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Review Article

Decentralized Clinical Trials: Bridging Innovation and Regulation

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ABSTRACT

Decentralized Clinical Trials (DCT) utilize digital health technologies, remote monitoring, and telehealth, eliminating the need for traditional in-person visits to clinical sites. This model provides significant benefits for both academic researchers and business stakeholders. Probably, better retention of patients could be a result of the simple nature and the increased pool of recruitment of patients across boundaries; more data collection with these digital tools, which entail wearables and apps is another benefit. More technologies include real-time data capturing, less burden in on-site visit, and more efficient and accessible. DCT can be hybrid models combining on-site and remote participation or stand-alone models carried purely online. Such trials would include telemedicine and cloud-platform solutions in handling vast data pools recovered from disparate sources. However, there are several disadvantages with DCT, some may have issues with technology, processing health data remotely poses privacy and security concerns, and regulation is largely unestablished in some locales. New waves of augmentation for AI-driven analytics call for improved data interpretation and predictive modelling in the further development of DCT. Proper regulatory frameworks, conducive to a decentralized approach, need to be drafted. As DCT would be much more accessible, they would not only bring clinical research to a larger population but also demand greater inclusiveness in terms of different patient demographics, thus offering better and more cost-effective studies.

Keywords: Decentralized clinical trials, Remote data collection, Web based study, Telehealth, Patient care, Regulations.

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INTRODUCTION

Clinical trials have historically faced challenges in recruiting a diverse and representative pool of participants, with only 5% of eligible patients ever being able to take part in clinical research. Under representations are more significant in minority groups facing a variety of barriers: geographical, distrustful, incommunicative and discriminative. An intersectional conception of inclusion in clinical trials makes challenges within trial design and participant recruitment. In response, the US FDA has just proposed that DCT can reduce burdens and are more likely to involve a broader population by reducing costs and commitments involved in participation. While DCT, which entail conducting trials with participants remaining at home rather than visiting research facilities, offer several possible advantages with regard to convenience, reduced travel, and infection control, it is yet to be known with absolute certainty whether they really increase the inclusivity of trial participants. Digital studies that have aimed to increase inclusivity in race, ended up reducing it in other features, such as education and gender. Use of DCT presents several new concerns as opposed to the traditional system, which includes: the digital divide; some tests and procedures cannot be excluded; the problems associated with the medication to be self-administered at home; and new infrastructure is needed. With increasing adoption, DCT presents challenges and opportunities for researchers. It would be possible for the research community to generate robust, generalizable evidence representative of diverse populations through detailed adaptation of the approaches of DCT. The challenges and opportunities will be discussed, and a roadmap for future modifications and enhancements in the way that DCT are implemented will be presented (Van Norman, G. A. 2021).

ROLE OF COVID-19 ON CLINICAL TRAILS

Long-term analysis reveals that the COVID-19 pandemic significantly impacted the initiation of clinical trials in both Europe and the United States. Notably, the number of interventional clinical trials in 2020 saw an increase compared

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to 2019. Otherwise, the relative increase of phase II trials was larger than that of phase III trials for the United States, while in Europe, an increase in phase III slightly outweighed that of phase II trials. Although general Phase II and Phase III clinical trial numbers increased during this time, initiation of non-COVID-19 trials in 2020 was reduced compared to the yearly trial numbers in the past decade and affected the United States and Europe together. Moreover, the short-term time pattern of influence on non-COVID-19 trials was also different between the United States and the EU. There was a key drop in April 2020 in the U.S., followed by a speedy recovery that carried through for the year, with the trial numbers well exceeding the 2019 average from June 2020. Conversely, the European Union presented the largest drops in trial initiation in May, June, and August 2020, in comparison with the average of 2019. Although this decrease in the European Union was less as compared to the United States in the beginning, the numbers, overall, remained below the average of 2019. In summary, the impact of COVID-19 on the initiation of clinical trials in Europe compared to the United States varied in both the short and the long run. Both regions had an increasing trend in interventional clinical trials published in 2020 compared to 2019; however, the relative increases in phase II and phase III trials were quite different between two regions. Moreover, the short-term time pattern of impact on trial initiation differed by region by both the magnitude and duration of the decrease. These findings bring out the complexity and the multidimensional effects of the COVID-19 pandemic on the initiation of clinical trials in Europe and the United States (Goodson, N., Wicks *et al*., 2022).

INITIATIVES AND STATISTICS

Despite being relatively new before the pandemic, DCTs are receiving a lot of fresh and renewed support. Pfizer conducted the first fully web-based study, known as REMOTE (Research on Electronic Monitoring of Overactive Bladder Treatment Experience), in 2011 under an Investigational New Drug application. The study scientists employed online recruiting, online questionnaires, electronic diaries, and home delivery of experimental medicine during REMOTE, with no in-person site visits taking place. The FDA and Duke University jointly launched the Clinical Trials Transformation Initiative (CTTI) in 2007 with the goal of identifying and advancing the efficacy and quality of clinical trials. The CTTI has now released guidelines for DCTs. The FDA was tasked with developing a framework and guidelines for innovative trial designs and the use of evidence from sources other than traditional clinical trials to support medication clearance when the U.S. Congress approved the 21st Century Cures Act in 2015. As of this moment, the FDA has released detailed guidelines about virtual study methodologies that will probably be used long after the pandemic. To advance DCT techniques, the FDA and patient advocacy groups joined together with over 50 international organizations to form the Decentralized Trials and Research Alliance (DTRA), which was established on December 10, 2020. DCTs appear to have "arrived" and have the potential to significantly alter the nature of human clinical trials in medication and therapy research going forward, especially given the increasing acceptance of virtual healthcare and technology (Lasch, F., Psarelli *et al*., 2022).

According to the latest data, the adoption of DCTs has remained much higher than in 2020 even if it slowed down following the COVID-19 pandemic. There was a 2% decrease in the total number of DCTs started in 2023 as compared to the levels observed in 2022 as shown in Figure 1a. A decade ago, Phase III trials were the most likely to utilize decentralization. But in recent years growth in use has been particularly strong for Phase II trials, which now make up almost one in every two decentralized trials as shown in Figure 1b. As the usage of decentralization components in clinical trials increases over the years but there is a significant leap during COVID-19 pandemic and the percentage varies depending on the Regulatory Authority and Country such as high-income countries as shown in Figure 1c and middle-income countries as shown in Figure 1d. However, the adoption of decentralization is expected to have an upward trajectory this year.

IMPORTANCE OF DCT

The generation of clinical evidence, stakeholders such as clinical researchers, regulators, industry professionals, and patient advocates, are actively engaged in reshaping this landscape. This is known to refocus attention on real-world setting data collection, including routine care locations and sites outside the traditional boundaries of health care systems. The widespread adoption of electronic health records in ambulatory medical practices has been combined with the maturation of mobile technologies, telemedicine, and machine learning algorithms to enable modernization efforts. The enactment of the 21st Century CURES Act in December 2016 marked a pivotal milestone in the U.S. healthcare system. The enactment of this law was particularly drafted to speed up new cures and treatments discovery, development, and delivery. One of the key goals of the Cures Act was to provide legal authority to the US Food and Drug Administration to create a system through which it could adjudicate the potential utility of real-world evidence to support regulatory decisions related to product approvals. In response to this congressional mandate, the FDA has framed a series of demonstration projects internally, and workshops, which finished with the latest publication of a framework enunciating how the agency will strategically take towards better leveraging regulatory review purposes. Within this framework, traditional clinical trials are delineated as studies characterized by stringent eligibility criteria, typically conducted at specialized facilities distinct from routine clinical settings. While the current discourse on real-world evidence predominantly revolves around retrospective analyses of data routinely captured in treatment processes, both pragmatic and decentralized clinical trials are prospective study formats.

Prospective study formats can be realized in such study formats, but also in the real world. Pragmatic trials focus on the setting of routine care, while decentralized studies bring highly controlled clinical studies into the broader context of patient's daily lives and working conditions right to the comfort and familiarity of one's home (Khozin, S., Coravos, A. 2019).

Enhanced Patient Access and Participation

DCT eliminate the aspect of patient's mobility to centralized sites, it is thus easy for those in distant or rural areas to participate. It makes the patient to be able to participate in trial activities from the comfort of their homes, can balance their participation with other activities, hence reducing the number of hours spent.

Increased Diversity and Inclusivity

Including people from different demographics in trials is crucial, and since DCT expands the geographic access to trials, participants from different backgrounds are included, buy Pfizer stocks, and hence more reliable results are obtained. Concerning health disparities, DCT solves the problem of lack of access to clinical research among the targeted beneficiary populations.

Improved Data Quality and Real-Time Monitoring

Mobile applications and wearable sensors for health help to monitor a patient's health on a regular basis, thus offering a more extensive insight into the general health state of a patient. Live data allows for an immediate reaction to the occurrence of an incident or variation from the standard, which makes trials safer for patients and the outcomes more trustworthy (Agbo *et al.*, 2019).

Cost Efficiency and Resource Optimization

The demand for having less outlet and on-site employees brings down overhead expenses. Technology such as the use of computers in the storage of information makes the trials less cumbersome with regards to paperwork.

Adaptability and Resilience

DCT can be informed by and incorporate aspects that relate with other patients' needs and trial designs and therefore can be applicable to various types of trials. In cases where face-to-face interactions are pertinent unachievable, DCT keep on with the assessment of clinical studies and preserves the records.

Regulatory and Ethical Advancements

Concerning the regulation of DCT, there are legal requirements that have been issued by several agencies to promote the understanding of how they should be conducted and monitored. Specifically, adherence to principles of informed consent, the protection of participants' data, and respect for their decision-making are proactive measures against ethical issues while sustaining trust and increased transparency as shown in Figure 2 (Apostolaros *et al.*, 2020).

Principles of DCT

Patient-Centricity

Concern for the patient's characteristics, wishes, and the trial convenience from the trial creation to its conduct.

Flexible Scheduling

A feature to enable the patients to choose their own convenient timing for virtual visits. For example, telemedicine appointments of a trial on chronic pain management may be during the evening or weekends to include working population.

Home Health Visits

Ensuring there is transport, appointment booking for the health care providers to attend patients' homes for services that cannot be performed in a virtual manner like blood tests or administration of medicine. An example could be a diabetes trial where, instead of participants coming to the facility to provide blood sample, the nurses take the sample from the participants' homes (Banks, M. A. 2021).

Remote data collection

Remote data collection is the process of acquiring data and information from afar, as is remote monitoring. Using telemedicine for data gathering and patient health tracking through various health technologies.

Wearable Devices

Wearable technology like smart watches, or continuous glucose monitors to monitor vital signs and other health parameters in real-time. For instance, while undertaking a cardiovascular trial, the patients may be required to wear heart rate monitors to give real time data to the researchers.

Mobile Apps

Creating apps to facilitate patients' inputs of symptoms, analysis of symptoms, use of medication, and other such related data. An app trial for asthma may involve having the users enter their events like symptoms and medication used daily.

Flexibility and Adaptability

Developing the kinds if trials that could be easily modified to meet various changes that patients as well as the societies involved in clinical trials are likely to encounter.

Adaptive Trial Designs

Applying trial designs in which adjustments are possible on that basis of the data that have been acquired during the trial.

For example, a cancer trial may need to change the schedule of administering a drug because of the results of its effectiveness.

Protocol Adjustments

Being able to alter the expectations of visitation or the types of data to be collected because some events are unanticipated, for example, changes in participants' availability due to a virus outbreak (Betcheva *et al*., 2023).

Inclusivity and Diversity

Making sure that the people participating in the trial are a good depiction of the population in that they are diversified.

Targeted Recruitment

Marketing via social media and community engagement for recruiting participants from the marginalized groups. An HIV prevention trial might coordinate with relevant organizations in the communities to reach out to the minorities.

Multi-Language Support

This is available in multiple languages. The texts and directives are offered in Spanish, Mandarin, and a host of other languages during the hypertension clinical investigation.

Regulatory Compliance and Ethical Conduct

Following the regulation and ethics is a requirement that needs to be fulfilled for the rights and safety of participants throughout the course.

- **Data Privacy Measures:** Using encryption and data storage is the way the patient's information is secured. For instance, encryption could be utilized by a mental health trial to be sure the data is confidential.
- **Informed Consent:** Electronic consent can avoid the scenario that some patients are not able to understand the drug trial and their rights. Besides, it gives parents' power to choose that consent the children on behalf of them if needed (Boughey *et al*., 2021).

Technology Integration

Using state-of-the-art technologies to make the procedures of clinical trial more efficient.

- **Electronic Health Records (EHR):** Untangling participants' EHRs and the trial data will bolster up data collection and data accuracy. Consequently, a trial service such as diabetes could result in fluttering the EHRs.
- **Artificial Intelligence (AI):** Employing AI in the analysis of patients of a greater sample size and in identifying patterns that can enhance the trials. For the case of the upcoming trial of osteosarcoma, AI could play a pivotal role in isolating genes that are suppressive toward OMM, the breakthrough therapy that is being developed.

Cost Efficiency

It refers to the strategy of minimizing expenses related to the conductance of clinical research without sacrificing the excellence of the quality and patient participation.

- **Infrastructure Costs Reduction:** There is a minifying the necessity of trials being physically present and the associated expenses they bring. Suppose a firm such as Merck would complete a study on a new drug with the DCT method that can be entirely done through the internet, in this way the costs of maintaining the trial sites are reduced.
- **Digital Tools:** On this particular case, the digital tools are the creation of programs that can manage and control the collection of data related to the patients. For example, a study on rheumatoid arthritis may use the application for the automatic collection of patient-reported outcomes

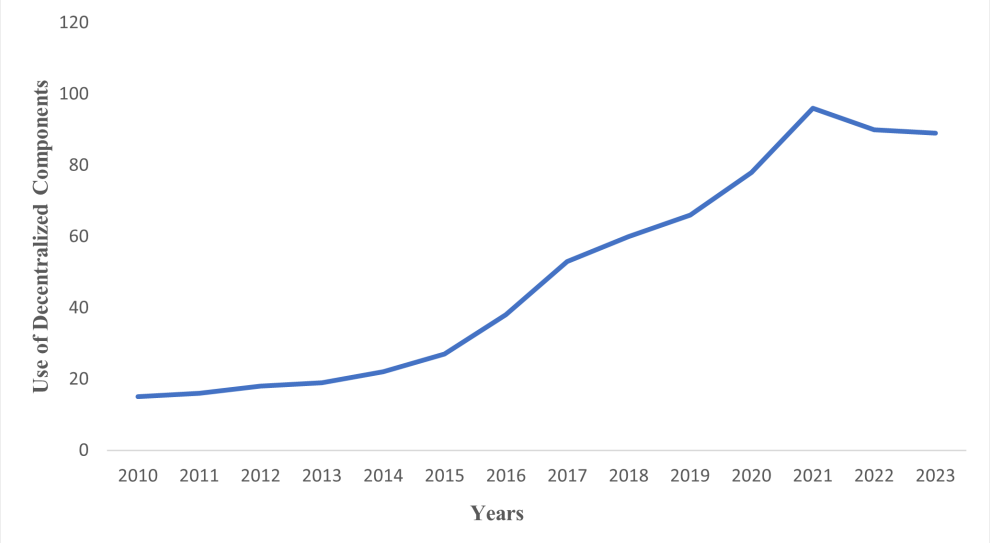

Figure 1a: Decentralization in clinical trials.

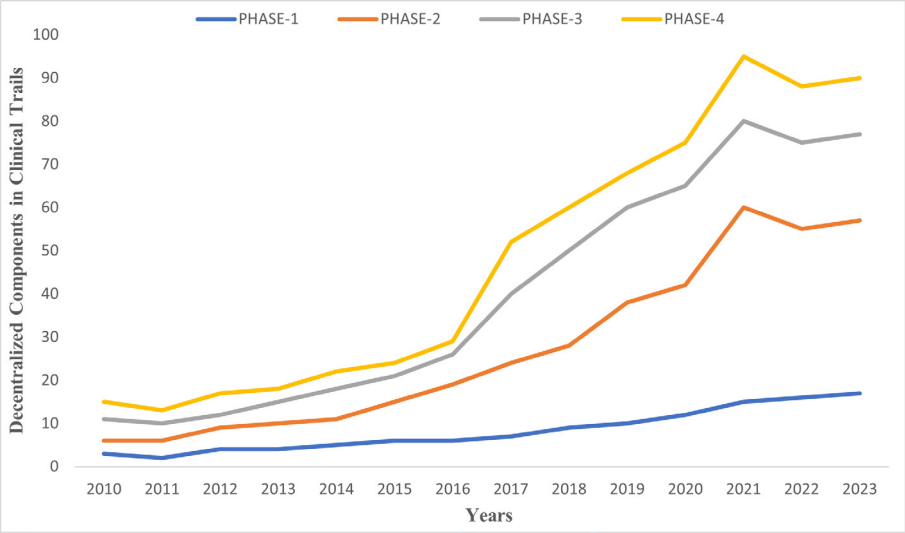

Figure 1b: Amount of drug trials with a decentralized component relative to 2021.

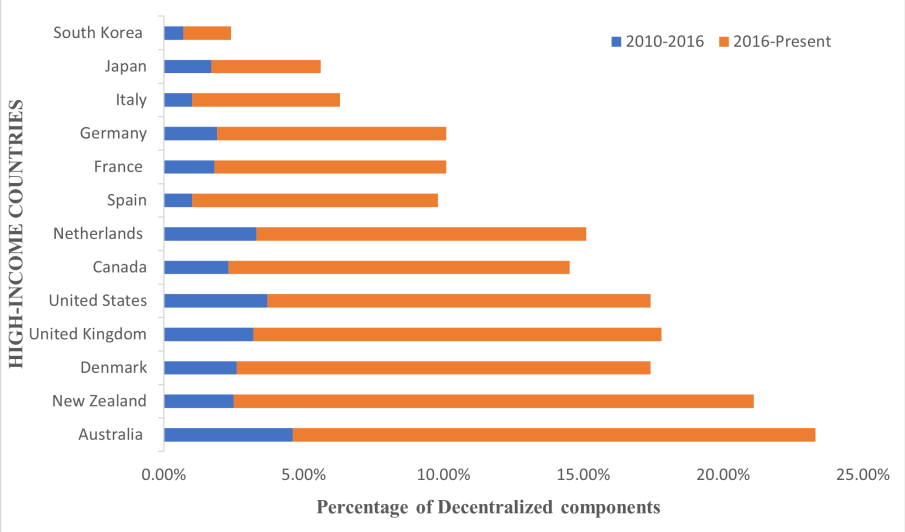

Figure 1c: High-Income Single-country Clinical trials involving Decentralized Components.

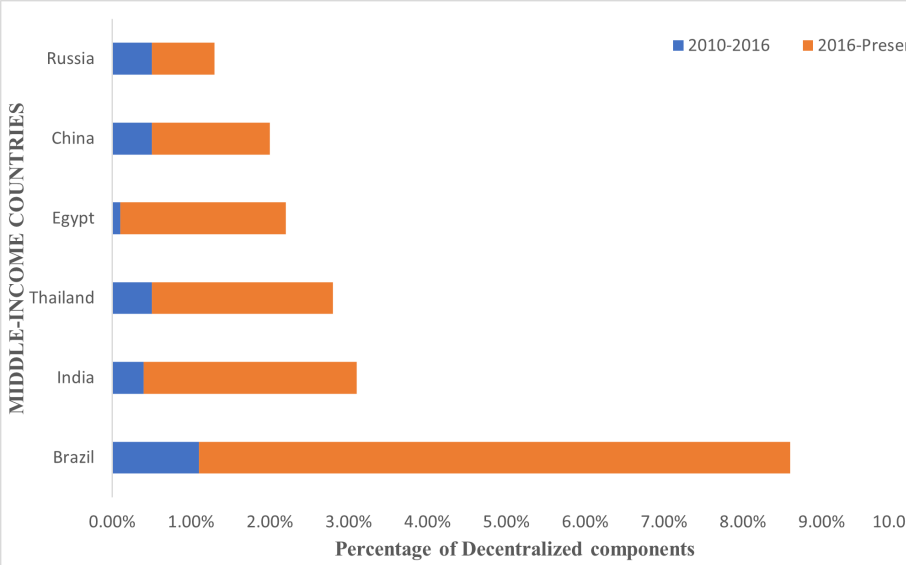

Figure 1d: Middle-Income Single-country Clinical trials involving Decentralized Components.

thus reducing the need for manual data entry (Center for Connected Health Policy, 2018).

- **Real-Time Data Access and Analysis:** This is all about getting access to and analyzing data in real time during the trial. It's super important for making decisions and drawing conclusions.
- **Cloud-Based Platforms:** Imagine using these fancy cloud-based systems to store and analyze data in real time. For instance, in a cardiology trial, they might use a cloud platform to keep an eye on participants' ECG data constantly.
- **Real-Time Alerts:** This is when systems are set up to send alerts for abnormal readings or adverse events. It allows for immediate intervention. Let's say there's a hypertension trial going on. If a participant's blood pressure goes over a certain limit, the researchers will get an alert right away.

Enhanced Communication and Engagement

This one is all about keeping communication going strong with the trial participants and other important people involved.

- **Telemedicine Consultations:** This is when they use video calls to have regular check-ins and consultations with the participants. So, in a trial on chronic pain, they might schedule video visits every two weeks to see how the patients are doing and address any concerns they might have.
- **Digital Newsletters:** These are like regular updates and newsletters sent to the participants to keep them in the loop about how the trial is progressing. Let's say there's a weight loss study happening. They might send out monthly newsletters with tips and updates on the progress to keep the participants engaged and motivated (U.S. Department of Health and Human Services, 2015).

Collaboration and Partnerships

This is all about working together with different people involved in the trial, like patients, healthcare providers, regulatory bodies, and technology companies.

- **Multi-Stakeholder Initiatives:** This means collaborating with technology companies to come up with new tools for data collection and tracking. For example, a pharmaceutical company might team up with a tech firm to create a custom app specifically for a clinical trial.
- **Regulatory Collaboration:** This is when they work closely with regulatory bodies to make sure the trial design meets all the necessary guidelines. Let's say there's a group of biotech companies working on gene therapy research. They might join forces with the FDA to develop standards for data collection and tracking in this field as shown in Figure 3 (Davis *et al.*, 2019).

Data collection methods

In clinical trials, the data collection will most often occur through the use of an intermediaries, normally a trained individual on the study team. These intermediaries play the role in capturing protocol information from detailed sources in the case report form as stipulated in International Conference on Harmonization Guidelines for Good Clinical Practice. This printed, optical, or electronic form captures all the required information about participants of the research study in a duly substantiated manner. Virtual data collection is defined as the use of digital technologies to collect data remotely and passively. If data collection is said to be completely virtual, no intermediary is needed in the process of collection. By collecting the data passively virtually, one would avoid involving a participant in a clinical test interacting

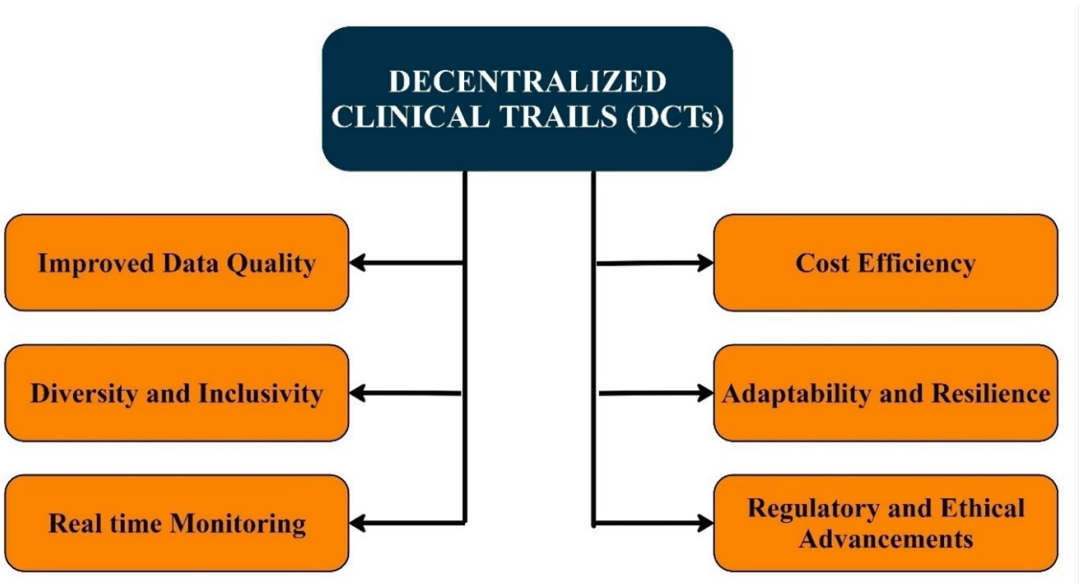

Figure 2: Importance of Decentralized Clinical Trails (DCT).

with a data collection tool or intermediary. To illustrate this difference, telemedicine platforms and mobile applications for tracking dietary intake are characteristic of tools falling under the semi-virtual category because they have some intermediate or patient activity in collecting data. For example, a wearable gyroscopic accelerometer is an epitome of a fully virtual tool that enables the passive collection of data without active engagement by patients or intermediaries. Recent advances in regulation, such as the FDA's INFORMED program and the Pre-Certification Pilot of the Centre for Devices and Radiological Health, will be gaining momentum toward the increased use of fully virtual, digital health tools in product development and patient care as shown in Figure 4 (de Jong *et al.*, 2022).

Advantages of DCT

DCT offer significant benefits over traditional trials including

- **Enhanced Patient Recruitment and Retention:** Through bringing the modalities and intervention services closer to the people through decentralized centres, DCT can access and treat populations that would otherwise be out of reach due to geographical and accessibility related issues.
- **Improved Data Quality and Real-Time Monitoring:** The results provided for use of the digital health tools imply that data collection is done on a continuous basis thus providing datasets that have higher quality and are more comprehensive.
- **Cost Efficiency:** DCT may also be effective in decreasing cost in site management and travel of patients to the centres (Flaherty *et al.*, 2021).

Challenges in DCT

Despite their potential, DCT face several challenges:

- Regulatory and Ethical Considerations: Valuing complex regulatory demands of various global areas can be challenging. Sometimes the need to conform to several regulations from various places may not be easy.
- Data Security and Privacy: Security has always been the major challenge especially when a patient's data is shared in a decentralised system.
- Technical and Logistical Issues: The application of remote monitoring technologies and the guarantee of their efficiency can be problematic (Fogel, D. B. 2018).

Key Milestones

- **Development of Mobile Health Apps:** Telemedicine applications for patients popped up and were used for raising engagement and monitoring both before, during, and after participation.
- **Adoption of Telemedicine:** Telemedicine such as consultation and follow up appointments made people

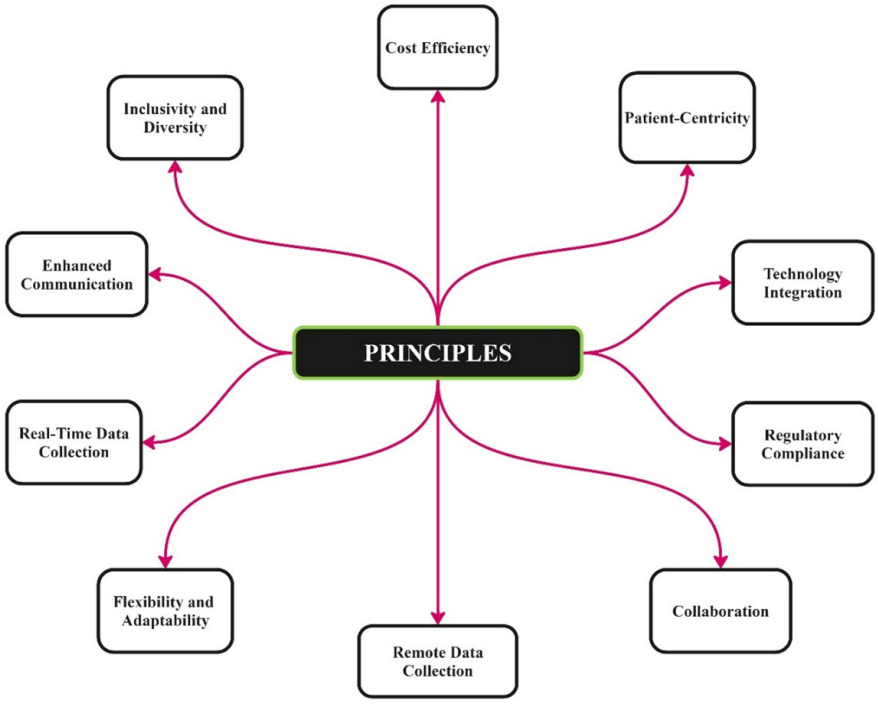

Figure 3: Principles for DCT.

interact with their doctors without having to be physically present (Freedberg *et al.*, 2020).

- **Regulatory Support:** As can be seen, regulatory agencies noted the possibilities of DCT, after that they began to produce guidance and frames for improving it. For instance, the U. S. FDA released considerations on clinical trials during the COVID-19 outbreak referring to remote approaches.
- **COVID-19 Pandemic:** COVID-19 greatly influenced the use of DCT because new clinical research could not resume with traditional approaches due to restrictions caused by the pandemic (U.S. Department of Health and Human Services, 2013a).

Efficiency Improvements

- **Reduced Time to Recruitment:** In traditional trials, recruiting participants can be a slow process due to factors like location constraints and the need for patients to physically visit specific sites. However, with the help of digital tools and a broader reach, Direct-to-Consumer Trials (DCT) can speed up the recruitment process. Online campaigns, social media, and patient registries are used to quickly identify and enroll eligible participants (U.S. Department of Health and Human Services, 2013b).
- **Enhanced Patient Retention:** One challenge in traditional trials is that many participants drop out due to the burdens of travel, time commitment, and inconvenience. DCT address this by reducing the need for travel and offering more flexible scheduling options. Remote monitoring and telehealth consultations allow for continuous engagement without the requirement of frequent site visits.
- **Cost Savings:** Traditional trials can be expensive to run, with costs associated with maintaining physical trial sites, staffing, and logistics. DCT, on the other hand, have lower operational costs. This is because they require fewer physical sites and involve reduced travel expenses. Additionally, digital tools and automation streamline data collection and management processes, further contributing to cost savings (Hecht, C. J., Ii, Friedl *et al.*, 2024).
- **Improved Data Quality and Real-Time Monitoring:** In traditional trials, data collection can be sporadic and reliant on-site visits. DCT, however, offer continuous data collection through the use of wearable devices and mobile apps. This ensures that high-quality, real-time data is collected. Having immediate access to this data allows for prompt interventions and adjustments as needed (Huh, K. Y., Moon *et al.*, 2022).
- **Increased Geographic Diversity and Inclusivity:** Traditional trials are often limited to participants who are located in close proximity to the trial sites. DCT eliminates geographic barriers, making it possible for a broader and more diverse population to participate. This inclusivity leads to more generalizable results, meaning the findings can be applied to a wider range of people.

By leveraging digital tools, DCT offer several benefits over traditional trials, including faster recruitment, better retention rates, cost savings, improved data quality, and increased diversity. These improvements contribute to a more efficient and inclusive approach to clinical research as shown in Figure 5 (Izem, R., Zuber *et al.*, 2023).

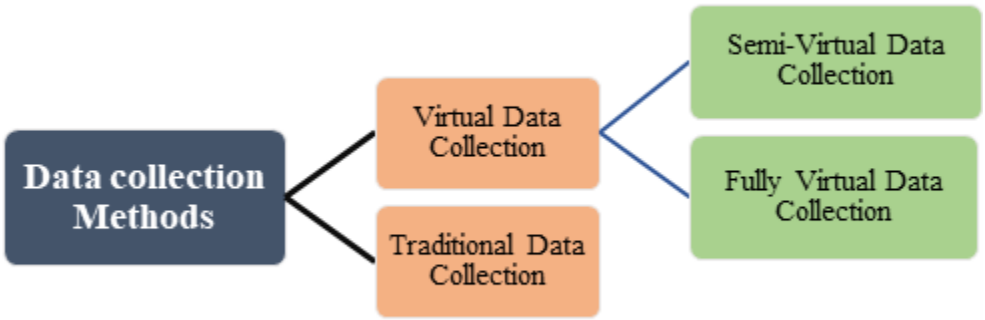

Figure 4: Types of Data Collection in DCT.

Figure 5: Efficacy Improvements for DCT.

CASE STUDIES DEMONSTRATING DECENTRALIZED CLINICAL TRIALS

Case Study 1: The RADAR-AD Study

Objective: The study aimed to assess the feasibility and acceptability of a bidirectional home-based remote assessment system in Alzheimer's disease research studies. The methods involved are:

- **Participants:** Patients with amnestic mild cognitive impairment and early Alzheimer's disease.
- **Technologies Used:** Body-worn devices capturing activity, sleep, and heart rate; mobile apps for cognitive assessments and symptom logging.
- **Approach:** Participants used technology from their private homes. Continuous collection and transmission of data to researchers for ethical analysis. Outcomes:
- **Efficiency:** The time to recruit was much faster compared to traditional site-based studies, with higher retention rates.
- **Data Quality:** The study made provisions for continuous data collection in real-time thereby improving the quality of data in terms of its accuracy and comprehensiveness.
- **Patient Feedback:** The patient satisfaction and willingness to participate in future DCT were high.

Case Study 2: REMOTE Trial by Pfizer

Objective: Test the efficacy and safety of a new drug for Overactive Bladder (OAB). The methods involved are:

- **Participants:** Adults with OAB in the United States.
- **Ensure Technologies:** Online recruitment, e-Consent, Telemedicine Consults, Digital Diaries for Symptom Tracking.
- **Approach:** Participants completed any initial screening remotely, follow-up visits via telehealth, and reported symptoms through a mobile application.
- **Outcomes:** Fully enrolled to the target sample size ahead of schedule.
- **Cost Savings:** Reduction of costs associated with maintaining sites and traveling of the patient.
- **Data Collection:** Higher quality data in real-time directly from Patient Reported Outcomes through the use of the mobile app.

Case Study 3: The VERKKO Study

Objective: Conduct a remote, decentralized clinical trial in patients with chronic conditions wholly in Finland. The methods involved and the outcomes produced are:

- **Participants:** Patients with some kind of chronic condition, such as hypertension and diabetes.
- **Devices Used:** Wearable devices enabled for continuous monitoring; mobile apps logging data; telemedicine for doctor-patient consultations.
- **Approach:** Patients received devices with instructions at home, accompanied by regular virtual check-ins by healthcare providers.
- **Patient Participation:** Studies showed high adherence and participation rates due to the convenience of participating in study visits from home.

- **Data:** Continuous data, accurate, and complete data sets.
- **Scalability:** It showed potential to scale up DCT for several chronic conditions.

Regulatory Frameworks

U.S. Food and Drug Administration (FDA)

The FDA published special guidance to aid and abet the conduction of clinical trials during the COVID-19 pandemic, underlining remote approaches and tools. This includes guidance on Remote Monitoring Use of telehealth with remote data collection to minimize new in-person visits; Informed Consent Broadening consent processes to allow for electronic informed consent (eConsent); Safety Reporting Ensuring the reporting of adverse events through remote means in a timely fashion. "Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency", this document provides detailed suggestions about the maintenance of the integrity of trials in view of adapting to pandemic-related challenges. "Use of Electronic Records and Electronic Signatures in Clinical Investigations", this guidance sets out the position of the FDA in relation to electronic systems used in clinical trials that assure data integrity and compliance with 21 CFR Part 11 as shown in Table 1.

European Medicines Agency (EMA)

The EMA has published guidance to help incorporate decentralized elements in clinical trials, especially due to the COVID-19 pandemic. This includes the following remote source data verification; this will offer informative guidance on how sponsors may remote-source data verification in order to independently verify electronically generated source data in a clinical trial, telemedicine; this is the recommendation about telemedicine for the performance of clinical assessments and patient safety monitoring. "Guidance on the Management of Clinical Trials During the COVID-19 (Coronavirus) Pandemic", this document presents the EMA's guidance on keeping clinical trial operations running as presented in response to the pandemic. "Reflection Paper on the Use of Mobile Health (mHealth) Tools in Clinical Trials", it provides a discussion of the regulatory considerations and possible benefits with respect to the use of mHealth tools in clinical research.

ICH guidelines

GCP E6(R2): The GCP by ICH provides a broad platform underlying the conduct of clinical trials in an ethical and science-based manner. However, this guideline is currently under update by the ICH to embrace contemporary designs in clinical trials involving DCT. ICH E6 (R2) Guideline for Good Clinical Practice, focuses on the roles of sponsors, investigators, and monitors, with specific attention given to data integrity and protection of participants. ICH E8(R1) General Considerations for Clinical Studies, this updated guideline addresses new innovative designs and methodologies of clinical trials, including those used in DCT.

Health Canada

Health Canada has provided guidance to maintain flexibility around the operations of clinical trials, especially during public health emergencies, which underlines decentralized approaches. The Management of Clinical Trials during the COVID-19 Pandemic Guidance to Sponsors of Clinical Trials. This would be a guided document on remote methodologies and how they may be implemented with trial integrity and patient safety diligently taken into account.

Medicines and Healthcare Products Regulatory Agency in UK

The MHRA has produced guidance to assist with the implementation of decentralized elements in clinical trials; this put greater emphasis on patient safety and data integrity measures. "Guidance on Minimizing Disruptions to the Conduct and Integrity of Clinical Trials of Medicines during COVID-19",

Table 1: List of Guidelines for DCT by various Regulatory Authorities.

Sl. No.	Regulatory authority	Guidelines
1	U.S. Food and Drug Administration (FDA)	FDA Guidance on Clinical Trials During COVID-19,FDA Guidance on Electronic Records and Signatures.
2	European Medicines Agency (EMA)	EMA Guidance on Clinical Trials During COVID-19,EMA Reflection Paper on mHealth.
3	ICH: International Council for Harmonization	ICH E6(R2) Guideline,ICH E8(R1) Guideline.
4	Health Canada	Health Canada Guidance on Clinical Trials During COVID-19.
5	Medicines and Healthcare Products Regulatory Agency-UK	MHRA Guidance on Clinical Trials During COVID-19.

this guidance document details the MHRA's recommendations for adjusting the operation of clinical trials during a pandemic.

Key Considerations involved in DCT

- **Informed Consent:** Most of the regulatory bodies accept eConsent as a technique of acquiring knowledgeable consent; however, the method should ensure comprehension and voluntariness (E., Daizadeh, N., Bretz *et al.*, 2024).
- **Data Privacy and Security:** Compliance with the Data Protection Laws: Ensuring that Data protection laws, as ruled in Europe by the GDPR and in the U.S. by HIPAA are complied.
- **Remote Monitoring (rSDV):** Agencies advise on the implementation of rSDV, in order to ensure data quality and integrity without an on-site visit (Johnson, E., and Marsh, L. 2023)
- **Telemedicine:** Use of telemedicine for clinical assessments and follow-up, subject to it being conducted appropriately to maintain patient safety and assure integrity of the data.
- **Technology Validation:** The regulatory bodies strongly underline that the digital tools in use within DCT undergo stringent validation to ensure reliability and accuracy (Kelsey, M. D., Patrick-Lake *et al.*, 2022).

Challenges to Adoption of DCT

Whereas several exciting possibilities exist with DCT, challenges have to be overcome for general adoption. They are.

Technical and scientific issues

- **Data Quality and Standardization:** Data collected remotely through wearables or patient-reported outcomes may potentially be variable, unlike that obtained in controlled clinic settings. Ensuring data quality and consistency across heterogeneous platforms and methods of collection calls for careful planning and validation (Khozin *et al.*, 2019).
- **Technology Integration:** It is quite more difficult and costly to integrate DCT technologies with the currently used CTMS. Moreover, the systems must be made user-friendly for both patients and researchers.
- **Generalizability Limitation:** Not every clinical trial is easily decentralised. In some studies, complex procedures or specialized equipment or very detailed physical assessments are involved and therefore call for a traditional clinic setting (Kim, Y.-S., Kim *et al.*, 2024).

Economic and market barriers

- **Technology Cost:** Up-front investments in software, wearables, and possible telehealth infrastructure are required to implement the technologies. This may act as a barrier to smaller research institutions and institutions with limited budgets (Lalanza *et al.*, 2023).
- **Reimbursement Models:** Traditional clinical trial reimbursement structures might not appropriately account for differing costs and resource needs of DCT. There is a need to come up with new models that would foster their wide adoption.
- **Restricted provider network:** Building a network of health care experts to be able to make clinically proper functioning from the patient's place of convenience, or perhaps manage lesion data collection in DCT, can be tricky across a geographically dispersed area (de Las Heras *et al.*, 2022).

Regulatory and policy challenges

- **Dynamic Regulatory Environment:** Most of the regulatory scenarios for DCT are still evolving with respect to data privacy, remote monitoring practices, procedures for informed consent, and so on. Sponsors need a clear guideline for tackling these complexities (Li, S. X., Halabi *et al.*, 2022).
- **Country-wise Regulations:** Country-wise regulations pertaining to DCT vary widely. This brings additional challenges in multinational studies and requires careful planning for its compliance across geography.
- **Data Privacy Concerns:** Robust security measures in DCT would mean really tight security on patient data subjects' privacy as the most important factors. With concerns over data breaches and unauthorized access, rigorous measures in cybersecurity and transparent data governance policies become imperative (Moore *et al.*, 2022).

Strategic Assessment and Risk Mitigation Framework of DCT

Assessment Methods

Several methods can be put into place to ensure the effective assessment of DCT

- **Remote Monitoring:** Technology can be put to work in monitoring remotely the conduct of trials for adherence to protocols and data integrity.
- **Centralised Data Evaluation Procedures:** Thorough procedures would entail a review of data to establish any probable data quality issues and consequently handle them.

- **Questionnaires on Patient Feedback:** Feedback from participants to understand their experience with the DCT format and bring out improvement areas.
- **Cost-Effectiveness Analysis:** The economic impact of the DCT should be rated against the traditional trials on cost, resource use, and probable benefits (M., Lipset *et al*., 2014).

Management Strategies

Traditional approaches to trial management need changes to accommodate DCT.

- **Selection and Integration of Technologies:** Choose user-friendly, secure, and compliant DCT technologies with regulations.
- **Standardized Operating Procedures:** Clearly laid down SOPs for every aspect of DCT, from data collection, via remote monitoring to communication between participants and data security.
- **Training and Support:** Impart thorough training to the researchers, health providers, and patients involved in the DCT for its smooth execution.
- **Patient Engagement:** There should be proper engagement with patients addressing their queries and motivating them to report data correctly and consistently.
- **Research Risk Management Plan:** Carry out a risk management study plan that is well conceptualized with respect to the identification of potential risks in the DCT approach (Østervig *et al*., 2015).

Risk Assessment

Risk assessment in DCT becomes more important than in the traditional ones due to various complexities inherently associated with remote data collection and monitoring. An effective risk assessment makes the DCT a success through identify potential risks and prioritize; development of mitigation strategies that will minimize the impact of such risks; monitor how effective mitigation measures are against the risks and DCT design or its procedural alteration, if necessary, regarding emerging risks (Petrini *et al*., 2022). The techniques are:

- **Data Security and Privacy:** Severe consequences occur in case of a breach or unauthorized access to sensitive information pertaining to the patients. A robust risk assessment aids in recognizing and mitigating potential vulnerabilities within the DCT design.
- **Technology Dependence:** All dependencies upon technology come with the risks associated with the failure of the system, data quality problems, and user error. A risk assessment helps to plan for such contingencies and to ensure the integrity of the data (Randell, *et al*., 2023).
- **Participant Selection and Bias:** Additional selection bias may be introduced by the remote recruitment process in populations with limited access to technology or the internet. Risk assessment will allow for the realization of such biases and the formulation of measures for the same.
- **Difficulties of Remote Monitoring:** It may become difficult to ensure accurate data collection, its completeness, and adherence to the protocol in a remote setting. Risk assessment enables proactive measures in mitigating such challenges (Sarraju *et al*., 2022).

Notable Success Stories in Decentralized Clinical Trials: DCT field becomes rapidly growing, and different companies demonstrate the viability of the approach.

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It teamed up with big pharma names such as Novartis, Sanofi, and many others to execute remote trials. This includes partnering with AOBiome to complete a Phase 2b trial for their novel acne treatment. Using the DCT model, full enrolment of 372 subjects was reached in just three months-unheard of for any study, which clearly shows a potential increase in the speed of enrolment.

Medable: It is built for the digitalization of DCT procedures. It has partnered with institutions in running remote trials in a wide array of therapeutic indications.

Understanding the Impact of DCTs

In Pharmaceuticals

- **Faster Drug Development:** Thus, with better recruitment and lesser site costs, the studies can be conducted at a faster pace, and thus these new treatments can hit the market faster.
- **Diverse Pool of Patients:** DCT can capture patient populations that are geographically dispersed or weak, providing diversity in the clinical trial data and eventually more potent drugs for a wider range of patients (Smith, Z., Getz, K. 2024).

In Manufacturing

- **Remote clinical trial site monitoring:** DCT may be empowered through technology to monitor the conduct of the trials remotely, hence reducing the possible number of on-site visits required by the manufacturing sponsor to ensure compliance with protocols.

- **Improved supply chain efficiency:** Where a DCT integrates telemedicine and remote collection, such may go a long way in smoothening communication and data sharing between researchers and manufacturers, bringing about more efficient supply chain management for clinical trial materials (Fu, Z., Liu *et al.*, 2023).
- **Overall impact:** DCT can help in changing the landscape of clinical research in some well-documented ways that involve improving patient access to potentially life-altering therapies, diminishing time and cost of drug development, increased quality and generalizability of the data generated by clinical trials and incentivising further collaboration and innovation in health (Copland *et al.*, 2024).

Future Perspective of DCT

The future for DCT looks bright, with colossal growth and wide adoption expected over the upcoming years.

- **Technological Advancements:** A naming of new advancements in telemedicine, remote monitoring technologies, and wearable devices further increases the feasibility and efficiency of DCT.
- **Regulatory Harmonization:** Regulatory authorities are working together to align activities that will offer more uniformity and streamlining of DCT guidelines across regions, making it easier to conduct multinational trials (Welch *et al.*, 1992).
- **Changing Landscape:** With the obvious advantages that accrue to DCT, the pharmaceutical firms and the contract research organizations will quite likely increase investments in DCT-related infrastructure and expertise.
- **Increased Patient Focus:** Although it exists now, the patient-centric approach in DCT will possibly be at the heart of future practices, focusing much more on participant convenience, flexibility, and communication (Feinstein 2025, National Cancer Institute, 2025).

CONCLUSION

Decentralized Clinical Trials (DCT) are aimed at changing the paradigm of clinical research. Digital health technology, remote monitoring, and telehealth make clinical trials more efficient, universal, and accessible. DCT may increase patient retention, expand enrolment, and improve data collection, but there are also technology limitations, privacy issues, and regulatory complexity taken into consideration. As technical improvements accelerate, regulatory frameworks become more aligned, and industry investments in DCT infrastructure increase, the future of DCT is good and promising. DCT can help to improve clinical research efficiency, effectiveness, and diversity by focusing patient-centricity and encouraging involvement from stakeholders.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DCT: Decentralized Clinical Trails; **MHRA:** Medicines and Healthcare Products Regulatory Agency; **ICH:** The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; **CTMS:** Clinical Trial Management System; **rSDV:** Remote Source Data Verification; **FDA:** Food and Drug Administration**; EMA:** European Medicines Agency; **OAB:** Overactive bladder; **EHR:** Electronic Health Records; **CTTI:** Clinical Trials Transformation Initiative.

SUMMARY

Decentralized Clinical Trials (DCTs) are a concept that is starting to show promise in mitigating the problems associated with traditional clinical trials, particularly with regard to participant recruitment and diversity. DCTs have benefited greatly from the COVID-19 pandemic and enable trial activities by the participants through their home surroundings. While DCTs do increase quality, increase accessibility, and help with cost-effectiveness, they also bring with them new challenges related to technology, data security, and regulations. By utilizing DCTs and with continuous improvement, clinical research will fundamentally help future clinical trials become more equitable and effective.

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