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Virtual Clinical Trials: Reducing Barriers to Participation

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ABSTRACT

Through technology, virtual clinical trials are redefining the field of clinical research by removing long-standing obstacles to participant enrolment and retention. By enabling remote participation through digital telemedicine, mobile applications, and electronic data collecting, these trials have the potential to increase the scope and diversity of clinical research. This study compares virtual clinical trials with traditional trials to analyse the advantages and difficulties of the former. Essential characteristics and possible benefits of virtual trials like lessened travel expenses and burdens as well as their drawbacks and methods for raising participant involvement are covered. Virtual trials aim to improve the accessibility and efficiency of clinical research by tackling these variables; nevertheless, they also encounter obstacles with participant involvement and technological uptake.

Keywords: Virtual Clinical Trials, Electronic Data Collection, Telemedicine, Participant Engagement.

INTRODUCTION

Virtual clinical trials are changing how the clinical research community approaches participant enrollment and engagement. Virtual clinical trials hold promise for increasing study participation, retention, and comprehension. By employing tools of new technology and reducing the need for participants to travel to a central site, virtual clinical trials can alleviate some of the prominent challenges investigators face when enrolling and retaining demographics that are historically underrepresented in clinical research. However, these trials are not without risk and cannot replace traditional, purposeful outreach and educational efforts that are tailored to underserved populations. The aim is to see if virtual trials will make it easier for people to join studies as participants. It is intended to teach about the rewards and possible risks of volunteering for clinical research and hopefully motivate the viewer to consider becoming a participant in a clinical trial [1].

THE CONCEPT OF VIRTUAL CLINICAL TRIALS

The prospect of completing clinical trials remotely using electronic data collection holds great promise to decrease barriers to participation while reducing the time and cost of trials. Despite the rapid adoption of many electronic data collection processes, the clinical trials industry has slowly incorporated these advances. This evaluates source data, electronic consent, digital telemedicine, and mobile medical applications, providing a roadmap to decreasing barriers. By combining these developments, clinical trials can greatly reduce the travel burden, potentially expanding and diversifying the clinical trial population while exploring patient-centric clinical outcomes [2]. Conducting clinical trials at a fraction of the current cost, with high integrity, and at a greater speed holds great promise to deliver therapies rapidly to those in need. This seems like the logical extension of collecting a century of experience: if we rely instead on a limited number of subpopulations, including white males from rural New England, can we generalize to all racial and ethnic groups, people of all ages, and those from diverse geographic regions? It is simply outdated to assert that each patient should spend the time and resources required to accommodate the trials to suit very narrow eligibility criteria [3].

DEFINITION AND SCOPE

The term "virtual clinical trials" has seen a growing interest over the past few years. The increasing focus on defining virtual trials and describing the various ways technology is being used to make trials more patient-friendly and patient-centric is notable. This growing focus is matched by activity and interest from regulatory bodies in such models and the potential for increased patient recruitment and retention that patient-tailored solutions may offer. But, are virtual clinical trials genuinely a new way of conducting clinical trials, or a series of services and technology different from those traditionally provided? [4]. The motivation for this meeting was the large number of pre-existing names for trials of this type, many of which are clouding effective communication and the potential comparison of results of such studies. We aimed to bring together a diverse group of stakeholders to develop a comprehensive and clear definition and to propose a term that represents a use case for all virtual patient models. We developed the following high-level definition: "A virtual clinical trial is defined as taking the site out of the site." The term "virtual clinical trial" has now received multiple endorsements from diverse stakeholders and has spread. Anthologies of these "site-less" studies are emerging, and existing terms or emerging terms like "remote" and "site-less" will be replaced with "virtual" in the future as a unified language unrolls [5].

KEY FEATURES

Implementing a virtual trial is, in many ways, similar to implementing an onsite trial, but there are important differences. In this section, we describe six key features that distinguish a virtual clinical trial from a more traditional trial. Recruitment is a critical aspect of any clinical trial, and virtual trials are no exception. To the extent that the patient population that can be reached via the internet differs from the patient population treated by the existing healthcare system, unique challenges arise in patient recruitment for virtual trials, but the internet also provides unique and powerful solutions [6]. In informed consent, the consent form regulations that govern traditional clinical trials provide valuable protections for patients and have been described as the original patient decision aids. However, the utility of typically voluminous consent forms is reduced if the patient cannot follow the text or put the material in context. For future potential participants who have done their homework and are unclear on key technical aspects such as randomization or even the purpose of the new intervention, current regulations are irrelevant. Maintaining privacy and safeguarding health data collected in any clinical trial is an overriding concern, and virtual trials must adopt strict security measures to avoid breaches and potential harm to patients. Cost savings on infrastructure and staffing can be huge advantages of virtual trials and are achieved not by cutting quality, but by automating and delegating tasks that are routinely performed in traditional settings [7].

BENEFITS OF VIRTUAL CLINICAL TRIALS

Clinical trials historically take place at universities, research centers, physician offices, and hospitals. Patients must have a physical presence at facilities to participate, but virtual clinical trials could break down some of the longstanding barriers to participation, potentially boosting recruitment and retention. There is evidence to support this benefit. Sensitive topics: In interviews conducted over the telephone, patients tend to disclose information related to sensitive topics more than when facing an interviewer directly. Telephone interviews have been used to collect data on sensitive topics. Patient-centric: Virtual clinical trials can have positive implications for diverse patients, for reasons that include the ability of virtual trials to address longer travel time needed by rural and remote patients [8]. Time and savings: Virtual clinical trials could greatly expand the number of clinical trial-eligible patients, who could participate from their homes, essentially embodying the concept of "patient-centric" convenience. The resulting efficiency could benefit the speed with which studied drugs could move to market, reducing costs. Recruiting: Virtual clinical trials could also reduce the time and cost of clinical trial recruitment since they would be open to people not able to travel to particular sites. Given the high failure rates of drugs vying to make it to market, the ability to more quickly and cost-effectively recruit appropriately diverse patient populations could play a significant role in industry and new drug discovery. Outreach and access: A key tenet of recent clinical trial recruitment marketing has been aimed at raising awareness within diverse at-risk populations. Those not likely to have internet access could rely on mobile trucks outfitted with an adjustable patient booth, medical equipment, and a telehealth connection to directly support virtual access to clinical treatment and real-world data protocols that include the collection of data generated from clinical trials [9].

CHALLENGES AND LIMITATIONS

It is important to balance the excitement and potential of virtual clinical trials with reality. It is also important to consider the potential benefits and return on investment with different methods of conducting and demonstrating the benefits of these trials. Therefore, we must also lay out the cautions and considerations that come with this new method. There is a real need to find a way of bringing clinical trials to patients that is less bias-prone and less expensive than the traditional approach. Such an approach could remove many of the obstacles to participation in trials, as patients would not need to travel to the clinic; they could participate in the trial from home [10]. Several challenges and limitations will need to be addressed as virtual clinical trials move forward. Even the mere mention of a 'virtual' clinical trial raises immediate doubts in most health professionals. There is good experience in using virtual consultations in the clinical setting. Participants in this type of research are known to be a dedicated group of citizens with the highest motivation and readiness to work with the Public Health Service. They do not represent the total community, nor are they involved in chronic multimorbidity. They are the ones that might benefit least from virtual consultation in clinical practice. A virtual clinical trial changes very little for them in real terms, other than some travel time and cost to attend eternally repetitive and sometimes mindless hospital tests. It is also not the end point for all clinical trials, which would, in our view, be the option with the greatest leverage for benefits from disease-modifying treatments of all varieties [11].

STRATEGIES FOR ENHANCING PARTICIPATION

This article explores strategies that sponsors, researchers, and others can use to reduce barriers to participating in virtual clinical trials. This approach seeks to help all stakeholders in their decision-making processes. For sponsors and CROs, better understanding the unique needs and concerns of trial participants can streamline the design of more efficient and successful trials. Project sponsors that receive a granular view and foster frequent communication with participants help create a more engaged group of study subjects and streamline continuous populations. Virtual trial companies may also find that these insights could help make their offerings more accessible and appealing. Sponsors, CROs, and any other stakeholders involved in a virtual trial need to be mindful of the many variables that might encourage someone to participate in a clinical trial. Equally important is understanding the common barriers to trial participation. By making changes to the way virtual trials operate and their study protocols, stakeholders can make participation more feasible for a wide variety of people [12].

CONCLUSION

Virtual clinical trials represent a significant advancement in clinical research, offering the potential to increase participation rates and improve participant diversity by reducing the need for physical travel. The integration of digital tools and remote technologies can streamline processes, lower costs, and make trials more patient-centric. However, these trials are not without their challenges, including concerns about technology access, data privacy, and the need for robust engagement strategies. Addressing these challenges and leveraging the benefits of virtual trials could lead to a more inclusive and efficient research environment. Future research and development should focus on refining virtual trial methodologies and ensuring that they complement rather than replace traditional outreach and educational efforts tailored to underrepresented populations.

REFERENCES

1. Brathwaite JS, Goldstein D, Dowgiallo E, Haroun L, Hogue KA, Arakaki T. Barriers to Clinical Trial Enrollment: Focus on Underrepresented Populations. Clinical Researcher.;703:6. acrpnet.org
2. Sessa C, Cortes J, Conte P, Cardoso F, Choueiri T, Dummer R, Lorusso P, Ottmann O, Ryll B, Mok T, Tempero M. The impact of COVID-19 on cancer care and oncology clinical research: an experts' perspective. Esmo Open. 2022 Feb 1;7(1):100339. sciencedirect.com
3. Apostolaros M, Babaian D, Corneli A, Forrest A, Hamre G, Hewett J, Podolsky L, Popat V, Randall P. Legal, regulatory, and practical issues to consider when adopting decentralized clinical trials: recommendations from the clinical trials transformation initiative. Therapeutic innovation & regulatory science. 2020 Jul; 54:779-87. springer.com
4. P Bateman K. The development of patient-centric sampling as an enabling technology for clinical trials. Bioanalysis. 2020 Jul 1;12(13):971-6.

5. Zhuang Y, Sheets L, Gao X, Shen Y, Shae ZY, Tsai JJ, Shyu CR. Development of a blockchain framework for virtual clinical trials. InAMIA Annual Symposium Proceedings 2020 (Vol. 2020, p. 1412). American Medical Informatics Association. nih.gov
6. Sathian B, Asim M, Banerjee I, Pizarro AB, Roy B, Van Teijlingen ER, do Nascimento IJ, Alhamad HK. Impact of COVID-19 on clinical trials and clinical research: a systematic review. Nepal journal of epidemiology. 2020 Sep;10(3):878. nih.gov
7. Bani Issa W, Al Akour I, Ibrahim A, Almarzouqi A, Abbas S, Hisham F, Griffiths J. Privacy, confidentiality, security and patient safety concerns about electronic health records. International nursing review. 2020 Jun;67(2):218-30. researchgate.net
8. Bennett CB, Ruggero CJ, Sever AC, Yanouri L. eHealth to redress psychotherapy access barriers both new and old: A review of reviews and meta-analyses. Journal of Psychotherapy Integration. 2020 Jun;30(2):188. [HTML]
9. Fujimoto D, Morimoto T, Tamiya M, Hata A, Matsumoto H, Nakamura A, Yokoyama T, Taniguchi Y, Uchida J, Sato Y, Yokoi T. Outcomes of chemoimmunotherapy among patients with extensive-stage small cell lung cancer according to potential clinical trial eligibility. JAMA network open. 2023 Feb 1;6(2):e230698-. jamanetwork.com
10. Hanley Jr DF, Bernard GR, Wilkins CH, Selker HP, Dwyer JP, Dean JM, Benjamin Jr DK, Dunsmore SE, Waddy SP, Wiley Jr KL, Palm ME. Decentralized clinical trials in the trial innovation network: value, strategies, and lessons learned. Journal of Clinical and Translational Science. 2023 Jan;7(1): e170. cambridge.org
11. Tejedo-Romero F, Araujo JF, Tejada A, Ramírez Y. E-government mechanisms to enhance the participation of citizens and society: Exploratory analysis through the dimension of municipalities. Technology in Society. 2022 Aug 1; 70:101978. sciencedirect.com
12. Briel M, Elger BS, McLennan S, Schandelmaier S, von Elm E, Satalkar P. Exploring reasons for recruitment failure in clinical trials: a qualitative study with clinical trial stakeholders in Switzerland, Germany, and Canada. Trials. 2021 Dec; 22:1-3.

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