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FUTURE AND SCENARIO OF CLINICAL TRIAL BY ARTIFICIAL INTELLIGENCE

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ABSTRACT

Over the last decade, digital technologies have revolutionized practically every area of our lives, including how we interact, purchase and read. Despite its reputation for over-promising and under-delivering, digital health technologies have the potential to improve clinical trials if they are backed by proper funding and regulatory support. This cannot, however, be accomplished by simply reproducing current research techniques and converting them to digital form. Clinical trials, which aim to confirm the safety and efficacy of novel therapies by conducting controlled tests on patients, are riddled with difficulties that drive up R and D expenditures and delay the introduction of promising new treatments. Remote monitoring is used to acquire continuous clinical data from sensor-equipped wearable devices, and machine learning techniques are used to establish objective criteria for assessing symptoms and measuring the impact of therapies.

KEYWORDS

Artificial intelligence, Clinical trial, Trial design, Patient selection and Medical sensor.

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INTRODUCTION

Clinical trials are one of the most time-consuming and expensive processes in the pharmaceutical industry. Here's how technology could change clinical research in the future, reducing the trial procedure from nine years to a few hours[1]. Clinical trials take up the second half of a single new drug's 10 to 15year development cycle, which costs 1.5-2.0 billion dollars. As a result, a failed clinical trial costs not just the trial itself but also the preclinical development costs, resulting in a loss of 800 million to 1.4 billion dollars each failed clinical trial.

High trial failure rates are due to a combination of poor patient cohort selection and recruiting strategies, as well as an inability to appropriately monitor patients during trials[2]. Clinical researchers and biopharma investors must consider the probability of success (POS) of a clinical study while making scientific and financial decisions. Risk assessment must be precise and fast in order to allocate resources wisely[3]. AI technologies enable advances such as seamlessly merging phase I and phase II clinical trials, establishing unique patient-centered endpoints, and gathering and analysing Real World Data, all of which are critical for modernizing clinical trials[4]. To aid in health decision-making, a plethora of prediction techniques have been created and validated. To evaluate the probability of an individual's current disease or predict specific conditions or events in the future, prediction systems typically use many predictors. Concerns about research design and reporting have been highlighted as the number of RCTs examining the therapeutic effectiveness of AI tools has increased recently[5].

Trial design

Participants must follow instructions even in trials with well-designed protocols. A little error, such as forgetting to take a tablet at the proper time, could jeopardize the accuracy of a study's findings.

"When guidelines are followed correctly, medication development is quicker and less expensive," Lip set explains.

In statistical planning, AI will play a significant role (i.e., the predictive analytics in interim analysis and the final analysis[6]. One possible area for improvement is the reduction of uncertainty while optimizing study design. This was a cross-sectional assessment of RCTs published in peer-reviewed clinical research publications that included traditional statistical or artificial intelligence (TS/AI) tool interventions[7].

Randomized clinical trials had the following inclusion criteria: the study should be conducted in a clinical setting with patients or health professionals, or both (population), TS/AI prediction tools were used as a clinical intervention in RCTs (intervention), any type of control group was chosen (comparison), and quantitative outcomes of the study were presented (outcome) Research not relevant to interventions employing TS/AI technologies, reviews and/or meta-analysis, model creation and/or validation studies, observational studies, study protocols or pilot studies were all excluded[8].

Adaptable trial

The following a pre-set adaptive trial design technique, cutting-edge trials learn as they go and allow process and operational updates on an iterative basis. The following are some examples of these updates; Sample updates (more patients may be recruited) guarantee that statistical power isn't squandered); These adaptive trials have a proven track record of improving outcomes. Trial success rates are much higher, and time and resource costs are significantly lower[9]. You can use Adaptive Trial Designs to carefully assess clinical data in real-time and make informed decisions about how to adjust the study's path for a better likelihood of success.

An adaptive trial design that is well-designed and implemented can:

1. Increase the likelihood of your new therapy's success.
2. Make the most of the trial's data to cut down on development time.
3. Cut down on total development costs.
4. Lessen the risk to study participants and sponsors.
5. Increase your chances of success with regulators and payers.

As researchers wrestle with COVID-19, adaptive design which entails a more flexible approach to running a trial has been a prominent trend. These activities could give learning opportunities for researchers as alternative alternatives to established study design techniques are tested as clinical trial designs are scrutinized during this worldwide epidermic[10].

Patient selection

Every clinical study has its own set of eligibility, suitability, motivation, and empowerment requirements for patients who want to participate.

The use of biomarkers in patient selection has been found to improve the efficiency of the clinical trial process significantly. We test this in cancer by calculating the PoS of drug development programmes that employ biomarkers in patient selection and compare them to those that don't[11]. As biomarkers have become more widely used to select patients, improve safety, and act as surrogate clinical endpoints, it has been postulated that biomarker-based studies are more likely to succeed. By comparing the POS of medications with and without biomarkers, we can evaluate this theory[12].

Patient monitoring

Recruiting the correct patients for a clinical research takes a significant amount of effort and money. The only way to get a return on this investment is to complete the trial successfully. As a result, it is critical that patients remain in the study throughout, follow trial protocols and standards, and that all data points for monitoring the impact of the tested medicine are collected efficiently and reliably[6].

Continuous patient data

People are now adopting wearable technology to track their exercise, heart rates, sleep patterns, and much more in their daily lives. An individual's health data can now be acquired with their agreement more easily, passively and "cleanly" than ever before in the medical profession. Patients' data may be collected easily and constantly 24 hours a day using built-in sensors in clothing, phones, and household equipment[13].

Personalized trial

Personalized (or precision) medicine is at the forefront of omics research, with Nature publishing a number of important studies on the topic in 2018. This research, together with improvements in the accuracy of predictive modelling with healthcare data, is predicted to fuel the widespread adoption of customized treatment in the future. In-depth, accurate understanding of a patient's history and environment will be possible thanks to access to large amounts of patient-specific data. Individualized treatment changes based on well-informed predictive models will be possible[14]. Many clinical trial difficulties, such as patient retention and engagement, can be addressed by incorporating Digital Health technology into clinical trial designs. Future, new technologies such as artificial intelligence (AI) and machine learning are enabling deeper data gathering and collecting, resulting in insights that can be used to make better medication and medical device development decisions sooner[15].

Stay at home trial

Clinic appointments will be conducted at a time and location more convenient for the patient, thanks to connected devices, developments in home delivery, and greater virtual communication. The AOBiome Trial is a fantastic example of this. More than 8,000 people were assessed and participated in this Phase 2b acne research. For a 12-week study with no site visits, 372 participants were enrolled. It also grew in popularity. Recruitment that is inclusive (specifically an increase in non-white participants) when compared to conventional trials Patient-centered connected gadgets will be crucial in this situation. Connected gadgets (e.g., smartphones) Wearables, nanotechnology, XR, virtual assistants, bots, and other technologies can all be used to help people[16]. During virtual appointments, take accurate and efficient measurements Virtual communication's widespread uptake and use is already facilitating. Improved home-delivery technology, such as advancements in cold chain, 3D printing for medical devices and medications (as discussed in this Forbes article), and the use of delivery drones, will allow trial materials to be delivered directly to patients[17]. There is a greater risk of depersonalization as a result of technology. As we become more reliant on technology, human interactions become increasingly crucial, and advancements like stay-at-home trials will need to take this into account[14].

Digital clinical trial

Big data and predictive analytics, which allow for the rapid identification of interesting research subjects and locations. Artificial intelligence (AI) that analyses massive volumes of data to assist in patient management and protocol creation. The proper conditions are in place for digital innovation

in clinical trials, thanks to the explosion of electronic health records (EHRs) and the exceptional penetration of both mobile technology and the Internet of Things[18]. Despite their limitations, digital health technologies have the potential to improve people's lives. The environment of trials should be compatible with clinical practise, and participants should be representative of the people who would utilize the novel medicines or delivery modalities[17].

Health and wearable

Wearable devices and sensors have a lot of potential for collecting more data and insights to help us better understand how treatments work. Wearables and sensors, on the other hand, present significant obstacles for clinical trial conduct, data storage, and interpretation. By allowing patients to undertake assessments utilizing the comfort and familiarity of their own hardware devices, BYOD promises to improve patient centricity[19].

The collection of these data has the potential to reduce trial times, lower costs, and improve safety. To realize these benefits, the clinical trial community must address present technology limits and overcome downsides[20].

Medical sensor

A global, in-house capability to deliver the clinical trial to your patients is a core of our patient-centric concept. To make the experience genuinely patient-centric, the patient can choose where the visit should take place at home, at school, or at work. Our global network of clinicians can also provide patient education and training to assure study compliance, chaperone patients to investigator site visits, and assist with questionnaire data collecting[18].

Advancing clinical trial

Protocol development is the first step in the AI revolution of clinical trials. Clinicians in traditional trial models frequently construct protocols based on prior experience, relying on the replication of previous trial designs or even dubious procedures. As a result, enrollment criteria frequently include a mix of clinical inclusion and exclusion criteria, making it challenging to discover suitable participants. Poor protocol design can impede enrollment and lead to low patient retention, resulting in higher trial expenses or even the program's demise.

Using wearable sensors to collect real-time, real-world patient data, on the other hand, can assist consistent, objective evidence of genuine illness states and treatment side effects. This data comprises heart rate, blood pressure, and movement gathered 24 hours a day, seven days a week. It is far more thorough and richer than data acquired in clinics, making it far more dependable[21].

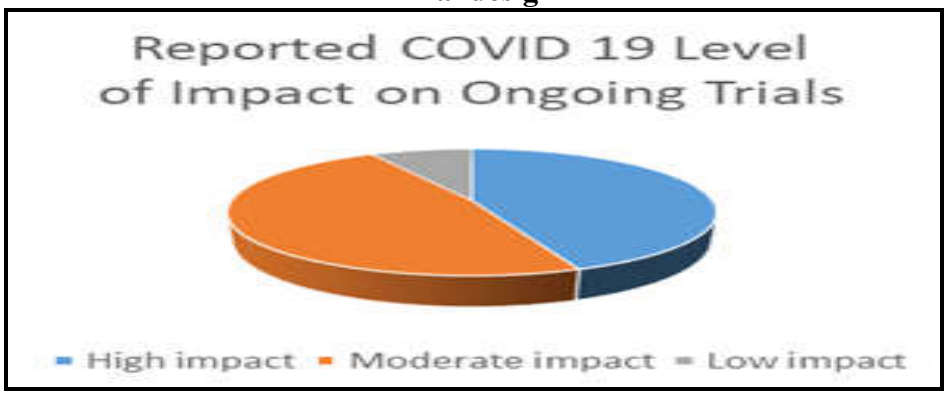
Future prospective

Modern AI approaches have progressed to the point that they may now be used in real-world situations to help human decision-makers in computer vision, navigation and in certain circumstances, medical and healthcare contexts. Pharma and healthcare, on the other hand, remain among the most heavily regulated and risk-averse businesses. Infusing innovation that disrupts established procedures is a challenging endeavour that must be approached and implemented in stages[22]. Although AI has the ability to influence many areas of clinical trial design, from planning to execution, any AI pitch that attempts to address all aspects at once is certain to fail[6]. Overall, AI has the potential to enable novel trials and the creation of new interventions more quickly, thanks to growing wearable technology and large data. Wearable gadget technology, in particular, could be useful in novel designs for studying new pharmaceuticals by capturing unique data like better monitoring potential adverse effects or tracking real-time medication adherence[23].

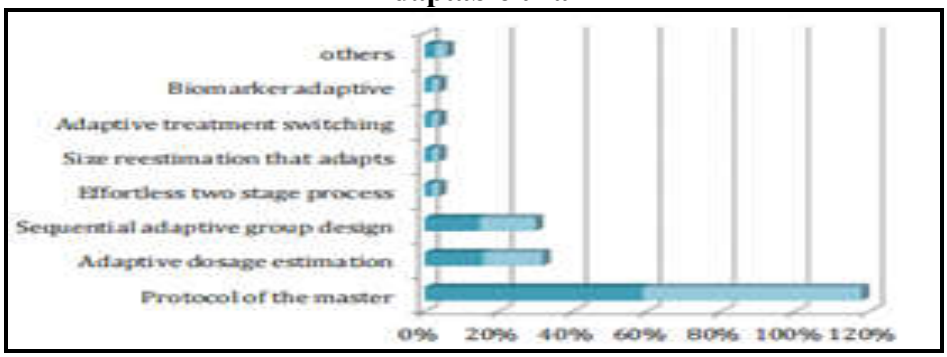
The prospect of future experiments including secure wearable technology and data storage in shareable cloud systems or block chain, a massive, public, secure, and decentralized data repository, is encouraging. Furthermore, during interim analysis, AI-guided clinical decision support using multi-omics techniques to increase effective treatment groups or reduce ineffective treatment groups[24].

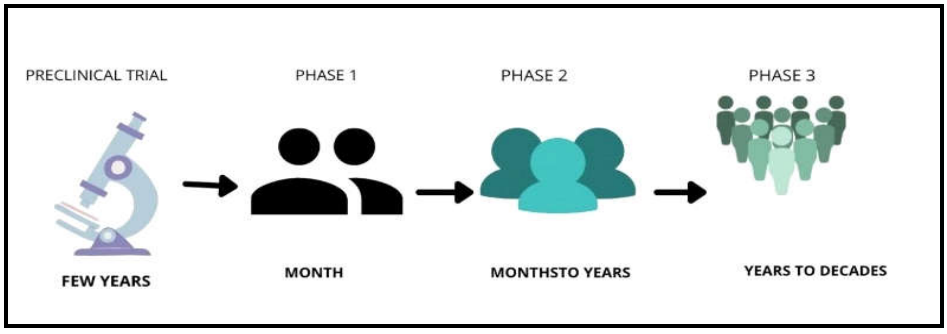
Clinical trial

Trial design

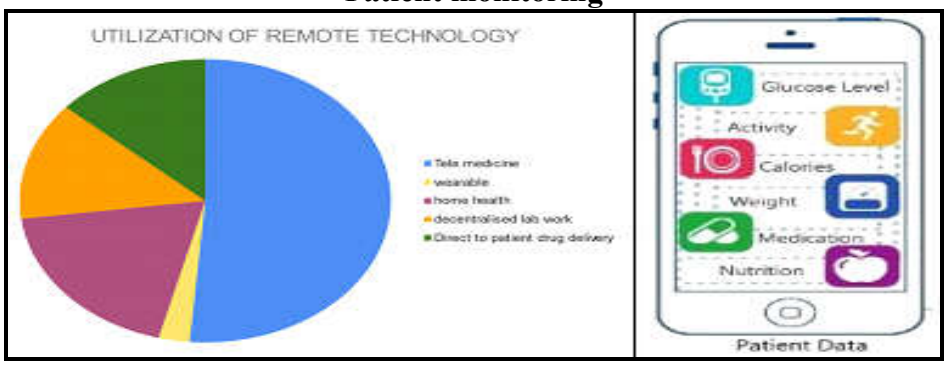


Adaptable trial

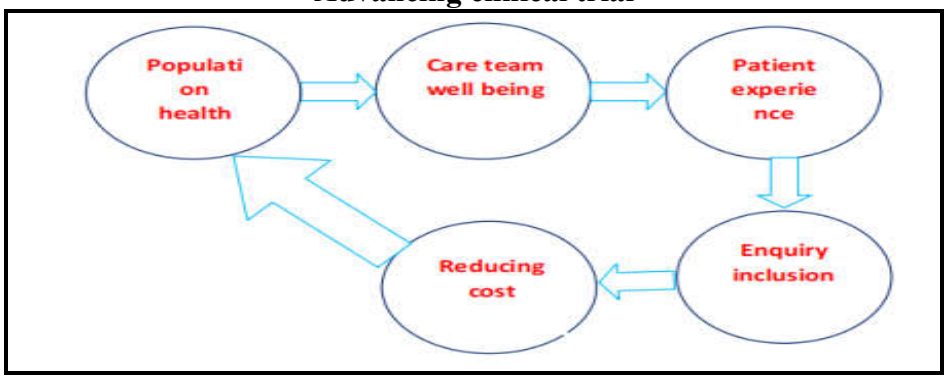




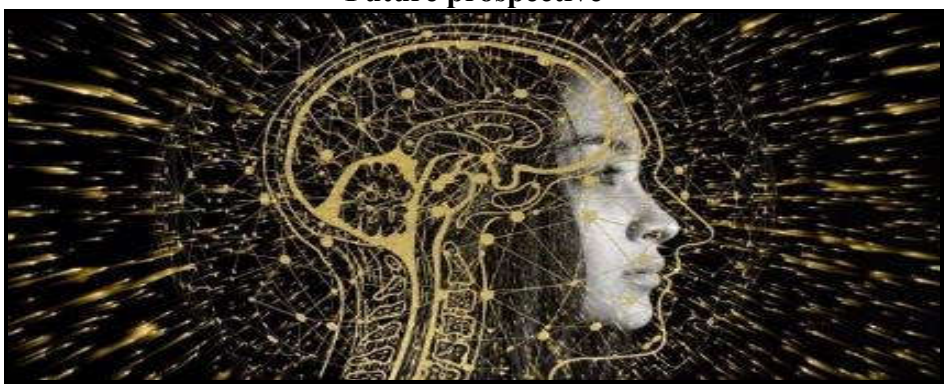
Patient monitoring



Advancing clinical trial



Future prospective



CONCLUSION

A paradigm shift to the new sustainable path of growth and development requires a fundamental change in the basic business and innovation model of the entire industry. Furthermore, completed trials have gathered a corpus of data that contains a plethora of information on the relationships between trial design characteristics and trial results. Failed trial data, in particular, is a neglected asset that has been unused on the shelves for far too long.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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