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REVIEW ON AI IN CLINICAL TRIALS

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ABSTRACT

Despite the recognized financial investments and risks for pharmaceutical companies, clinical trials (CTs) remain the gold standard for developing safe medications. The integration of artificial intelligence (AI) is being explored to enhance drug development through the analysis of vast clinical and molecular data. AI models are necessary for extracting actionable insights, expediting drug research, and improving patient recruitment and monitoring. Preclinical research, essential for assessing the safety and efficacy of new treatments, involves both in vitro and in vivo investigations focused on pharmacodynamics, pharmacokinetics, and toxicology. This phase aims to establish safe starting doses for human trials and must adhere to strict ethical standards before regulatory approval allows clinical studies to commence.

KEYWORDS: *Artificial Intelligence (AI) · Machine learning (ML) · Clinical trials (CT) · Opportunities · Challenges · Implications*

INTRODUCTION

Despite the long-standing recognition of the significant financial outlay and elevated risks for pharmaceutical companies, the evidence produced by CTs is generally acknowledged and is probably going to continue to be the gold standard for the creation of safe and effective medications. [1,2]

Several uses in CTs are being suggested and are starting to be investigated in practice as AI is acknowledged as a means of achieving sustainable and optimal drug development. Large and complicated amounts of categorized and uncategorized clinical, molecular, and imaging data are made available to medical research through the growth and extension of randomized trials. While having access to data is essential for developments in data-driven and personalized medicine, using comprehensive AI models that have been developed and trained using relevant datasets is necessary to produce actionable insights from the information that is already accessible , to efficiently speed up and simplify the many drug research tasks. [2, 3]

Numerous potential have already been noted in the literature, beginning with AI's role in discovery in fields (rare diseases, tailored medicines) where profitability may not be supported by return on investment. Furthermore, it is proposed that expected improvements in protocol design and patient recruitment efficiency will raise the likelihood of trial success, while AI-powered patient monitoring and analysis could have a beneficial effect on measurement and result interpretation.[2–5]

METHODS

A search was conducted using the general phrases "artificial intelligence" or "machine learning" along with the term "clinical trials" in the PubMed, SCOPUS, International Pharmaceutical Abstracts, and Google Scholar databases to find pertinent English-only papers. The vast list of irrelevant results was narrowed down by using exclusion criteria that referred to AI/ML uses outside of CTs (e.g., “clinical practice”, “surgery”, “diagnosis”, “treatment”).

Using the same keywords, the websites of the Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the European Commission (EC) were searched to find pertinent regulatory papers. Between October 7 and October 14, 2021, searches were conducted. The results were taken from websites and source databases and compiled into a single Excel file. Any publications published before 2017, those that were irrelevant to the US or the EU, and any duplicates were eliminated to guarantee that research was conducted on cutting-edge AI .

This made sure the most current and relevant publications stayed. Lastly, articles and/or materials that did not discuss applications of AI or ML in the context of CTs were deemed out of scope and excluded from this review. The findings were manually condensed based first on the title and then on the abstract content. [6]

DISCUSSION

Here are several major CT actions or regulatory-relevant documents that summarise the opportunities and problems that have been found, as well as the potential future effects of integrating AI.

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1. Pre-Clinical Research =>

Pre-clinical research is the initial phase of pharmaceutical and medical research that occurs prior to the start of clinical studies with human subjects. In order to guarantee the safety and possible efficacy of novel medications, treatments, or medical equipment, it is essential.

Usually carried out in vitro (in test tubes or petri dishes) and in vivo (in animal models), preclinical investigations evaluate the following:

Pharmacodynamics,
Pharmacokinetics,
Toxicology.

The effectiveness Finding a safe starting dose for human trials is one of the primary objectives of preclinical research.
Determine the levels of toxicity and possible adverse consequences.
Collect preliminary data regarding the treatment's efficacy.
Compile first information regarding the treatment's efficacy.

To guarantee the validity of results, preclinical research must abide by stringent ethical and scientific standards, such as Good Laboratory Practice (GLP) requirements.

As part of an Investigational New Drug (IND) application or a comparable procedure, data from preclinical research are submitted to regulatory bodies (such as the FDA in the US or the EMA in Europe). The start of human clinical studies is contingent upon regulatory approval. [4]

2. Design

In clinical trials, "design" refers to the methodical approach or planned strategy that is employed to carry out a clinical investigation. It describes the trial's methodology to guarantee that the information gathered is accurate, trustworthy, and competent to address the particular research issues.

Crucial Elements of Clinical Trial Architecture:

Type of Study
Interventional (experimental): Participants are given certain treatments (new medication, for example).
Observational: Researchers watch results without assigning any interventions.

Phases of the study (Drug Trials)
Phase I: Dosage and safety (small sample of volunteers in good health).
Phase II: Side effects & effectiveness (wider group of people with illness).
Phase III: Large-scale testing and comparison with standard treatment.
Phase IV: Surveillance after commercialisation. Research Design Models:

Study Design Models
Parallel: Individuals are randomised to 1 or 2 or more groups (drug against placebo, for instance).
Crossover: As their own control, participants get several therapies in order.
Factorial: Considers a number of interventions together. To lessen bias,
participants are assigned to treatment groups at random via randomisation.
Blinding: Participants in a single-blind study are unaware of the treatment they are receiving.
Double-blind: The researcher and participant are unaware of each other. eliminates prejudice in the evaluation and administration of treatment.

Control groups are frequently used to compare the effects of an intervention by including a placebo or standard treatment group. The effectiveness of the intervention is evaluated using predetermined metrics known as endpoints or outcomes (e.g., survival rate, symptom improvement). If a statistically significant difference is there, sample size and power guarantee that there are enough individuals to detect it. [8]

3. Recruitment

One of the most important and frequently difficult aspects of the research process is recruiting for clinical trials. Studies with adequate participant numbers are guaranteed to have statistical power and produce insightful findings through efficient recruitment.

However, participant registration is frequently hampered by obstacles like strict qualifying requirements, ignorance, mistrust of research, and practical difficulties.

Strategies like community involvement, collaborations with patient advocacy groups, the use of digital recruitment tools , & streamlining trial designs are being employed more frequently to improve recruitment rates and participant diversity in order to address these issues.[9]

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4. Conduct

In order to protect participant rights, safety, and well-being as well as the integrity of the data gathered, researchers must adhere to certain ethical and procedural requirements.

Important components of appropriate behaviour include:

1. Informed Consent: Before agreeing to participate in the study, participants must be fully informed about it.
2. Ethical Approval: An independent institutional review board or ethics committee must approve all clinical research.
3. Good Clinical Practice: GCP guidelines, which offer globally accepted ethical and scientific standards, must be followed by researchers.
4. Data Integrity: It is essential to collect and report data in an honest and accurate manner.
5. Participant Safety: Constantly keeping an eye out for unfavourable incidents and responding appropriately when necessary.

Inadequate behaviour might result in participant injury, erroneous findings, and legal repercussions. [10]

5. Analysis

To ascertain the effectiveness and safety of an intervention, analysis in clinical trials entails statistically assessing the data gathered. Reliable and valid scientific conclusions are guaranteed by proper analysis.

Crucial elements consist of: Before the trial starts, a Statistical Analysis Plan (SAP) is created that outlines the primary and secondary outcomes, statistical techniques, and how to handle missing data.

Often overseen by an impartial Data Monitoring Committee (DMC), interim analysis is carried out throughout the trial to evaluate patterns or early indications of efficacy or damage. Analyses that examine impacts in particular populations or assess the robustness of findings include subgroup and sensitivity analyses. [11]

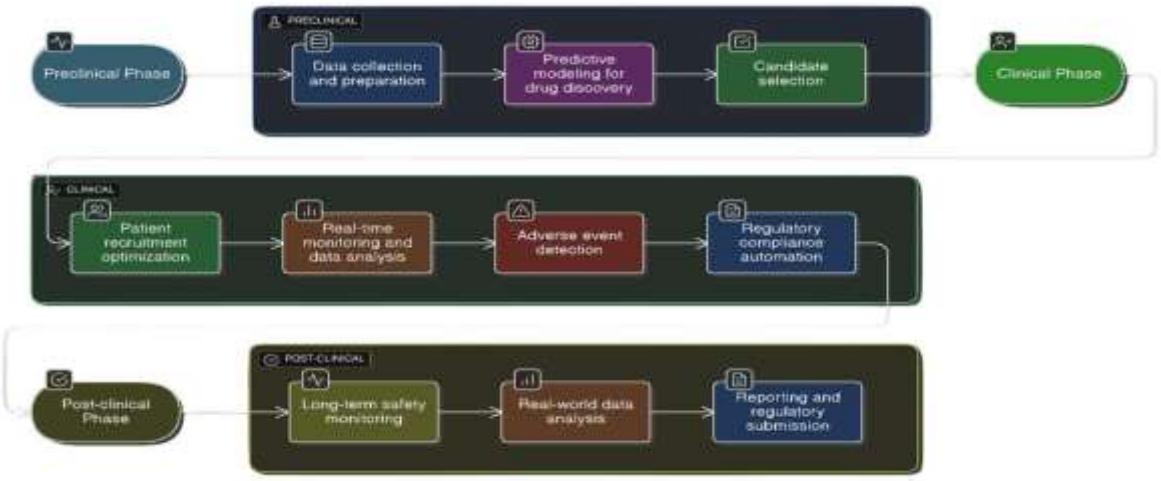

Table :- Procedure of Clinical Trials

CONCLUSION

By automating data gathering, patient recruitment, monitoring, and analysis, artificial intelligence (AI) dramatically accelerates clinical trial procedures. This lowers manual lab or and cuts down on the amount of time needed for trials. Large and complicated datasets may be intelligently interpreted thanks to AI, which also automatically feeds downstream systems and produces thorough analysis reports that increase accuracy and decrease errors. By tracking patient medical histories and customizing trial protocols to meet each patient's needs, AI enables customized treatment by enhancing adherence, retention, and results.

Artificial intelligence (AI) optimizes resource allocation and reduces overall clinical trial expenses by optimizing operations and minimizing the need for rework. By mimicking biological processes, finding new targets, and forecasting drug efficacy and safety, artificial intelligence (AI) aids in drug discovery and increases the success rate of novel treatments. A radical change in medical research and patient care is anticipated with the use of AI in clinical trials, which promises quicker medical discoveries, more accurate treatments, and wider access to cutting-edge therapies.

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