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DISRUPTING HEALTHCARE:

The Transition Towards Decentralized Clinical Trials

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The Future of Clinical Trials

ARE TRADITIONAL CLINICAL TRIALS A THING OF THE PAST?

Current State of Clinical Trials

Clinical trials have long played a vital role in evaluating medical, surgical, and behavioral interventions to ensure safety in patient populations [1]. A clinical trial may also explore and assess programs to improve outcomes for people living with a life-threatening disease or a chronic health condition. Traditional clinical trials are typically conducted in person, follow a "brick and mortar" design, and use a site-based or a multi-site implementation approach to carry out trial activities.

Healthcare is currently experiencing a shift towards a modernized, patient-centered care delivery model by focusing on increased technology integration and patient empowerment. Traditional clinical trials can be slow, cumbersome, and do not leverage innovative implementation strategies. Following current digital advancements, innovations to traditional clinical trials are needed to significantly impact and improve key pain points in their operational execution.

The challenges associated with traditional clinical trials

Clinical research is the first step to introducing a diverse set of interventions for patients and requires the highest levels of data quality, compliance, and safety. Achieving these standards in traditional clinical trials is often accompanied by common challenges in the areas of **enrollment**, **infrastructure**, and **time**.

No Participants, No Outcomes

Enrollment

Enrollment in clinical research rarely occurs as quickly as desired; the delays experienced at this stage often affect the timing and execution of trials. The number of patients participating in a trial is also critical — when there is an inadequate number of participants, true differences may not be statistically detected [2]. Even when recruitment is successful, and the desired number of participants enroll in the study, other barriers such as poor participant engagement and motivation often lead to difficulties in completing the trial. Finally, traditional clinical trials usually involve paper-based processes and physical travel, which contribute to inconvenient time commitments and financial burdens; these barriers limit the number and diversity of interested participants.

Structures Are Only as Strong as Their Foundation

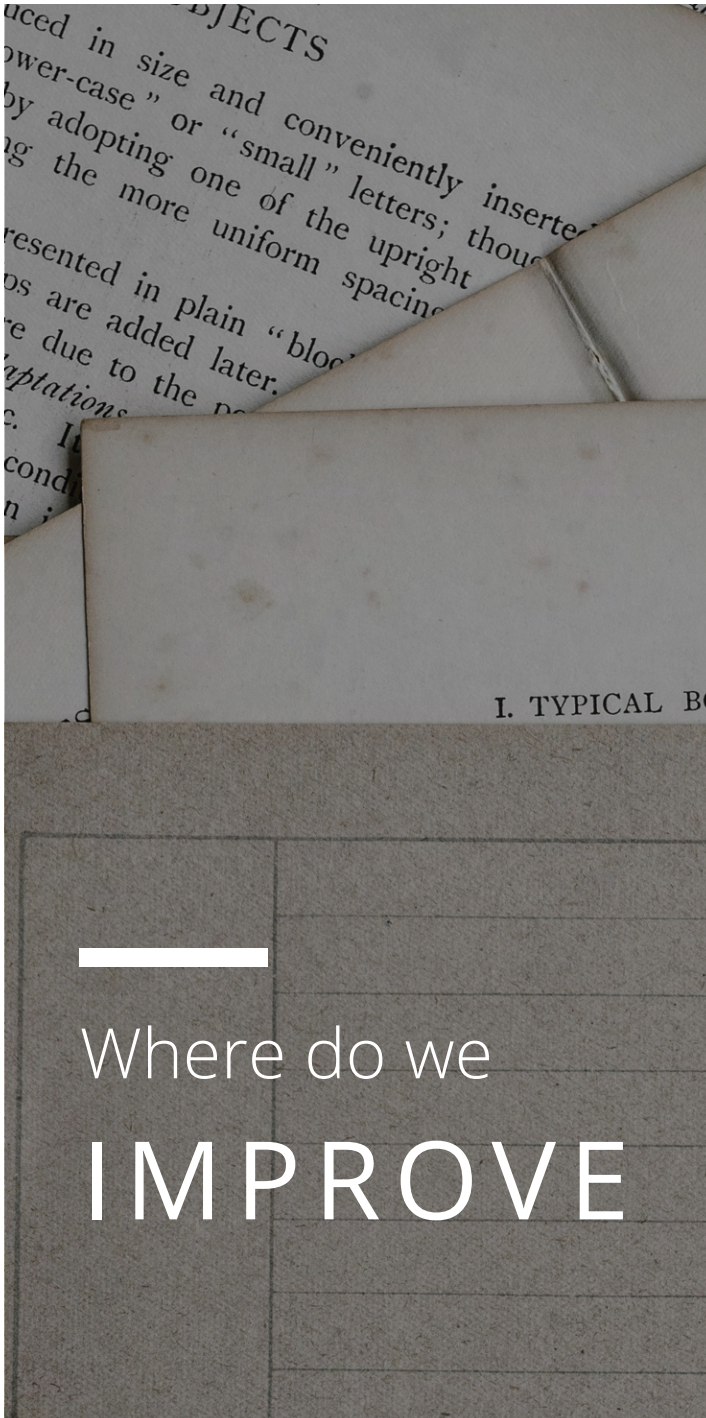
Infrastructure

Clinical trials are composed of diverse processes that have been slow to modernize, in particular, study documentation and the implementation of data capture systems. Traditional strategies such as paper diaries or data collection forms require a significant amount of time and resources, contributing to substantial barriers that affect the outcomes of a trial. Major obstacles may include the lack of personnel, high cost, and gaps in stakeholder communication, causing challenges during the implementation process. Finally, traditional clinical trials largely follow a location-based model and do not favor healthcare's current shift towards patient-centered care delivery. This outdated approach impacts the implementation process and contributes to undesirable study outcomes.

Time is a Limiting Factor

Time

Time is a critical limiting factor when implementing systems that can successfully generate high-quality data with the statistical power to draw accurate conclusions. However, traditional clinical trials lack the technological innovations that effectively accelerate study completion and address procedural barriers. Moreover, globally, the location-based model adopted by traditional clinical trials leads to more than 80% of trials failing to enroll on time [3]. Delays caused by the inability to reach these study milestones in a timely manner contribute to overhead costs during the extended study period and ultimately delay the market launch of the interventional product or program of interest.



DISRUPTING THE LANDSCAPE OF TRADITIONAL CLINICAL TRIALS:

COVID-19 as a Critical Disrupter

THE PANDEMIC HAS PLAYED AN INTEGRAL ROLE IN SHIFTING THE WAY HEALTH CARE IS DELIVERED... THIS IS THE TIME TO SPEARHEAD ADVANCEMENTS IN CLINICAL TRIALS AND ADVOCATE FOR A HIGH-TOUCH, HIGH-TECH, HIGH-SCIENCE APPROACH.

COVID-19 has added to these ongoing challenges and has played a significant role in highlighting areas of improvement in traditional clinical trials. Over the course of the pandemic, clinical trials experienced shortages of medical and support staff, travel restrictions, decreased enrollment, interruptions of supply chains for investigational products, uncertainty over continued funding, and others completely stopped due to limited participant ability (for example visiting physical testing sites) [4]. A study conducted by Asaad et al. (2020) queried the US National Library of Medicine's website ClinicalTrials.gov and identified that in two months, between March/April 2020, 86% of clinical trials were suspended due to rising COVID cases. As a result, like in many other industries, clinical trials were required to rapidly integrate technology into their study workflows to resume operations. Since the beginning of the pandemic, many examples of successful implementation have demonstrated the healthcare industry's capacity to drive technological innovation to modernize traditional clinical study workflows and consider new solutions, for example, the implementation of decentralized clinical trials or DCTs.

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TRANSFORMING THE LANDSCAPE OF TRADITIONAL CLINICAL TRIAL MODELS

Introduction to Decentralized Clinical Trials

Connectivity within the healthcare system is rapidly expanding, and the drive to modernize the current state of traditional trials is becoming imperative. Decentralized clinical trials (DCTs), as the name implies, are not dependent on a central study location; they are conducted remotely and across multiple study sites. Most importantly, DCTs play a vital role in overcoming the challenges mentioned above in traditional clinical trials.

Improvements in technologies and methods to drive clinical trial innovations have focused on incorporating DCTs. With both software and hardware technological solutions, such as clinical trial management tools and wearable measurement devices, stakeholders participating in a fully decentralized clinical trial can effectively remotely manage the collection, processing, and interpretation of data from multiple locations.

COVID-19 has significantly accelerated the adoption of DCTs; this has allowed the rapid virtualization of numerous trial activities, including remote monitoring, electronic consent (eConsent), electronic patient-reported outcomes (ePRO), and electronic case report forms (eCRF).

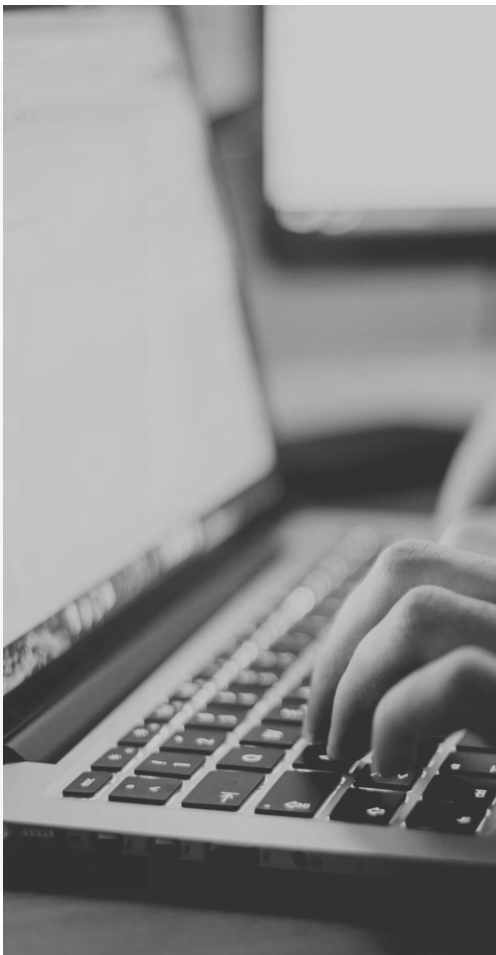
Finally, in the context of clinical studies, the core goal of decentralization is centered around modernizing the current infrastructure used to conduct clinical trials and improving the individual experience of participants, captured in a real-world setting — this is primarily achieved by incorporating technological solutions into data collection workflows.

Core Pillars Supporting DCTs

01 | Streamlined data collection and study management

02 | Patient-centered engagement and retention

03 | Digitization



CORE PILLARS

Streamlined data collection and study management

DCTs facilitate the increase in participant enrollment and better data collection. However, on their own and without adequate tools, successfully improving enrollment and data collection becomes difficult and can impose limits on a trial's design. In order to effectively streamline the process and maintain data accuracy, DCTs usually employ electronic data capture (EDC) systems. Additional methods for virtual data collection in DCTs may include virtual/telehealth visits or remote patient monitoring. Additionally, Patient-centered clinical trial management tools enable these processes and are necessary for the successful implementation of DCT projects. Lastly, well-developed clinical trial management solutions have the capability and capacity to monitor and ensure the integrity of high-velocity, high-volume data.

Patient-centered engagement and retention

In traditional trials, physical sites are the central location of all study activities. This is where participants are enrolled, where their data is collected, and where personnel can monitor research outcomes. DCTs, on the other hand, aim to reduce on-site visits as much as possible. This supports a patient-centered model that positively affects retention and engagement. Moreover, depending on the study population, engagement will differ based on key demographics such as age, gender, health condition, socioeconomic status, and knowledge of technology. Knowing the audience is essential to leveraging a high-touch approach not typically accounted for in traditional trials. High touch is created through participant interaction. This could be in the form of text messages, notifications (eReminder), informational emails, phone calls, and participant support (for example, call centers). Furthermore, study interactions, staying aware of engagement & retention metrics, and support queries can help determine where trials are succeeding and how to improve. Overall, online engagement presents a modern take on clinical trials and can be done successfully by gaining knowledge of the study population, targeted interactions, and a high-touch approach, ultimately creating a safe environment.

Digitization

Finally, digitization offers clinical trials a new avenue for efficiency. This may include completing informed consent forms using a mobile device, virtual study monitoring, electronic questionnaire completion, and digital forms of study compensation in an audit-ready manner.

HARNESSING THE POWER OF DCTS

Benefits of Decentralized Clinical Trials

01

REDUCED BARRIERS TO PARTICIPANT ENROLLMENT AND PARTICIPATION

Participants encounter a variety of obstacles when enrolling in traditional clinical trials. This includes requirements for on-site participation and variable time commitments that often causes disruptions to their daily activities. DCTs, however, apply a patient-centered approach by leveraging digital tools such as teleconferencing and electronic data capture, allowing participants to participate in studies remotely at their convenience, effectively decreasing barriers to participation.

02

HIGHER PARTICIPANT RETENTION RATES

As a result of remote study participation, DCTs are ideal for accommodating those who are traditionally excluded from clinical research. A study conducted by Khozin & Coravos (2019) observed a 30% attrition rate for most traditional clinical trials. Successful retention typically involves mechanisms that empower participants to be positively engaged and motivated till trial completion. Therefore, when barriers to participation are decreased, and participant convenience is taken into account, there is a positive downstream effect that leads to lower attrition rates.

03

ENHANCED SPEED AND DATA QUALITY

Decentralization and study digitization aims to improve trials' overall speed and simultaneously promote enhanced data quality. Due to digital tools like electronic data capture through mobile devices, participants can complete electronic case report forms (eCRF) at their convenience and comfort, contributing to faster completion time and improved quality of collected data.

04

HIGHER-QUALITY RESULTS

Effective communication between participants and study personnel is an essential requirement for any clinical trial, as it promotes motivation and enhances retention. Additionally, the integration of teleconferencing makes it easier for participants to interact with the study personnel at their convenience. Moreover, eReminders or push notifications can help participants remember to submit required data consistently and in real-time, driving higher-quality study results and patient satisfaction.

05

Key benefit: DCTs Have the Power to Employ Stronger Recruitment Initiatives

The key benefit of decentralizing clinical trials is the possibility of widening the study population, both geographically and demographically. This is particularly important to address the challenges clinical trials experience during enrollment and the lack of representation from populations who have historically experienced difficulties participating in research. Physical and central study sites are restricted by their geographic area; permitting remote participation allows trials to enroll those largely excluded due to socioeconomic factors. Other demographic factors, such as age, will positively benefit from this decentralized model. Trial enrollment tends to favor older participants who may have more flexible schedules. DCTs help overcome time constraints experienced by younger populations by giving them the ability to participate with the devices they already use in their daily lives.

WHERE ARE THE GAPS AND HOW DO WE BRIDGE THEM

Improvements to DCTs

While DCTs offer a promising solution to the current problems experienced by traditional clinical trials, there are significant challenges, while addressable, that must be considered. Implementing digital technologies in clinical research offers comprehensive methodologies to facilitate information capture. With this increasingly digital integration, it should be considered whether a chosen electronic data capture system can integrate with other digital technologies and host the required volume of data. Moreover, DCTs that require the collection of larger volumes of data may face other specific challenges. For example, connected devices such as sensors and wearables, while improving exponentially, are in early development and require clinical validation of the extracted data [6]. The availability of technical support and the practicality of continuous monitoring with in-home devices and wearable sensors are critical infrastructure considerations. Current digital infrastructures require advanced technical, organizational, and regulatory capabilities that are not yet present in standard clinical development programs.

Moreover, collecting data through digital devices raises concerns surrounding privacy and security. Protecting the privacy of personal health information (PHI) stored on digital devices and distributed channels requires strict guidelines governing the collection and use of PHI.

FUTURE OF CLINICAL TRIALS

COVID-19 has catalyzed the healthcare industry and spearheaded novel opportunities for modernization. DCTs can bolster diversity in trials and play a key role in achieving an industry of truly patient-centered care. As stakeholders begin the transition to leveraging the power of digitally supported trials, there is a clear need for technology to help support and drive efficiency. Modern clinical trial operations and data management solutions are essential as we move forward. DCTs take advantage of technological solutions to bring clinical research directly to patients, allowing for remote collection of data that is representative of the individual experience of patients in real-world settings. Through the continued development of new solutions that support the various requirements of DCTs, the healthcare industry will continue to experience a shift towards patient-centered research — research that is high-powered, more inclusive, diverse, and high-touch.

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