

LITERATURE ANALYSIS OF ARTIFICIAL INTELLIGENCE APPLICATIONS IN CLINICAL TRIAL DESIGN FOR ENHANCED EFFICIENCY AND PATIENT OUTCOMES

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INTRODUCTION

Artificial intelligence (AI) is advancing healthcare by improving diagnostic efficiency, service quality, and reducing complexity through technologies like machine learning, deep learning, and natural language processing. While AI shows strong performance in research, its real-world impact remains underexplored. Studies demonstrate AI's potential to match or surpass human capabilities in certain tasks, but concerns persist about translating these results into practical healthcare settings. Comprehensive, quantitative research is still needed to assess AI's performance in real-world medical environments

OBJECTIVES

The objectives of this study are to explore the utilization of Artificial Intelligence (AI) in clinical trial design for optimizing patient inclusion and exclusion criteria, expediting processes, and enhancing overall trial outcomes.

MATERIAL AND METHODS

A comprehensive literature analysis was conducted following the PRISMA guidelines to identify relevant studies on the application of AI in clinical trial design, utilizing databases such as Web of Science and PubMed. Key themes and insights were synthesized to provide an understanding of the current status and potential of artificial intelligence in this domain. The literature search strategy involved systematically applying specific search terms and their combinations, including "Artificial Intelligence," "clinical trial design," "efficiency," "efficacy," and "effectiveness." The temporal scope of the study was restricted to articles published from January 1st, 2021, to January 1st, 2024. Subsequently, a thorough review and evaluation of the abstracts and full texts of these publications were conducted to ascertain their relevance to the research topic. Only publications directly related to the research topic focus were included in the final analysis.

RESULTS

A total of 497 publications were initially identified, but after screening, only 10 were deemed directly relevant to the research topic.

Areas where AI may enhance clinical trial (CT) design were identified:

- (1) Predicting patient outcomes: AI simulations can improve statistical outcome measures, aiding precision medicine and informing trial design.
- (2) Predicting trial success: AI predictions in early research phases can enhance trial design and reduce failure rates in later stages.
- (3) Reshaping CT design: AI facilitates hypothesis generation, disease understanding, drug discovery, cohort composition, monitoring, adherence, and endpoint selection.
- (4) Recruitment: AI tools match patients with complex inclusion criteria, improving recruitment efficiency and expanding participant reach.
- (5) Patient monitoring and adherence: AI algorithms, combined with wearable technology, enable continuous patient monitoring and real-time treatment feedback.
- (6) Automation for analysis support: AI automates data extraction and analysis, reducing manual effort and human error.

Benefits of AI application in CT design include improved efficiency, increased accuracy, personalized treatments, cost reduction, accelerated time to market, and better patient outcomes.

Challenges of applying AI in CT design include data quality, interpretation of results, and ethical concerns regarding patient data protection and informed consent.

CONCLUSIONS

The integration of Artificial intelligence into clinical trial design holds immense promise for advancing patient care and driving medical research forward. By harnessing the capabilities of AI, researchers can foster healthcare innovation by overcoming challenges and seizing opportunities..

This study highlights key areas where AI can enhance clinical trial design, including patient recruitment, outcome prediction, and drug adherence. However, it also underscores the importance of addressing issues such as data bias and ethical considerations, emphasizing the need for robust governance frameworks and collaborative efforts among stakeholders in AI implementation.

