognized the power of AI in this area, underscoring its potential to transform recruitment in clinical trials [40].

13.2 Predictive analytics

Artificial Intelligence (AI)-pushed predictive models are instrumental in forecasting various crucial elements of clinical trials, including trial outcomes, affected person responses, and protection profiles. By leveraging massive datasets and complex algorithms, AI can provide valuable insights into how a scientific trial will spread. One of the most significant blessings of AI-driven predictive

Table 2 Emerging trends in AI applications for clinical trials

Sr No.	Emerging Trends	Applications	Key Benefits
1.	Patient Recruitment	Predicting suitable Candidate for the trials Identifying eligible participants [11]	Faster recruitment of participants Reduce trail costEnhanced patient diversity
2.	Drug Discovery	Predicting potential drug candidateIdentifying molecular targets	Accelerated drug discovery Cost-effectiveness screening of compoundReducing trail errors [68]
3.	Real-time Data Analysis	Predicting patients' responses Monitoring patient trials progress in real-time	Easy and early detection of safety efficacy issues Improved decision-making based on real-time data available [67]
4.	Adaptive Clinical Trials	Optimising trial design and managing sample size, which minimises risk	Improve efficacy in patient outcome Faster drug approval [40]
5.	Regulatory Compliance and Reporting	Automating compliance reporting and streaming the approval process	Enhance data accuracy Ensuring regulatory standard compliance
6.	Personalised Medicine	Modify treatments based on the patient data Predicting patient response [40]	Improved patient outcomes reduce adverse reactions and customised patient care [52]
7.	Data Security and Privacy	Protecting patient information and implementing a secure AI System	Building trust, AI-based clinical trials, and ensuring compliance

analytics is the early identification of capacity problems [22]. Researchers can hit upon anomalies or deviations from expected consequences, enabling quicker choice-making and the adjustment of study parameters. This enhances the overall efficiency of medical trials and is essential to affected persons' safety. Early identification of adverse occasions or safety issues permits fast intervention, ensuring the well-being of participants. Scientific journals have significantly documented the positive effect of AI-pushed predictive analytics on clinical trials, recognizing its capability to streamline studies strategies, lessen fees, and improve the overall success charge of studies [5, 63].

13.3 Real-world data analysis

Traditionally, drug efficacy has been monitored through randomised clinical trials, limited by the ability to capture real-world scenarios and patient experiences. The use of AI empowers researchers and healthcare providers to explore more real-world data with electronic health records and wearable data [64]. AI tools can identify patterns, relationships, and trends in this data, find effective drugs for patient populations, identify potential side effects, and diagnose unexpected benefits or risks. This in-depth understanding of drug action by health professionals can inform more informed decisions by regulators and pharmaceutical companies [65, 66]. AI tools can also help identify subgroups of patients who may respond differently to a drug, enabling personalized treatments. However, challenges such as data privacy and security, addressing biases in data, and maintaining transparency and interpretability are critical to fully harnessing the potential of AI in this field [62].

13.4 Natural language processing (NLP)

Algorithms are transforming healthcare by analyzing medical records. They automate tasks like coding and data entry, freeing doctors for patient care. NLP a special type of algorithm, extracts valuable information from clinical data, even unstructured records. This allows for improved diagnosis, treatment plans, and identification of adverse drug reactions. As NLP advances, even better patient care and medical research breakthroughs are expected [64].

14 The ethical and regulatory implications of using AI in clinical trials

The increasing use of artificial intelligence (AI) in clinical trials brings ethical and regulatory challenges. Ethically, concerns are centered around data availability, standards, and privacy. Integrating AI requires ensuring data privacy and obtaining informed consent, especially when patients may not fully understand the implications of AI data usage. Additionally, addressing bias in AI algorithms is essential to prevent unequal treatment and outcomes [67]. On the regulatory front, specialized approaches to regulating AI in healthcare are necessary due to their complexity and potential impact on patient safety and data protection. Balancing the foreseen benefits of AI in clinical trials with these ethical and regulatory considerations is crucial to harness its full potential responsibly [6].

14.1 AI liability in clinical trials

In clinical trials the investigators might face failure scenarios related to incorrect diagnosis due to programming errors

or biased training data sets available. AI developers can be stand accountable for hardware malfunction or any design flaws leading to patient harm. The sponsors and data providers can be liable for data breaches, failure in monitoring the patient confidentiality. However, clearer guidelines and robust safeguards are essential to minimize risks and protect all data used for conducting the trials [68, 69].

14.2 Current legislation and potential remedies on liability

Liability for AI use in clinical trials is governed by a mix of international and national regulations, frameworks like the European Union's general Data Protection Regulation (GDPR) address data protection and privacy, crucial for handling patient data in AI based clinical trials. The European Union proposed AI Act which aims to set comprehensive rules for AI usage, including in healthcare. The U.S. Food and Drug Administration (FDA) provides guidance on AI in Medical devices, focusing on safety and efficacy. The UK MHRA has its own AI strategy, emphasizing ethical considerations and regulatory compliances. Potential remedies for liability include stringent validation processes, regular audits, and adherence to best practices for AI development and deployment [44, 48]. Establishing clear accountability, enhancing transparency, and ensuring robust data protection are essential to mitigate risks and safeguard all stakeholders in clinical trials. Global harmonization efforts are underway to develop international standards and guidelines for AI in healthcare, such as World Health Organization (WHO) and the Organization for Economic Cooperation and Development (OECD). Moreover, it is essential to stay updated on the rapidly changing legal landscape to effectively manage AI-related risks in clinical trials. Consulting with legal experts specializing in AI and healthcare law is crucial for navigating the complexities of this area [7, 15, 68].

15 Conclusion

AI can design more effective studies, analyze vast amounts of data, improve upon data analysis, patient recruitment, and trial design. AI algorithms can analyze large datasets and identify trends that might indicate treatment effectiveness or side effects. Nevertheless, ethical and regulatory considerations must be addressed. Regulatory agencies must develop frameworks to encourage transparency, patient safety, and data integrity. Artificial intelligence applications include image analysis, natural language processing, and personalised treatments. As artificial intelligence (AI) continues to influence medicine, it is critical to strike a balance between innovation and patient safety while maintaining transparency and responsibility. By implementing solid laws and encouraging ethical AI use, we can unlock the full potential of AI in clinical studies, paving the way for a more efficient, effective, and patient-centered future of drug discovery.

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