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Decentralized Clinical Trials:

Transforming the future of healthcare

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Introduction

According to the FDA, Decentralized Clinical Trials (DCTs) are clinical trial operations that uses technology to communicate with study participants, collect data, and perform trial-related activities in locations other than conventional clinical trial sites.[1]

DCTs represents a revolutionary shift in the way clinical research is conducted, using technology and remote methodologies to improve the efficiency, accessibility, and participant experience of conventional clinical trials.[2] Unlike traditional trials, which require participants to travel towards centralized locations like hospitals or research facilities, DCTs enable many trial-related activities to occur remotely, in participants' homes or local environments. This approach uses digital tools, such as wearable devices, telemedicine, mobile health applications, and home healthcare services, to track and monitor patient outcomes and collect data in real-time.[1]

The COVID-19 pandemic triggered the adoption of decentralized models, since social distancing measures and lockdowns rendered the traditional trial approaches impractical. To facilitate the adoption of DCTs, regulatory agencies such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have provided frameworks and guidelines. The regulatory support for these trials and the growing infrastructure suggests that DCTs play an increasingly prominent role in the future of clinical research.[3]

Evolution of DCT's

With the help of technological advancements, patient-centric approaches, and regulatory support, the development of DCTs has increased significantly in recent years, transforming the clinical research perspectives.

1. Initial exploration of DCTs (2000s-2010s)

The framework for DCTs were established initially by experimenting with telemedicine and digital tools. The initial exploration aimed towards remote data collection, using electronic patient-reported outcomes (ePROs) and wearable devices.

2. The emergence of Patient-Centered Research Models (2010-2018)

As patient-centered care gathered attention, DCTs aligned well with the attempt to improve patient convenience and decrease dropout rates. This period embraced telemedicine, mobile health applications, and wearables to reduce the burden of site visits.

In 2011, Pfizer led the REMOTE (Research on Electronic Monitoring of Overactive Bladder Treatment Experience) trial, which was the first fully web-based clinical trial conducted under an Investigational New Drug application. This study included online recruitment, online questionnaires, electronic diaries, and home delivery of the investigational medicine in place of any in-person site visits.[4]

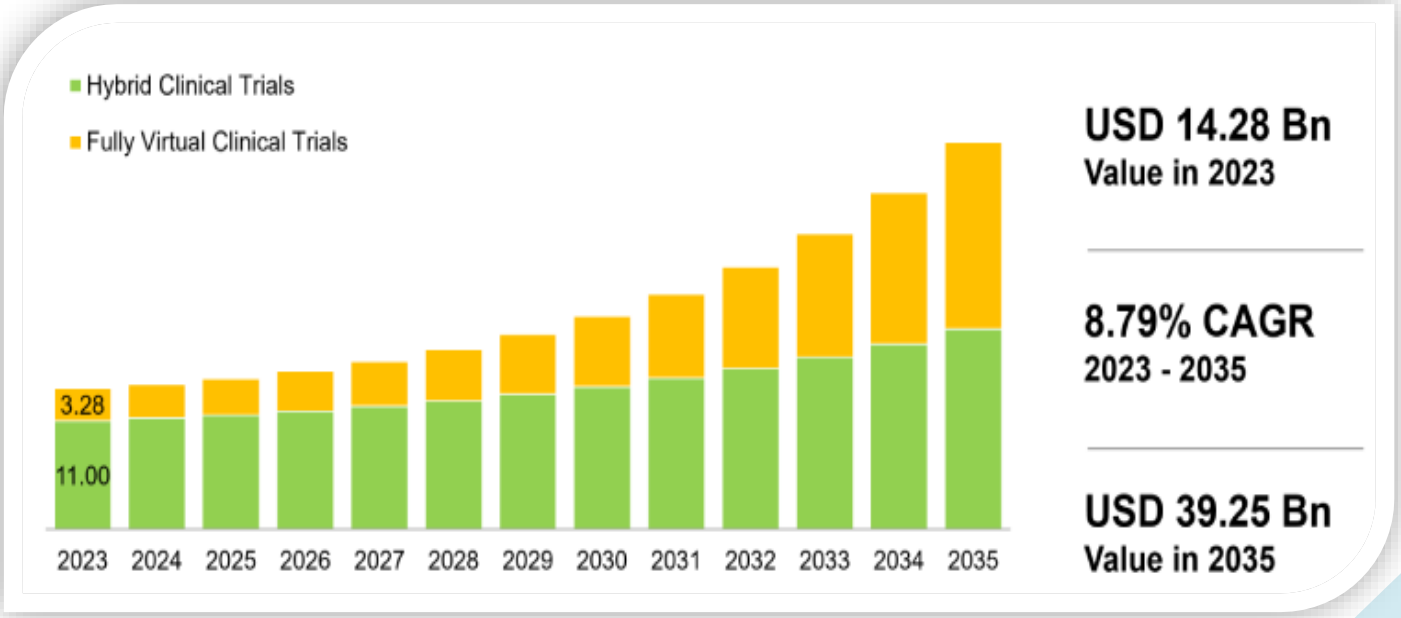
3. COVID-19 as a driving force for adoption of DCT (2020-present)

A major turning point was the COVID-19 pandemic, which compelled sponsors and CROs to switch to remote operations. To ensure trial continuity, particularly for chronic illnesses, regulatory bodies released recommendations on the application of DCT.

Decentralized Clinical Trial Market Report

The market for clinical trials is undergoing a significant transformation due to the globalization of clinical trials The underline growth is directed by the expanding clinical trials indicating a significant shift in the healthcare landscape. Accelerating drug development timelines, reducing costs, and making innovative treatment approaches more accessible to a wide range of patient population are all becoming increasingly important. According to an Industry Standard Research poll conducted before to the pandemic, 38% of biopharmaceuticals and CROs anticipated that DCTs would constitute a significant portion of their portfolios, and 48% anticipated that they would perform a trial with most of the activities taking place in patient's home.[5] 85% of participants in the Clinical Trials Transformation Initiative survey of academics, business, and other stakeholders said they switched to virtual or remote visits in one or more ongoing trials during the epidemic.[6]

From 2024 to 2034, the global decentralized clinical trials market is projected to grow at a compound annual growth rate (CAGR) of 7.6% from its 2024 valuation of US$9,231.3 million.[7]



Source:https://www.rootsanalysis.com[7]

The Spectrum of Decentralization

Site based	Virtual
Recruitment	
• Recruitment and pre-screening at sites using television, radio, newspapers, physician referrals, and recruitment agencies.	• Strategic digital recruitment and pre-screening via social media platforms
Enrolment and Onboarding	
• In-person consent process • Screening and assessments conducted on-site during scheduled appointments • Hands-on training provided during scheduled appointments	• Electronic consent (e-Consent) with guidance • Access to live chat and clinical study team • Secure multifactor identity verification • Virtual, on-demand training
Investigational Product Distribution and Administration	
• Study staff to manage dispensing, collection, and performance monitoring • Accountability ensured at sites during scheduled appointments	Delivered directly to patient
Data Collection	
• Paper diaries for home use • In-person data collection at sites during scheduled appointments	• Electronic patient-reported outcomes (ePRO) with support for image, audio, and video capture • Remote monitoring using digital tools like wearables and medical devices • Event driven notifications and reminders
Evaluation	
• In-Person Clinical Trial Outcome Evaluation by Healthcare Professionals at Study Sites • Digital Clinical Outcome Assessment (eCOA) Conducted by Healthcare Professionals at Study sites	• Electronic clinical outcome assessment (eCOA) through telehealth • Mobile HCP visits • Centralized expert raters

Summary

Is the transition to decentralized clinical trials nearing? The answer is yes. With the goal to provide the industry with more accurate, real-world data from a wider range of populations on shorter research timelines, it is necessary that we make trials easier, safer, and more accessible. The thoughtful integration of traditional trial designs with decentralized components is the key to the future of clinical research. Hybrid models, combining the best aspects of these approaches, may be the most effective way to achieve the scientific rigor necessary for the next generation of clinical research. By adopting a patient-centric approach and fostering stakeholder collaboration, the potential of DCTs to accelerate drug development and enhance the healthcare outcomes can be achieved.

References

1. *Conducting Clinical Trials with Decentralized Elements. Guidance for Industry, Investigators, and Other Interested Parties [Internet]. U.S. Food and Drug Administration. 2024. Available from:https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements*
2. *https://globalforum.diaglobal.org/author/dev. The Evolution of Decentralized Clinical Trials: Blending Innovation and Regulation in the Digital Age [Internet]. DIA Global Forum. 2024 [cited 2024 Dec 3]. Available from: https://globalforum.diaglobal.org/issue/october-2024/the-evolution-of-decentralized-clinical-trials-blending-innovation-and-regulation-in-the-digital-age/*
3. *Decentralised clinical trials: ethical opportunities and challenges Vayena, Effy et al. The Lancet Digital Health, Volume 5, Issue 6, e390 - e394*
4. *Orri M, Lipset CH, Jacobs BP, Costello AJ, Cummings SR. Web-based trial to evaluate the efficacy and safety of tolterodine ER 4mg in participants with overactive bladder: REMOTE trial. Contemporary Clinical Trials. 2014 Jul;38(2):190–7.*
5. *Stepping up the decentralization of clinical trials McKinsey [Internet]. www.mckinsey.com. Available from: https://www.mckinsey.com/industries/life-sciences/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials*
6. *Adapting Clinical Trials During COVID-19 - CTTI [Internet]. CTTI. 2020 [cited 2024 Dec 3]. Available from: https://ctti-clinicaltrials.org/type/media-coverage/adapting-clinical-trials-during-covid-19/*
7. *Virtual Clinical Trials Market, Size, Share, Trends, Forecast (2035) [Internet]. www.rootsanalysis.com. Available from: https://www.rootsanalysis.com/reports/virtual-clinical-trial-service-provides-market.html*