International Journal of Pharmaceuticals and Health care Research (IJPHR)

IJPHR |Vol.13 | Issue 3 | Jul - Sept -2025

www.ijphr.com

DOI : https://doi.org/10.61096/ijphr.v13.iss3.2025.382-386

ISSN: 2306-6091

Review

Virtual Clinical Trails and Reshaping Research Delivery

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Published on: 13 Aug 2025

Published by:
Futuristic Publications

Abstract

The global clinical research is transforming with the integration of digital technologies and giving rise to Virtual Clinical Trials (VCT). This system allows participants to engage remotely through technology rather than traditional site based trails. By giving them flexible, patient centric approach to drug development and collection of data. In covid-19 pandemic time, this way of conducting the trails has gained significant attention, where physical interaction between the patient and clinical trial co-ordinator is neglected. And also during the pandemic time different terms are used in different jurisdictions including teletrials, networked trails, digital trails and decentralized clinical trials (DCT). Virtual clinical trials also use variety of tools that include Electronic informed consent(eConsent), Remote monitoring devices, mobile health applications, telemedicine etc. These technologies are mainly used for transmission of real-time data, reducing the need for in-person visits while involving in data collection, patient adherence, and overall trail efficiency. Virtual clinical trials are mainly involving in following the guidelines that are issued by authorities like the Food and drug administration (FDA), European medicine agency (EMA), International council for harmonization of technical requirements for pharmaceuticals for human use(ICH). However, to ensure trail integrity and participant safety the challenges such as data privacy, platform interoperability, cyber security, validation of digital endpoints must be carefully addressed. To ensure equitable access to virtual research platforms, especially in developing countries, there is a need for robust digital infrastructure. For combining both the virtual and in-person components, the pharmaceutical companies and contract research organizations are increasingly investing in hybrid models.

Keywords: Virtual Clinical trials (VCT), Decentralized trails, eConsent, Remote monitoring devices, Telemedicine, tele trails, digital trails.

INTRODUCTION

Virtual clinical trials are clinical studies that use digital tools to monitor participants, collect data and to manage trail processes without requiring subjects to visit physical clinical sites frequently. Rather than traditional trails which burdens heavily on in-person visits to hospitals or research centres, decentralized trail activities, and allowing the subjects to participating from their homes or local healthcare centres. There are some key components of virtual clinical trials. Despite significant progress in the quality of services offered by healthcare systems over the last decades, leading to drastic improvements in health and wellbeing of the general public, our healthcare systems still fail millions people each year[4][6].

Key components of VCTs

Electronic consent (eConsent)

Electronic consent refers to the use of digital tools to inform participate in clinical trials. In virtual clinical trials the trails are conducted remotely without involving in physical site visits. In such a way eConsent play an vital role in ensuring ethical and legal compliance. This also include some challenges that include, it requires digital literacy and internet access. And it also needs validation and approval from ethics committee, it may raise concerns about data privacy and security. There will be many benefits regarding these electronic consent like it enhances the compliance and traceability and it also increases engagement and understanding regarding the clinical trails. It also reduces the paper based costs and errors[1].

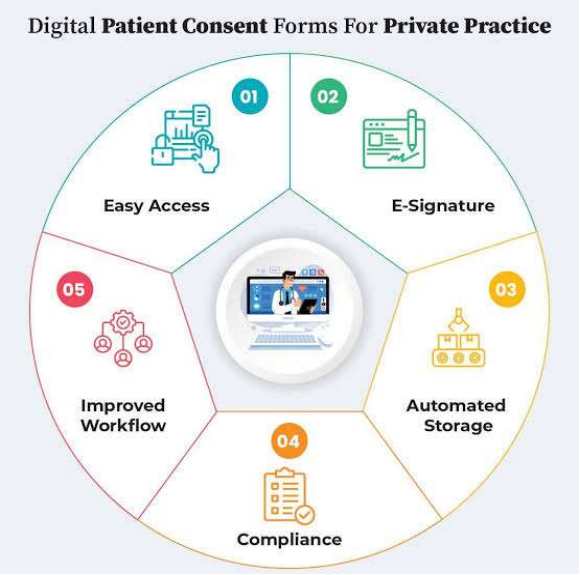

Fig 1: Digital Patient Consent Forms For Private Practice

Tele medicine

Telemedicine mainly refers to the delivery of healthcare services remotely using telecommunication technology. It is helpful to patients to consult with healthcare professionals without visiting the clinical trials in-person. Telemedicine also involves in video consultations that is real time video calls between the doctors and patients. Telemedicine also involves in remote monitoring that means the use of devices that are used to track the patient's health conditions and vital signs that is for example heart rate, blood pressure, temperature etc., it also involves in store and forward, its nothing but sharing of medical data like x-rays, reports for remote diagnoses without meeting health care professionals or visiting the hospitals and clinical trial sites. In these telemedicine the doctors can send the prescription directly to the patients or pharmacies[3].

Benefits of telemedicine:

- Patients can take care from their homes that reduces the waiting time and reducing the travel
- Cost Effective: It saves the money for both patients and providers
- It also helps in minimizing the exposure to infections in pandemics such as covid-19 etc..
- It is more helpful in rural and remote areas with limited health care resources.
- Its ideal for follow-ups and mental health consultations.

Disadvantages:

- Requires internet access, smartphones or computers.
- Patients data must be confidential
- Doctors may need specific telehealth certifications
- It will be not suitable for emergencies or procedures that need physical contact.

Mobile apps

Mobile apps play a vital role in virtual clinical trials. They are mainly useful for collection of data and analysing the data. These apps act as a bridge between the subjects and clinical research coordinator by using digital technology to conduct the clinical trials remotely. These apps have several benefits like collecting health related data that is vital symptoms, adverse reactions etc. By using the mobile apps, the patient can easily understand all the procedures and requirements regarding the clinical trials.

These increase the engagement with push notifications, reminders, and educational content and improve patient involvement. It also involves in convenience that improves enrolment and reduces the dropout rates.

There will be some disadvantages like privacy and security. And also not all participants are comfortable for using mobile technology. Sometimes participants may face the internet and device problems. Working of app and regulatory approval may vary by region[2].

Home based services

Home based services are key components of virtual clinical trials that involves in providing studies to the participants from the comfort of their homes. These replace the in-person site visits with healthcare delivery and collection of data that conducted in home and that will be supported by mobile technology and home health professionals. These home services will cover the recruitment of patients from rural or underserved areas. These also avoids the travelling for participants, and help in making the trails more accessible. And can also collect the real time through digital tools that improves speed and accuracy.

Home based services that are conducted at the participant's residence are

- Collection of samples like blood, saliva, etc.
- Usage training of medical equipment
- Remote visits through telehealth
- Monitoring of vital signs
- Drug administration (injectable, oral)
- Health assessment
- Medical equipment setup

All these services will be carried out by trail sponsor or contract research organization. The core purpose the clinical trials is to determine the effectiveness and safety of any therapies and the process to achieve this have been evolving for over a century. The volume of the clinical trials is increasing by 7-8% per annum in order to evaluate the ever increasing number of developments in medical therapy. The global spend o clinical trials of new drug is currently around us$ 48.4 billion in 2020 and this is expected to grow by 6% per year up to us$82.5 billion by 2030, yet despite this investment a high proportion of trails fail to recruit to time and target or suffer with poor retention time and retention rates. The cost of failure of clinical trials to biopharma companies is not limited to the cost are associated with carrying out the trails but also all the prior work done.

Improved digital health technology

The development of digital health technology over the last 20 years as changed landscape of healthcare. These use computing platforms connectivity, software and sensors of healthcare and related uses. Electronic patient records (EPRs) the unable paperless healthcare systems, emails and video conferencing between healthcare personnel and patients, and wearable's technology that records and transmits data for active monitoring, diagnostics and treatment decisions are some of many examples in healthcare settings. The national institute of health and care excellence (NICE) under the department of health and social care in England. As part of a DCT, digital solutions improve efficiency and facilitate communication between patient and research team.

The first study to have virtual element was a randomized study of the efficacy and safety of tadalafil for the treatment of erectile dysfunction by Eli Lilly in 2001. In a post-study survey 77% of patients with traditional clinical trail experience indicated that the VCT was better than a traditional trail[8].

VCT in dermatology

The virtual clinical trials are more effective than usual clinical trials, virtual clinical trials in dermatology made huge impact and several VCT have been conducted and are on-going in dermatology. In 2017 AOBiome's randomized, phase 2b hybrid study evaluated a topical probiotic spray containing beneficial bacteria for mild-to-moderate acne. The 12 week clinical trials recruited volunteers through social media and internet advertisements.

More than 8,000 people were screened online to check eligibility. The resulting 372 participants received the drug or a placebo in mail. They used company – Issued iPhones to take selfies of their acne and a phone app to send the photos to physician investigators for evaluation. The study lasted less than 12 months and was much faster than anticipated. Further, AOBiome reported that the online recruitment was relatively fast, dropout rates were lower than expected, compliance was better than expected, and the trials was cheaper to administer than a traditional trial.

From 2016 to 2017, Pellepharm included 36 subjects in a double-blinded, dose escalating, randomized, vehicle-controlled phase-2 hybrid study. The study compared the efficacy and safety pf patidegib gel 2-4% applied once or twice daily in comparison with that of vehicle on biopsy-confirmed nodular basal cell carcinomas in four sequential cohorts. Within each cohort subjects were randomized in 2:1 ratio to receive active or vehicle gel. The sequential cohorts were as follows; cohort 1 – patidegib gel 2% or vehicle, once daily; cohort 2 – patidegib gel 4% or vehicle twice gel significantly more effective in clinical and histologic clearance of BCC after 3 months compared with the topical vehicle gel. Furthermore, patients using topical patidegib gel did not experience any significant side effects characteristics of oral hedgehog inhibitors (e.g., hair loss, taste loss, frequent muscle cramps).

The investors are hypothesized that eliminating resident disease- associated strains and replacing them with health-associated strains and improve, mitigate, and prevent acne. The study will evaluate the safety, tolerability, and clinical impact of the application.

The VCTs are collect the date from real-world data from wearable's and apps, complementing controlled trial data. This enables researchers to study drug performance in real-life settings, enhancing generalizability[5].

Limitations of VCT

Despite of benefits there are challenges of VCT that should be addressed. The REMOTE trials had many recruitment issues, possibly explained by the fact than the older generation did not use modern technology and social media to the same extent as the youth. Even though social media was great way to spread awareness of the trials, it did not build enough trust for patients to sign up as goal of up to 283 recruited participants was not reached. The lack of human interaction in the recruitment process can be a barrier, predominantly in patients with high age that need a personal relationship to get involved in a trial.

The self - enrol concept can lead to recruitment of a convenience sample population that may differ from the general population in terms of certain demographic or disease – related characteristics, making the results less generalizable. However, combining different methods of recruitment can improve the generalizability of the results

The study coordination centres requires a sophisticated information technology platform for implantation and operational efficiency. In addition, the regulatory framework for approving VCT for pharmaceutical development is still in its early phase, making the guidance in this field unclear

Some areas of clinical research are not ready for remote monitoring, and the virtual approach is not advanced enough to attempt in phase 1 studies where patients need to closely observed and located near a clinical site in case there is a reaction. Nor is it suitable for certain diseases that require sophisticated or in- hospital monitoring. Acute life threatening diseases are possibly not appropriate for a full VCT, further, VCT might not work if imaging examination, a full physical examination, or other types of evaluations cannot be completed by health staff during home visits[7].

Logistical challenges

Home delivery of drugs or lab kits requires reliable supply chains and cold -chain logistics for certain medications. Remote monitoring may strain site staff if not supported by adequate digital infrastructure. Reshaping research delivery virtual clinical trials are transforming the clinical research ecosystem by shifting from a site – centric to patient – centric model.

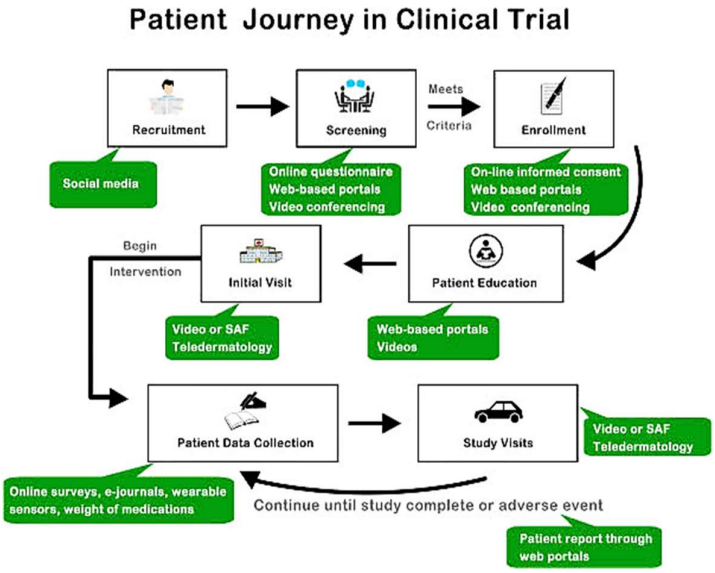

Fig 2: Patient Journey In Clinical Trial

CONCLUSION

virtual clinical trials are revolutionizing clinical research by enhancing accessibility, efficiency, and patient engagement. By leveraging digital tools, VCTs overcome many limitations of traditional trials, such as geographic barriers and high costs, while introducing new challenges like data privacy and technology access, as of July 2025, hybrid models dominate, but fully virtual trials are gaining traction, supported by regulatory advancements and technological innovations. VCTs are reshaping research delivery by prioritizing patient – centricity, integrating real-world data, and enabling scalable, adaptive trials inclusive and efficient future in clinical research. In this studies to date have demonstrated that VCT are not only operationally feasible, but also successful. VCT show high recruitment rates, have better compliance, lower drop used in phase 2-4 trials showing promising results. VCT meet the goal of the industry in being "low-risk, high-return" trials. We expect to see more of these trails in the future, particularly in dermatology.

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