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Review

A Review: Virtual Clinical Trials

Zainab Hussain, Farheen Fatima, Arfah Fatima, Ausaf Butool*, Dr. Anupama Koneru

Department of Pharmaceutical Chemistry, Sultan-ul-Uloom College of Pharmacy, Hyderabad, Telangana

*Author for Correspondence: Ausaf Butool
Email: ausafbutool@gmail.com

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Abstract

Virtual clinical trials allude to clinical trials that take advantage of digital technologies, including computer and mobile device apps, web-based tools, and remote monitoring devices, for one or more of the trial processes, such as participant recruitment, informed consent, counselling, measurement of endpoints, and adverse event monitoring, to prevent or lessen the need for participant visits to the trial site. The advantages of such trials may comprise higher recruitment rates, lower dropout rates, better compliance, reduction in time for trial completion, and lower costs. The use of such trials elevated multitudinous during the COVID-19 pandemic and is likely to continue in the future.

Keywords: Virtual Clinical trials, digital technology, data collection and management, regulatory compliance.

INTRODUCTION

Virtual clinical trials, also recognised as remote, digital, decentralised, or site less trials, involve the use of digital technologies to facilitate trial-related processes. [1] Sometimes, in-person and digital techniques may be merged, creating “hybrid” trials. Virtual clinical trials were established several years ago; however, in recent years, the challenges posed by the COVID-19 pandemic have resulted in an exponential rise in their popularity and conduct.

CHALLENGES WITH TRADITIONAL CLINICAL TRIALS

Conventional clinical trials are centred on the trial sites and need patients to visit the site to accomplish trial-related processes. The trial protocols tend to be complex and regulatory and safety requirements mandate frequent site visits at all stages of the trial, namely screening, counselling, consenting, administration of interventions, outcome assessment, and follow-up. Further, for performing these processes, the site needs

infrastructure and staffing, both of which consume resources. Thus, such research sites are typically set up in larger medical institutions, which may be located far from the participants' place of residence. The need for repeated visits to such institutions means that certain types of participants – those with disabilities or mobility issues, the elderly, and those living in remote areas – are disadvantaged and less likely to participate. In addition, site monitoring of the trial by the sponsor gives rise to additional resource expenditure.

VIRTUAL CLINICAL TRIALS

Virtual clinical trials aim to decentralise the conduct of a clinical trial, bringing some or all of the procedures closer to the participants' place of residence, thus making it more opportune for the participants (participant-centric approach). Experience shows that most outlooks of a clinical trial are manageable to be conducted digitally.

Ethical and regulatory approval

An incentive step in a clinical trial is the submission of documents to obtain ethics committee approval. Many ethics committees now permit and have amenities for the digital submission of documents. Members of the ethics committee may muster virtually rather than in person, to discuss and issue research approvals. The Indian Council of Medical Research guidelines for research during the COVID-19 pandemic permit the use of digital procedures for such meetings. [4]It is also possible to have centralised ethics committees and obtain a single ethics approval for multicentric projects; this is particularly useful for sites that do not have their own ethics committees or whose ethics committees are unable to summon meetings within a short time for any reason. Similarly, the process for obtaining regulatory approval from licensing authorities is also feasible through a web-based application.

Screening and recruitment of participants

Accruing adequate numbers of participants is a major obstacle in clinical trials. Artificial intelligence tools (comprising but not limited to natural language processing) can be used to search through electronic medical records to identify potential participants for clinical trials and match them to relevant trials. This is particularly beneficial in the identification of participants for trials in rare disease conditions. Screening of participants is important to ensure that trial preferability criteria are fulfilled, and to guarantee the safety of participants and validity of trial data. Screening can also be done virtually, by accessing participant data through digital tools [5].

Consenting and enrolment of participants

Consenting subjects for participation in a clinical trial is a significant and complex process. This encompases providing the participants information about the trial, allowing them enough time to understand this information, answering any questions or doubts they may have, and lastly documenting the voluntary informed consent. Conventionally, this could involve multiple site visits, which may be an impediment to participation. In a virtual clinical trial, technology is used to assist the consenting process. For instance, participant information sheets may be e-mailed to the subject or made available on a digital platform; discussions happen through a tele- or videoconference and finally, the participant either electronically signs the consent/approval form or signs a physical copy at home and mails it back to the investigator. [5]

Administration of study interventions

Participants visit research sites to acquire study interventions. Depending on the frequency of administration and complexity of the intervention, this could take a remarkable amount of the participant's time. In a virtual trial, various techniques could be used to preclude the need for site visits. For oral medications, the drugs may be directly dispatched to the participant by research staff, a courier or mail, or picked up by the participant from a location near their residence. For parenteral medications, participants could visit medical centres close to their house, or have research nurses visiting them at home/residence. [5]

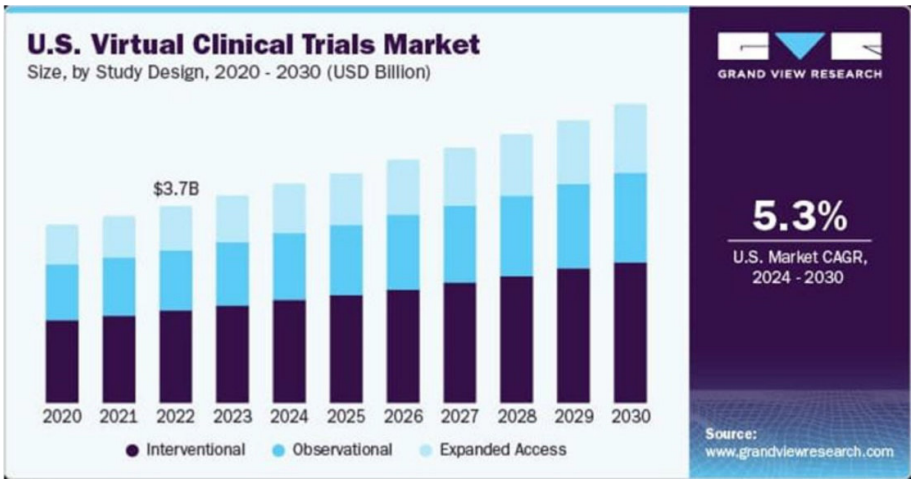
Care of study participants

Trial participants need periodic assessments and perpetuated medical care to ensure compliance to the trial protocol and allow early identification of any toxicity. In a virtual trial, the care of participants is outsourced to medical facilities situated close to the participants. The researcher procures information from these local centres through access to electronic records. In addition, the research team can utilise other methods such as home visits by research nurses or the use of tele-or video consultations to keep track of participants. The choice between these modes of assessment depends on the nature of the intervention in the trial as well as the data to be collected, for instance, whether these can be recorded by the participant herself or need measurement by another person. [5]

Similarly, several procedures/methodologies are available to monitor adherence to trial medication.

Assessment of efficacy and safety outcomes

Timely and reliable assessment of both efficacy and safety outcomes is one of the most crucial aspects of a research study. Virtual trials use diverse ways to allow study outcomes to be assessed without site visits. Clinical outcomes can be assessed routinely either at local centres or during home visits by a clinical team. Study outcomes can also be planned such that participants can self-report their data – for instance, home glucose testing by finger prick method or urine sampling for proteinuria. Several modern devices such as fitness bands and sleep trackers furnish continuous real-time data on physiological parameters, and can be programmed to directly relay information to the research team. Outcomes comprising questionnaires can be administered through email, telephone, or video consult by a member of the research team. Laboratory and radiological parameters can be assessed at amenities/facilities located close to the participant. From these amenities/facilities, test results can either be reported using standard formats, or the samples/images can be sent to a central facility for reporting by a study investigator (to ensure uniform assessment).[5]



Study monitoring

Monitoring of clinical trials is vital to ensure compliance with the study protocol, prevent harm to participants, and ensure that data are reliably captured. Methods of remote monitoring consists of accessing trial documents through email or video conferencing tools, or allowing monitors to access electronic medical records remotely. Risk-based monitoring is another adaptation which allows monitors to move away from 100% source data verification and reduce/decrease the intensity and volume of monitoring by focusing on areas at high risk for errors. [5]

ADVANTAGES OF VIRTUAL CLINICAL TRIALS

Virtual clinical trials provide several benefits. They decrease the need for site infrastructure and staffing, thereby reducing the price of the trials. They provide a vast spectrum of participants who can participate in the trial sessions. This serves to increase the universality of the trial results through the incorporation of more diverse participants as well as improve trial accrual. By sidestepping repeated site visits, participant compliance and retention are enhanced and the efficiency of measurements may improve. The need for dispersed trial operations provides real-world data on the potency of interventions. Innovative methods of data collection also provide continuous real-time data rather than data at specific time points and allow earlier recognition of adverse events. Additionally, VCTs can provide more precise evidence. Thanks to the real-time, real-world data gathering skills of digital technologies, the data collected is often less biased and more comprehensive, leading to better authentication of potency and safety end points.[6]On the cost front, the efficiencies achieved with VCTs can translate to significant financial savings. Reduction in travel expenses, site infrastructure needs, and investigator burden contribute to these savings, making trials more cost-effective. [7]

CHALLENGES IN CONDUCTING VIRTUAL CLINICAL TRIALS

Virtual trials are heavily dependent on the availability of technology such as access to the Internet and familiarity with web-based applications. This may itself, counter intuitively, lead to the exclusion of certain groups of participants. Virtual trials may not be suitable for all types of clinical trials – for example, early phase trials and trials investigating complex or potentially-toxic interventions, which may require specialist care, and are best carried out as site-centric studies. The dependence on digital methods for processes such as consenting, data transfer, and data storage (e.g. in the cloud) raises issues of participant confidentiality and data privacy. The remote delivery of study interventions is dependent on supply \chain logistics, and drug efficacy may be affected by storage and handling conditions. Similarly, quality control is essential when depending on local laboratories or imaging centres for study assessments.

Operational Challenges

Some clinical trials require tests and medical procedures which need to be carried out by a medical professional in a medical setting. Therefore, it isn't possible for all clinical trials to be conducted virtually. The rising popularity of Virtual Clinical Trials brings with it new opportunities and challenges that participants and Clinical trial staff are facing and learning about together. Having a hybrid approach to clinical trials might be the best way forward, as it will combine both with clinical trial staff, while still being able to largely participate in the trial from the comfort of their own home. [8]Orri et al. Describe a virtual clinical trial investigating the efficacy and safety of extended-release in participants with overactive bladder (the REMOTE the benefits of having a Virtual Clinical Trial and in-clinic ones. Participants have the opportunity to undertake medical tests/procedures and interact face-to-face trial).[6]The research team recruited participants through the Internet, screened them for suitability using web-based question sheets performed laboratory testing at community facilities, and maintained initial run-in data using electronic diaries. Physical examinations were performed by local physicians. An interactive web-based method was used to obtain informed approval countersignature by the physician. Study medications were shipped directly to the study participants. The VERKKO trial was a Phase IV clinical trial in persons with diabetes that assessed the use of a patient-centric online clinical trial platform integrated with a wireless blood glucose metre in a virtual clinical trial setting.[7] The study involved no site visit at all. The participants were invited through advertisements on social media to self-register their interest in an online system, and their applications were reviewed online by the study team. Selected participants reviewed electronically provided patient information before digitally signing the informed consent form, and had 3G-capable, wireless glucose metres directly delivered to them. Glucose measurements were automatically transmitted from the device into a digital application for real-time review by the participants and the study site. Performance indicators from this study were compared with those of a similar protocol which was carried out as a traditional site-centric study. The virtual trial showed better participant recruitment, the ability to include elderly participants, improved compliance, and excellent participant satisfaction. Furthermore, the study site reported having spent less time on the study coordination activities. Thus, both the participants as well as the researchers found this virtual trial to be useful. A Computerised Intervention for Depression. This study was entirely automated and did not require involvement of a live clinician, with the goal of providing access to participants who did not have access to traditional therapy due to living conditions or individual preferences. The computer-based treatment offered several advantages, such as the ability to use it anywhere and its standardised and consistent approach. For more information, please view the study record. [9] (ClinicalTrials.gov, 2017a).

CONCLUSION

Virtual clinical trials, also known as decentralised or remote trials, revolutionise traditional clinical research by leveraging digital tools for data collection and participant monitoring outside of traditional clinical settings. They offer advantages such as increased participant diversity, reduced costs, and enhanced efficiency. However, challenges like ensuring data security, maintaining participant engagement, and navigating regulatory complexities remain significant. Overall, virtual trials hold promise in advancing clinical research methodologies but require careful consideration of technological, ethical, and regulatory factors to maximise their benefits.

In conclusion, virtual clinical trials represent a transformative approach to conducting research, offering benefits such as increased accessibility, reduced costs, and improved efficiency compared to traditional methods. While promising, they require careful attention to address challenges like data security, participant engagement, and regulatory compliance. As technology continues to advance and regulatory frameworks evolve, virtual trials hold potential to significantly enhance the pace and inclusivity of clinical research, ultimately benefiting patients and advancing medical knowledge.

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