WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 7, 1456-1463. Review Article ISSN 2277–7105

THE ROLE OF ARTIFICIAL INTELLIGENCE IN MODERN CLINICAL TRIALS: A REVIEW

***L. Kavya Sri Reddy**

India.

Article Received on 05 March 2026,
Article Revised on 25 March 2026,
Article Published on 01 April 2026,

https://doi.org/10.5281/zenodo.19413446

***Corresponding Author**
L. Kavya Sri Reddy
India.

How to cite this Article: L. Kavya Sri Reddy. (2026). The Role Of Artificial Intelligence In Modern Clinical Trials: A Review. World Journal of Pharmaceutical Research, 15(7), 1456–1463.

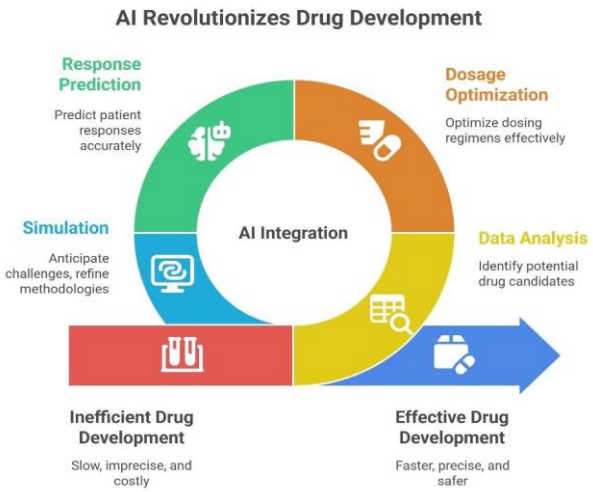
ABSTRACT

Clinical trials are very important for checking the safety and effectiveness of new medicines before they are allowed to be used by the general public. Traditional clinical trial methods have several problems like high costs, long periods of time, difficulty in finding enough people to take part, and complex ways of managing data. However, in recent years, Artificial Intelligence (AI) has become a big help in overcoming these problems and changing how clinical trials are done. This article talks about the different ways AI is used in clinical trials, such as improving patient recruitment, making trial planning more efficient, allowing real-time data collection, and making data analysis better. Technologies like machine learning and natural language processing help researchers find patterns, make predictions, and reach quicker decisions based on data. The article also gives real examples of how AI tools have made clinical research more efficient. Even though AI has many benefits like saving time and money, there are also worries about keeping data private, using AI ethically, and getting approval from regulators. The article also looks at these challenges and talks about the future potential of AI in making clinical trials more accurate, diverse, and focused on patients. Overall, AI is set to greatly change the clinical trial process and help develop safer and more effective drugs faster.

INTRODUCTION

The development of new pharmaceuticals and therapeutic interventions is a cornerstone of modern medicine, yet the process for validating their safety and efficacy is critically inefficient. Clinical trials, the gold standard for evidence-based medicine, are notoriously

long, expensive, and fraught with high failure rates. The journey from initial discovery to market approval can take over a decade and cost upwards of $2.6 billion per successful drug, with failure rates exceeding 90% for many therapeutic areas.[1] The main problems causing this lack of efficiency are well-known and include poor trial planning, slow recruitment of patients, not following medication as prescribed, and the big challenge of getting useful information from complicated and detailed data sets. To address these big issues, Artificial Intelligence (AI), especially a part of it called machine learning (ML), is becoming a major tool that can change how clinical research is done. By using a lot of computing power to find complex patterns and make accurate predictions from a lot of medical data, like electronic health records, genetic and protein data, medical images, and real-world information, AI provides a strong set of tools to make the clinical trial process much faster, more accurate, and more efficient.[2]



1) AI in Pre-Clinical and Trial Design Phase

The success of a clinical trial depends a lot on how well it is planned from the start. If the plan is not strong or thoughtful, it can cause unclear results, problems getting enough people to join, or even fail to show that a drug works, even if the drug is actually useful. Artificial intelligence can help reduce these risks during the early stages by moving away from old, fixed plans to ones that are more flexible, based on data, and work better.

1.1) Hypothesis Generation and Drug Target Identification

Before starting a trial, it's important to find a good target for a new treatment. AI, especially using deep learning and natural language processing, can look through a lot of biomedical information, patent records, and screening data to find new ways the body works and possible

targets for drugs that humans might miss. By combining different types of data like gene, protein, and metabolism information, AI can create detailed models of diseases and predict how a drug might work in the body. This helps make better, evidence-based ideas for testing in real patients.[3]

1.2) Optimizing Protocol Design with *In Silico* Trials

One of the biggest changes AI has brought to trial design is the creation of in silico clinical trials. These are computer-based tests that use "virtual patients" models made from real health data and actual patient experience to check a treatment plan before it's used in real life. Scientists can run tests with different settings, like various rules for who can join, how much medicine is given, how long the test lasts, and what results are measured. This helps them figure out the best way to set up the study, lowers the risk for people taking part, saves money, and makes the trial more likely to work before any real patients are involved.[4]

1.3) Intelligent Biomarker Discovery

AI is also helpful in finding new biomarkers that can act as better signs of how a disease is getting worse or how well a treatment is working. Machine learning tools can look at large sets of data from different sources like medical images, genetic information, or signals from wearable devices to find small patterns that are linked to health results. For instance, a deep learning model could spot a special texture in a brain tumour scan that helps predict if a patient will respond to a certain type of cancer treatment, making it a strong imaging biomarker.[4]

2) AI-Driven Patient Recruitment and Stratification

Patient recruitment is often considered the biggest challenge in running clinical research. About 80% of trials don't reach their goal of enrolling enough people on time, which causes expensive delays and, in some cases, leads to ending the trial early.[5] The conventional method of manually screening patients tends to be time-consuming, labour-intensive, and frequently inefficient. Artificial intelligence introduces a transformative approach by enabling quicker, more accurate, and fairer techniques for selecting and enrolling eligible participants in clinical trials.

2.1) Automating Patient Screening with Natural Language Processing

A large part of a patient's medical information is written in free text, like doctors' notes, discharge summaries, and lab reports. Going through these papers to check if patients meet

certain rules, is a huge job. AI, especially using Natural Language Processing (NLP), can do this work quickly and at a big scale. These AI tools are taught to read and understand medical records, pulling out important details like illnesses, medicines, test results, and how diseases develop. When used in full hospital electronic health record systems, these tools can quickly find patients who might qualify for studies. This cuts down the work for doctors and other staff by more than 90% in some cases and makes it much faster to get people into studies.[7]

2.2) Predictive Patient Stratification for Precision Medicine

AI goes beyond basic eligibility matching by enabling a more advanced method of patient selection called predictive stratification. Using machine learning, models can be trained on diverse data types such as genetic information, medical imaging, and patient history to pinpoint subgroups that are either more likely to benefit from a specific treatment or at greater risk of experiencing serious side effects. This strategy aligns with the core principles of personalized medicine. By focusing trials on participants with a higher chance of responding, researchers can conduct more efficient 'smart trials' that are smaller, shorter in duration, and statistically stronger ultimately improving the chances of success and ensuring the therapy reaches those who need it most.[8]

2.3) Enhancing Diversity and Equity in Enrolment

A big problem in clinical trials has always been that not enough different kinds of people take part, which makes the results less useful for everyone. But if AI is made and used carefully, it can help fix this issue. Still, if the AI isn’t designed well, it could actually make health differences worse for some groups.[9]

3) Accelerating Patient Recruitment and Stratification

Patient recruitment is a major challenge in clinical research, and about 80% of trials don't meet their enrolment deadlines. AI provides strong tools to help find and choose the right patients faster.

3.1) Automated Patient Screening

Natural Language Processing (NLP) algorithms can go through millions of unstructured EHR notes, physician letters, and pathology reports to find patients who meet specific eligibility requirements—a process that would be very slow and full of mistakes if done by hand.[10]

3.2) Predictive Patient Stratification

Besides checking basic qualifications, AI can find groups of patients who are most likely to benefit from a certain treatment or those who might face serious side effects. This helps create smaller, more focused trials, which is an important part of moving toward personalized medicine.[11]

4) Enhancing Trial Conduct and Monitoring

During the conduct of a trial, it is important to closely watch everything to keep patients safe and ensure the data is accurate. Using AI tools can help make these tasks faster and more reliable.

4.1) Remote Monitoring and Digital Biomarkers

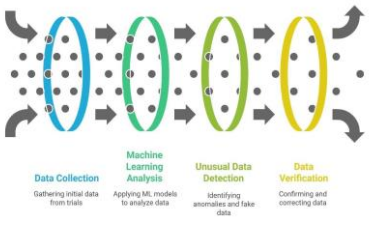
Data from devices like wearables, smartphones, and other sensors can be constantly checked by AI tools to watch how well patients follow their treatment, see how their illness is changing over time, and spot early warning signs of problems, which helps make clinical trials more flexible and spread out.[12]

4.2) Pharmacovigilance Automation

AI can check safety databases, social media, and electronic health records to find early and thorough signs of possible negative events, which traditional reporting methods can't do as well.[12]

4.3) Data Quality Assurance

Machine learning models can spot unusual or fake data right away, helping keep the trial data set accurate and cutting down on the expensive work of checking data by hand.[12]



5) Advanced Data Analysis and Outcome Prediction

The main purpose of a trial is to find out if a treatment is effective. AI can get deeper insights from complex, high-dimensional trial data than traditional statistical methods.

5.1) Analysis of Complex Datasets

Deep learning models are really good at looking at different types of data like MRI and CT scans, digital pathology slides, and genetic information. They can find tiny patterns that show how well a treatment is working, which people can't see with just human eyes.

5.2) Predicting Trial Outcomes

AI models can be trained on interim data to predict the final outcome of a trial with a certain probability, allowing sponsors to make earlier go/no-go decisions and allocate resources more effectively.

5.3) Causal Inference

New machine learning methods are being created to more accurately measure the real impact of treatments from both controlled experiments and real-world observations, making it easier to tell the difference between things that happen together and things that actually cause each other.[13]

6) Future Directions

AI is still being used in clinical trials at the beginning of its development. New advancements are expected to change the field even more in the future.

6.1) Digital Twins

Making detailed, accurate computer models of each patient that change over time could help create truly personalized tests and better treatment plans.

6.2) Generative AI for Hypothesis Generation

Large models and other types of AI that create new content can look through all the available scientific papers in medicine to come up with fresh ideas for research and suggest new ways to make drugs or combine different treatments.

6.3) Fully Decentralized and Automated Trials

The coming together of AI, wearable devices, and telemedicine could create a future where many medical tests and studies can happen mostly in a patient's home. AI would handle the planning, tracking, and gathering of information during these trials.[14]

CONCLUSION

Artificial intelligence is no longer just a futuristic idea in clinical research—it is a real and growing tool that is changing how drugs are developed. This review shows that using AI is not a one-time change but a big improvement that affects every part of the clinical trial process. From the very start, AI helps create computer-based models of trial plans and discover new biomarkers, laying the groundwork for more efficient and focused research. It also tackles a big problem in the industry—finding patients for trials—by using smart algorithms to quickly find and group people who fit the right criteria, something that traditional methods can't do as well. Once a trial is running, AI acts as a careful watcher, helping run trials from home through real-time data from digital health tools. This makes patient safety better and data more accurate. All these uses lead to clearer results: making clinical trials quicker, less costly, more likely to work, and more centred on the patient's needs. But there are challenges in fully using AI. We need to balance its potential with careful attention to ethical issues, rules, and how to implement it. Problems like unfairness in algorithms, not knowing how AI decisions are made, keeping patient data safe, and needing new rules all need teamwork from data experts, doctors, ethicists, and lawmakers to build trust and make sure everyone benefits fairly. Looking forward, the future of AI in clinical trials will be even more connected. New tools like digital twins for simulating personalized trials and AI that creates new ideas for research are coming. Using AI in a smart and ethical way is a key chance to end the long cycle of slow and inefficient drug development. By continuing to work together across different fields, we can use AI to turn scientific discoveries into life-saving treatments for people around the world.

REFRENCES

1. DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics, 47: 20-33. https://doi.org/10.1016/j.jhealeco.2016.01.012.
2. Topol, E. J. (2019). High-performance medicine: the convergence of human and artificial intelligence. Nature Medicine, 25(1): 44–56. https://doi.org/10.1038/s41591-018-0300-7
3. Vamathevan, J., et al. (2019). Applications of machine learning in drug discovery and development. Nature Reviews Drug Discovery, 18(6): 463–477. https://doi.org/10.1038/s41573-019-0024-5

4. Pappalardo, F., Russo, G., Tshinanu, F. M., & Viceconti, M. (2019). In silico clinical trials: a review of the state of the art and a research agenda. Briefings in Bioinformatics, 20(1): 329–338. https://doi.org/10.1093/bib/bbx107
5. Liu, Z., et al. (2019). A deep learning-based framework for prostate cancer diagnosis and grading in whole-slide images. Scientific Reports, 9(1): 1–11. https://doi.org/10.1038/s41598-019-39213-9
6. Applied Clinical Trials. (2012). Recruitment Woes: 80% of Trials Fail to Meet Timelines: Retrieved from https://www.appliedclinicaltrialsonline.com/view/recruitment-woes-80-trials-fail-meet-timelines.
7. Zeng, D., et al. (2021). Deep-learning-based natural language processing for screening patients for clinical trials: a retrospective study. The Lancet Digital Health, 3(10): e657–e666. https://doi.org/10.1016/S2589-7500(21)00185-2.
8. Beaulieu-Jones, B. K., Yuan, W., & Finlayson, S. G. (2021). Machine learning for patient stratification and classification. The Lancet Digital Health, 3(9): e590–e600. https://doi.org/10.1016/S2589-7500(21)00150-5.
9. Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019). Dissecting racial bias in an algorithm used to manage the health of populations. Science, 366(6464): 447–453. https://doi.org/10.1126/science.aax2342.
10. Zeng, D., et al. (2021). Deep-learning-based natural language processing for screening patients for clinical trials: a retrospective study. The Lancet Digital Health, 3(10): e657-e666.
11. Beaulieu-Jones, B. K., et al. (2021). Trends in clinical prediction model development and validation in the context of the big data era. The Lancet Digital Health, 3(9): e589-e599.
12. Coravos, A., Khozin, S., & Mandl, K. D. (2019). Developing and adopting safe and effective digital biomarkers to improve patient outcomes. npj Digital Medicine, 2(1): 14.
13. Rajkomar, A., Dean, J., & Kohane, I. (2019). Machine Learning in Medicine. New England Journal of Medicine, 380(14): 1347-1358.
14. Subbiah, V. (2023). The next generation of clinical trials. Nature Medicine, 29(1): 38-46.