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Generative AI in Clinical Trials: "Applications in Protocol Design, Data Management and Medical Writing"

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Abstract: Generative artificial intelligence (Gen AI), especially large language models (LLMs), is increasingly being examined to improve the efficiency of clinical trials. Clinical trials include complex tasks such as protocol development, data management, documentation and medical writing. This review examines the developing applications of Gen AI and LLMs in clinical trials, with a primary focus on protocol design, data management, and medical writing. In protocol design, Gen AI can support protocol drafting, optimization, development of eligibility criteria and assessment of trial characteristics. In data management, artificial intelligence (AI) can help with data cleaning, processing, coding, identification of inconsistencies and automation of routine processes. Gen AI also supports medical writing through literature review, summarization, document drafting, data analysis and preparation of clinical and regulatory documentation. These applications supports the clinical trials by processing the complex clinical information to decrease the workload, improve efficiency. Although they cause limitations like hallucinations, inaccurate outputs, algorithmic bias, limited generalizability, data privacy and security risks, and over dependence on AI generated information. Regulatory and ethical considerations, including accountability, audit trails, data protection, and validation, are also essential. Overall, Gen AI can support clinical trial tasks, but it should remain as an assistive technology with appropriate human oversight, professional review, validation and adherence to regulatory and ethical requirements.

Key Words: Generative Artificial Intelligence (GenAI), Large Language Models (LLM), Clinical trials, Protocol design, Clinical Data Management, Medical Writing, Natural Language Processing (NLP), Machine Learning, Data Management, Clinical Documentation, Regulatory Compliance, Human Oversight, Data privacy and security, Algorithmic bias, AI Hallucination, Data Validation, Clinical research.

Introduction

Clinical trials are research studies conducted to evaluate the safety and effectiveness of medical interventions, including medicines, vaccines and medical devices. They play an important role in the development and evaluation of new treatments for the prevention, diagnosis and management of diseases. Clinical trials are conducted in different phases to provide evidence regarding the safety, effectiveness and benefits and risks. The conduct of a clinical trial involves multiple interlinked activities that must be carefully planned and coordinated. Clinical trials are costly and time consuming. They also require subject recruitment and monitoring, systematic collection and management of data, assessment of safety and

outcomes, statistical analysis, regulatory and ethical oversight. The increasing complexity of these activities creates substantial demands on clinical research teams and requires accurate, consistent and timely handling of large quantities of data.

AI in clinical trials

The complexity, cost and duration of clinical trials have created a need for innovative approaches to improve the efficiency and quality of clinical research. Artificial intelligence (AI) has arised as advanced technology in this setting because of its capability to process large amounts of clinical data, identify patterns and support decision making. AI is increasingly being investigated across various stages of clinical trials including trial design, eligibility criteria development, patient recruitment and retention, data collection, monitoring and analysis. Natural language processing and machine learning can assist in extracting information from clinical documents and electronic health records, while generative AI and large language models can support tasks such as information, summarization, protocol development and clinical documentations and medical or scientific writing. These applications have the potential to reduce trial management workload, improve trial efficiency and support more data driven clinical research. However, the clinical use of AI requires appropriate validation, human oversight, transparency and regulatory consideration to ensure that AI supported decisions are reliable and safe.

Emergence of Generative AI and LLMs

Recent developments in artificial intelligence (AI) had led to the development of generative artificial intelligence (Gen AI), which differs from earlier AI approaches by its ability to generate new content in response to user inputs. Gen AI systems can produce text, images, audio and other forms of content, with recent advances in transformer base models rapidly expanding their capabilities. An important development in this field is the introduction of large language models (LLMs), which are capable of understanding and generating human like text and can perform a wide range of language base tasks without being specifically trained for each task.

Importance of Gen AI in clinical trials

The abilities of Gen AI and LLMs are highly relevant to clinical trials because their conduct involves detailed planning, information processing, data management and preparation of scientifically and regulatory important documents through medical writing. Clinical trial workflows require large quantities of information, including study protocols, eligibility criteria, informed consent documents, clinical study reports. LLMs can help with processes and producing such information, potentially reducing the time required for repetitive activities. Recent studies have also demonstrated the capability of LLMs to support randomized controlled trial design, including the generation of eligibility criteria, recruitment strategies, interventions, outcomes. Although it may cause limitations in clinical reasoning, accuracy affecting their outputs.

This review aims to examine the emerging applications in generative AI and large language models across clinical trials, with particular focus on protocol design, clinical trial data management and medical writing. It further evaluates the potential benefits, limitations and challenges associated with integrating these technologies into clinical trial workflows and considers the importance of appropriate human oversight.

History and Background

Evolution of artificial intelligence (AI) in healthcare

Artificial intelligence (AI) has evolved significantly over the past several decades, advancing from early approaches based on predetermined rules and symbolic reasoning towards machine learning and deep learning techniques. The development of neural networks and subsequent advances in deep learning advanced the ability of AI systems to identify complex patterns from huge databases, facilitating to their increasing applications in healthcare.

However, the development of AI has experienced periods of rapid growth as well as decreased interest due to technical and practical limitations, continuing advances in computational methods and data availability have strengthened its potential for healthcare applications.

Transition of AI and Machine learning into clinical Research

With the increasing availability of digital health information and advances in computational power, the applications of AI and machine learning (ML) gradually expanded beyond individual clinical applications into medical research and clinical development. AI based methods facilitated the analysis of large and complex biomedical datasets and provided opportunities to produce clinically relevant evidence from clinical trial data, electronic health records and other data sources. These developments created new possibilities for modernizing conventional approaches to clinical development and incorporating computational methods into evidence generation.

Expansion of AI across clinical trial activities

As AI and ML methods advanced, their applications expanded in different stages of clinical research and clinical trials. Machine learning has been examined for supporting aspects of trial design, participant identification, data management, medical writing, monitoring and analysis. The increasing interest in these applications focuses the potential of AI to enhance the efficiency of clinical research while supporting the processing and interpretation of increasingly complex clinical information.

Artificial Intelligence (AI) tools like ChatGPT can be highly useful, but they're not perfect. Sometimes AI Hallucinate may produce false, fabricated, or misleading information instead of true facts. That's why it's essential to think of AI as a helpful assistant rather than a definitive source.

AI tools may present complex topics based on their training data, which can misrepresent people or medical practices. Using AI in Medical writing presents significant drawbacks, primarily data quality, Errors, Fabrication and scientific integrity. The impressive capabilities AI, it isn't legally or ethically responsible for the work it helps generate. The responsibility always is on you, the writer.

AI should be viewed as a helpful assistant, never as a source of truth.

The advancing integration of AI and ML into clinical trial workflows has therefore established a foundation for the use of more advanced AI technologies in clinical research.

Types and approaches of Artificial Intelligence used in clinical trials

Machine Learning

Machine Learning (ML) is a key component of artificial intelligence in which computer based, algorithms which identifies patterns from data and use these patterns to produce predictions, classifications or other outputs without depending entirely on predefined rules. In clinical trials, ML methods can help in different stages of the trial, such as participant identification and recruitment, eligibility criteria assessment, trial design, monitoring and analysis of clinical endpoints. By analysing large and diverse datasets, ML can help researchers in detecting relevant patient characteristics, predicting endpoints and improving the efficiency of trial related processes.

Deep Learning

Deep Learning (DL) is a branch of ML that uses multiplayer neural networks to detect complex patterns within large and complex datasets. It has the capability to process the structural and unstructured information which helps in applications such as medical image analysis, patient phenotyping, prediction of clinical outcomes, and assessment of trial related risks. Deep Learning has also been introduced into clinical research including imaging base assessments, in which automated analysis can assist in retrieving clinically relevant information from visual data

Natural Language Processing

Natural Language Processing (NLP) allows computer based. systems to process, analyse and extract information from human language. As clinical trials generate large amounts of textual information, including electronic health records, eligibility criteria, clinical documentation and trial related documents NLP can help in the extraction and organization of relevant information from unstructured data. In clinical trials NLP can support participant identification and screening, information extraction, clinical documentation and the processing of trial related information. The advancement of transformer based, models further expanded the important basis for the development of large language models.

Computer Vision

Computer Vision describes a class of AI techniques that allows computer based, systems to process and interpret visual information. In clinical research, these methods are especially relevant when clinical trials

include medical imaging or other image based, assessment of treatment related findings and outcomes. The growing use of AI based image analysis in clinical research shows the increasing role of computer based, approaches beyond conventional numerical and textual trial data

Generative Artificial Intelligence and Large Language Models

Generative Artificial Intelligence (Gen AI) represents a newer class of AI system that is able to produce new content based on patterns learned from large datasets. Large Language Model is an important application of Generative AI and a prominent development within NLP, which is trained on extensive text databases and can generate, summarize, transform and produce natural language content. Their ability to interact with complex textual information has given the opportunities for their applications in different stages of clinical trials, including trial design, patient recruitment and screening, data management, safety monitoring and generation of scientific and clinical documentation.

Applications of Ai in clinical trial protocol design

Protocol drafting

Generative AI, especially Large Language Models (LLMs) has a greater role to support the design and drafting of clinical trial protocols by producing important protocol sections such as eligibility criteria and outcome measures. In one review, GPT 4 turbo preview produced core elements of randomized controlled trial designs with a total accuracy of 72%, with better performance noticed for intervention design and recruitment requirements (1) Likewise, GPT4 has been examined for producing clinical trial protocol sections, with Retrieval Augmented Generation (RAG) providing access to relevant information sources like scientific literature, regulatory guidance (2). These findings suggest that LLMs can assist in preparing initial protocol content and organizing information, which may reduce some of the manual effort required in protocol development.

Protocol optimization

In addition to initial drafting, AI can also support the enhancement and optimization of clinical trial protocols. Application Specific Language Models (ASLMs) have been proposed for detecting potential protocol flaws and enhancing important components such as outcomes and safety monitoring plans (3). LLMs have also been examined for reviewing existing protocols and identifying important study characteristics and statistical components. These applications show that AI may contribute not only in generating protocol content but also identifying areas that need further improvement during protocol development.

Eligibility criteria

Eligibility criteria are an important part of protocol development as they identify the characteristics of participants who should be included in a clinical trial. LLMs have been examined for both generating and assessing these criteria. Although GPT4 turbo preview was able to produce eligibility criteria, it's accuracy for this part was lower than that of intervention design (1). The use of RAG enhanced clinical reasoning when generating eligibility criteria (2). The findings suggest that AI may assist researchers in designing eligibility criteria, while careful evaluation is required to ensure that the generated criteria are clinically appropriate.

Trial design support

In protocol evaluation, GPT4o was able to obtain important study characteristics, including disease, population, intervention, sample size, trial phase and primary endpoints from clinical trial protocols. It was also used to assess statistical analysis plans and pharmacokinetic and pharmacodynamic components, showing the potential of LLMs to support trial design and analysis (4). Therefore, AI may provide support across several stages of trial design.

Overall role of Generative AI in clinical trial protocol design

Overall, generative AI may assist in various stages of clinical trial protocol development, from initial drafting to refinement and assessment. LLMs can provide key protocol components, while RAG based models can incorporate clinical, scientific and regulatory information to enhance the applicability of the generated content (1-3). AI based tools may also assist in evaluating technical aspects, such as study characteristics and statistical analysis plan (4). Although current evidence supports the use of AI as an

assistive tool rather than a replacement for clinical statistical and regulatory expertise. Professional review by human expertise remains essential to check the accuracy and appropriateness of AI generated content.

Data Management

Combining Past and Future of Clinical Data Management: The Revolutionary Influence of AI.

This article review illustrates how artificial intelligence (AI) and machine learning (ML) are revolutionizing the classical clinical data management (CDM) and transforming it into modern clinical data science. According to PRISMA-ScR guideline the author performed literature analysis from the year 2008 to 2025 across different databases including Scopus, Web of Science, and Pubmed. As a result, 26 appropriate papers have been selected. The basic emerging trends include risk-based quality monitoring, Blockchain technology, remote monitoring, patient-focused approaches with the use of wearable devices and mobile applications. Phase III trials are witnessing significant growth in the volume of data being collected. The technology boom brings about a huge need for advanced technologies such as Natural Language Processing (NLP) for analyzing non-structured text information.

Data Cleaning

The process includes forming information queries. As in the case of Pharmacovigilance, Adverse Drug Reaction (ADR) identification and Substance Use Disorder (SUD) situations. Technologies used: Generative AI solutions (ChatGPT-4, LLaMA-2), Natural Language Processing, and Deep Learning. The sources of Real-World Data (RWD) comprise Electronic Health Records (EHRs), insurance claims, databases, wearable devices, and social networking sites

Data Processing and Coding Support.

Recent research indicates that significant advancements have been achieved by Large Language Models (LLMs) and Multimodal Language Models (MLMs) in automating clinical administration processes and responding to basic questions of patients. Nevertheless, these models have not reached a level where independent diagnostic and surgical decisions can be made. For Instance, a scoping review conducted by Lui and Mobbs (2026) assessed the application of artificial intelligence in spinal surgery. To meet this objective, the research team carried out systematic research through PubMed, EmBase, and Scopus by searching for relevant papers published between January 2023 and January 2026 and filtering the total pool of studies from an initial number of 351 studies to 40 papers through the Population, Concept and Context (PCC) model. According to the results of this review based on applying Vertical Integration Maturity Scale (VIMS), the authors determined that the most intense research has been conducted at VIMS level 1 (level III). Based on these findings, the research reveals that current AI usages in medicine are mainly related to the process of simple collection of evidence-based practices instead of developing personalized medical treatments for patients. Finally, the review pointed out the gap between the two data sets since ChatGPT-4 performed well in accordance with the clinical benchmarks (with the agreement rate from 61.1 percent to 88.2 percent) though its diagnostic performance in when evaluating complex spinal lesions was only 11.1 percent.

EDM/CDM Support

This component describes tactics for improving the logic design of edit checks. In the past, processes related to clinical data involved a lot of work and were reliant on rigid logic and manual medical coding systems. The methods used in these processes are susceptible to error since they rely heavily on human labor and cannot be successful when strongly affected by the rapid growth of electronic health records (EHRs) and multi-omics information. When combined with AI technologies and ML systems, the medical data handling process is undergoing a remarkable evolution since these techniques facilitate the automation of routine processes and enhance the quality of the information far exceeding that which can be achieved through manual processing. Some of the advanced technologies that are utilized in this development include NLP, automatic or semi-automatic ML systems, predictive analytics, and Robotic Process Automation. The purpose of these automated workflows is to maintain both the safety of constructions and the integrity of the data. More specifically, this includes the application of the Total Product Life Cycle (TPLC) principles developed by the FDA and the Good Machine Learning Practice (GMLP) guidelines. While the application of AI/ML frameworks greatly accelerates the process of completing cycles and reduces error rates, they also expose new risks for compliance requiring continuous monitoring.

Generative AI in Medical Writing

Ethical Use of AI in Medical Writing

This article is designed to help those challenges with practical advice grounded in the latest research and ethical guidelines, so you can use AI to maintain high standards. Artificial Intelligence is transforming how we create medical content creation, AI- powered documentation, abstract writing, statistical summarization and data analysis faster and more efficient. It's important to recognize the both risks and benefits of using some AI tools.

The future of AI in Pharmaceutical regulatory affairs

As GenAI abilities become a document- based business processes, where AI tools used for evolving simpler drafting of content to providing content intelligence. Regulatory review agents trained on regulations and historical health authority queries, will collaborate with medical writers to ensure compliance with applicable regulatory standards.

Simple & Clear Version

High Academic Version

Technology: Large Language Models (LLM), Natural Language Processing (NLP), generative AI, Hallucination and Reference Validators.

Pros and Cons of AI in Medical writing

Pros of AI in Medical Writing

Quality Assurance

In the world of medical writing, precision isn't just a goal- it's a necessity. When writers spend hours on repetitive work like fixing citations and small mistakes are bound to happen, even minor error can affect the accuracy of the whole document. Further, integrated plagiarism detection safeguards the absolute integrity of medical research. These advancements minimize the risk of information- directly contributing to safer patient care and more reliable clinical decision- making.

Data Analysis: Maximizing Efficiency

We believe GenAi is here to stay and plays a vital role in future and its potential is real. Ai tools are useful for faster review and writing whether the drug reaches the patients in accurate time. GenAI should be used correctly, it can benefit both writers, companies and patients.

Saves Time and Resources

AI writing tools help speed up a wide range pf tasks, and reviewing literature to summarizing research findings, and drafting clinical study protocols, consent forms and reports.

Personalization

Medical writing tools make it easier to customize patent resources, such as brochures, and consent forms, to match the needs of each individual and study population.AI can also rewrite the complex clinical jargon into personalized "layperson" summaries. Summary can be tailored to patient primary language, age and health conditions.

Cons of AI in Medical writing

Potential for Bias and Inaccuracy

Larde language models (LLMs) have revolutionized automated content creation, but ensuring the dependability and correctness of AI-generated material remains a critical challenge. When tasked with analysing complex medical concepts, context specific data, or rare illness, AI systems often result in lack necessary training data to formulate accurate responses.

Over Reliance on AI

When technology replaces human oversight, the essential contributions of medical experts-such as deep contextual understanding, critical thinking, empathy, and ethical judgement- are dangerously sidelined.

Ethical Concerns

The use of generative Ai tools introduces algorithmic bias, lack of critical accountability and concerns regarding data privacy. Sometimes AI models can expose sensitive patient data to third-party serves. AI tools cannot be held legally or morally responsible for errors.

Cost and Accessibility

For medical writers with limited budgets, some AI tools are hard to afford due to their high cost. Systems require continuous software updates, and regular algorithmic retraining to remain compliant and safe.

Benefits of Generative AI in Clinical Trials

Faster Clinical trial design- It usually helps in producing the initial drafts of study protocols, inclusion and exclusion criteria and informed consent forms and simplifying administrative procedure.

Optimized Trial Design - Generative AI can optimize clinical trial design by transforming slow protocol planning into a data-driven' automated process that reduces design time from months to days.

Literature review- Conducting literature review is a critical and it's a time taking part of clinical trials. Using generative AI tools make this process easy and more efficient.

Data Management- In this the AI tools involve in the process by automating data entry, detecting inconsistencies and missing values, and ensuring compliance with regulatory standards**.** It also reduces human errors and improves data accuracy and integrity.

Clinical Documentation- It summarizes the massive volumes of patient day, safety logs, and trial results into structured regulatory formats. It also focuses on reviewing, refining and ensuring the data quality.

Challenges and Limitations

Hallucinations and Inaccurate Outputs- Using Generative AI in clinical trials is one of the risk of hallucinations and inaccurate outputs. It provides incorrect information about the drug's efficacy and safety. Generating incorrect, unsupported, or completely fabricated information even the AI system produces confident information. The errors in interpreting complex medical terminology in the outputs.

Algorithm Bias and Lack of Generalizability- Algorithm bias occurs when training datasets often lack adequate racial, gender, unrepresentative patient enrolment away from underrepresented groups. Generative models have massive parameters as they give good as they trained on. If that training data is not diverse and representative, the AI can produce biased results.

Data privacy and Security risks- Generative AI in clinical trials involve in the highly sensitive patient data. Relying on AI vendors without auditing their data storage and deletion policies can violate regulatory frameworks like HIPAA and GDPR.

Need for Human Oversight- In clinical trials AI cannot replace clinical experts. Because generative models lack clinical intuition, ethical reasoning and legal accountability, a human-in-the-loop (HITL) framework is required to human safeguard patient safety. Every AI-Generated output needs through review and validation by qualified professionals.

Regulatory and Ethical Considerations.

US FDA

The role of the FDA is very important in controlling medicines, biologics, medical equipment, and clinical trials in America. At the same time, the presence of AI technologies in drug development should be viewed in light of the applicable regulations. According to the FDA, the number of the applications using these technologies is changing very quickly. Their use can be found in clinical studies, real-world data analysis, the study of the safety of drugs, and production processes. Moreover, the FDA has carried out research into the use of AI in clinical trial designs and enrollment, and predictive modeling. The FDA has also considered the use of AI in the areas of clinical trial design, recruitment, predictive modeling and safety surveillance. The agency has issued guidance in relation to the use of computerized systems suggesting that changes to regulated records ought to be made in accordance with appropriate audit trails.**EMA**

The European Medicines Agency (EMA) oversees all scientific and regulatory matters pertaining to drugs in the framework of the European regulatory system. This document provides an overview of AI and machine learning applications from drug discovery up to post-marketing stages of medicine development. EMA is aware of the possibilities provided by AI for enhancing the process of drug

development. However, AI may also generate risks associated with bias, transparency issues, and the integrity of the model.**ICH and Good Clinical Practices (GCP)**

The International Council for Harmonisation (ICH) has developed guidelines that are useful in the fields of drugs and drug testing. The Good Clinical Practice guidelines (GCP) (ICH E6) define requirements for the development, implementation, and assessment of the safety of biomedical study procedures. GCP protects participants in biomedical studies while providing outputs of trials of high quality. Testing facilities should ensure the meaningful use of computerized systems for the recording and analysis of trial data. Data security practices must be applied in all stages of data interaction.

Data Protection

Clinical studies necessitate the use of sensitive personal and medical details.AI systems also need to have access to data that contains medical histories, lab tests, and genetic data and other sensitive information. The misuse of such information can lead to various privacy issues with regard to the individuals under the study. Because of this, it is important to gather and process such information for legitimate and clearly defined purposes only. EMA places emphasis on GDPR when talking about the use of AI in developing treatments. ICH GCP also stresses the importance of protecting people's data and keeping the information related to clinical studies secure**.**

Accountability

Accountability entails that a clear individual or organization is responsible for actions taken and outcomes of a given AI system. There is no place for ambiguity in responsibility due to the adoption of AI technologies. Sponsors bear the responsibility for the quality of clinical trials, regardless of the use of advanced technologies or external service providers to that end. Investigators should be responsible for protecting the rights and safeness of research participants, in accordance with the current rules of GCP. AI producers need to record the intended use and functionality of the developed systems as well as their limitations.

Audit

Audit trail is an entry created to keep the count of any actions done on electronic clinical trial data.It may show who created or altered the data.It should also allow recording when a chang took place and why. Audit trails are critical for maintaining the authenticity and traceability of clinical trial data. PDA guidelines define auditing as an electronic record that ensures the reconstruction of processing times associated with digital records.

Validation

Validation refers to whether the performance created by an artificial intelligence (AI) or computer program has fulfilled the stated capabilities. AI systems used in the context of clinical trials should go through the process of validation before individuals utilize their outputs for significant trial operations. According to ICH E6(R3), validation should take into account the purpose of the possible usage, significance of data and implications for the safety of subjects and reliability of trial outcomes

Future Perspectives:

Increased AI applications during conducting clinical trials.

In the future, using AI could become common during the vast majority of stages of clinical trials instead of only certain phases.AI use might extend from patient recruitment and designing clinical trials to data processing, monitoring, evaluating safety, and doing post-trial pharmacovigilance. In January 2026, both the FDA and EMEA recognized the significance of AI for various tasks during the drug development.

Multimodal models.

The future of clinical trials will see the use of various types of evidence. This can be in the form of EHRs, lab tests, images, wearable devices, genomic data and patient-reported outcomes. Multimodal AI is expected to combine these kinds of data to form a much wider image of patients. Multimodal AI should be able to integrate text, images, physical measurements and various other clinical data in a single analytical tool.

Clinical trials may become more patient-focused with the help of artificial intelligence.

Through the use of machine learning products, it is possible to process considerable amounts of clinical data and find correlations between patient characteristics and response to a treatment. This could allow for better patient recruitment and identification of the appropriate trial participants. Wearable devices and mobile applications can provide real-time information about the patient outside hospital visits. Currently, the future development of clinical trials should be centered on personalization and, at the same time, respect the principles of fairness, privacy, and scientific validity.

Conclusion

Generative AI and Large Language Models are developing as useful assistive technologies in different stages of clinical trials, particularly in protocol design, data management, and medical writing. The reviewed applications suggest that Gen AI can support protocol drafting, optimization, assessment of eligibility criteria and trial characteristics, while AI based approaches can support data cleaning, processing, coding and other routine data management activities. In medical writing, Gen AI can help with literature review, summarization, document drafting, data analysis and preparation of clinical and regulatory documents.

Even though there are many potential benefits, several challenges decrease the independent use of Gen AI in clinical trials. Hallucinations, inaccurate outputs, algorithmic bias, limited generalizability, data privacy and security risks, and over dependence on AI generated information may affect the quality and consistency of clinical research. Therefore, Regulatory and ethical considerations, including accountability, audit trails, data protection and system validation are essential for responsible implementation.

Overall, Gen AI has the potential to improve the efficiency of clinical trial workflows and reduce the burden of repetitive activities. However, it should be considered as an assistive technology rather than a replacement for human expertise. Proper human oversight, professional review, validation and adherence to regulatory and ethical requirements remain essential to make sure that scientific validity, data integrity, participant safety and reliable clinical trial outcomes.

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