VAULT HEALTH

Decentralized Clinical Trials as the Way of the Future

The challenges of conventional, site-based clinical trials

Why does it take so long to get new treatments and drugs to market? For many people who suffer from conditions that could benefit from new therapies, this question frustratingly remains top of mind. The COVID-19 pandemic opened the world's eyes to the importance of investing in flexible approaches to research and development to get novel life-saving treatments to market. But the speed at which the first COVID-19 vaccines were developed (under 1 year) without compromising safety is uncommon, and all the more incredible given that under normal circumstances, the clinical development process for a single drug therapy can take 10-15 years[1].

It helped that researchers weren't starting from scratch when confronted with SARS-CoV-2, the virus that causes COVID-19, and that amidst a global pandemic, researchers, governments, and institutions quickly mobilized and partnered to get the vaccines safely to market. But outside of COVID-19 research, conventional clinical trials remain slow and are more expensive and less efficient.[2]

While there have been great strides in the way clinical trials are conducted, the statistics keep reminding us that something is wrong:

- 68% of trials are terminated for reasons other than accumulated data from the trial, and among these trials, 57% are terminated due to insufficient patient recruitment rates[3]
- 86% of clinical trials don't reach recruitment targets within their specified time periods[4]
- Only 7% of patients who enroll in a clinical trial make it to the end of the trial[5]

An alternative way forward

Decentralized Clinical Trials (DCTs), also known as "direct-to-participant trials" or "virtual" studies, are broadly defined as trials that replace much—or all—in-person clinical trial activities with similar protocols conducted through telemedicine, sensory-based technologies, mobile/local healthcare providers, and other digital tools.

Given that decentralization's primary goal is to make clinical trial participation as easy as possible by using technology and approaches to recruit and retain participants, it becomes more clear how decentralized protocols have become not just an alternative model but a path forward for clinical research.

While some DCT protocols existed before the pandemic, they weren't commonly used across trials. However, COVID-19 accelerated decentralization as a way to maintain patient safety

and keep trials running amidst infection control measures.

But even as pandemic restrictions loosen and more clinical sites allow participants to return in person for studies, the preference for hybrid and virtual models in health care and clinical trials remains—and is hard to ignore:

- 76% of consumers in 2020 were interested in using telehealth moving forward, compared to 11% in 2019[6]
- About 4 in 5 adults say it's important that clinical trials be easy for participants to get to and that they be diverse[7]
- 56% of US adults are interested in fully virtual clinical trial visits, such as through an app[8]
- Adults were more likely to say they'd be interested in participating in a clinical trial if site visits were virtual or took place at retail clinics than if they were 30+ minutes away[9]

This trend is not only limited to consumers and participants, either. In a 2020 McKinsey survey of pharma and contract research organizations (CROs), 100% expected virtual trials to be a major component of their portfolios, and 89% expected to run a trial with most activities conducted from participants' homes.[10]

Vault's history of and success at providing clinical care and telehealth services directly to patients, combined with our advanced decentralized clinical research capabilities as a decentralized research organization (DRO), presents an optimistic future for the industry where new therapies can be brought to market faster, through a simple, efficient, and integrated model with the patient at the center.

This white paper explores three major ways DCTs have made a positive impact in trial development and implementation.

1. More diverse representation of patient populations than in conventional trials
2. Increased patient convenience and engagement
3. Enhanced data acquisition and reporting

THE BENEFITS OF DECENTRALIZED CLINICAL TRIALS

Decentralized Clinical Trial Benefit 1: More diverse representation of patient populations than in conventional trials

It's well known in the industry that requiring clinical trial participants to travel to and from physical trial sites is a major barrier in their willingness to be a part of a clinical trial, especially if a trial has a longer duration and requires multiple visits. Typically, 70% of potential participants live more than two hours from a clinical trial site.[11] More importantly, it narrows the field of eligible participants—those unable to commit to in-person visits due to mobility, age, socioeconomic status, or for other reasons are eliminated from participating even if they want to.

Lower enrollment rates in clinical trials are especially true among Black, Indigenous, and People of Color (BIPOC) — individuals who are well-documented to be highly underrepresented in clinical research.[12] Researchers understand the importance of diversifying trials, but BIPOC communities can often be reluctant to participate due to misinformation and a distrust of medical research and the healthcare establishment, while others simply

don't have the time or resources. The FDA has also outlined how inclusion/exclusion criteria can also result in a lack of diversity.[13]

Such factors leave a wide gap between trial outcomes and real-world outcomes, especially when only 5-10% of adults participate across most therapeutic areas. Without more diversity in trials, results are not wholly representative of the population for which a given treatment would be prescribed, limiting the ability to understand how that treatment would affect the general population.

Black patients account for just 5% of clinical trial participants.[15]

Recruitment can therefore often be very expensive, time consuming, and logistically frustrating for many CROs and sponsors. But because decentralized trials can be based anywhere, they play an important role in reaching out to underrepresented groups and facilitating their ability to participate with minimal disruption to their daily lives. By using technology already widely adopted in the business and consumer sectors, decentralized clinical trials broaden trial access by reducing the burden and expenses to patients related to travel, accommodation, childcare, mobility, or missed workdays.

Vault's established clinical practice, partnership networks, and logistics and data management capabilities enable us to quickly align eligible patients with clinical trials they can participate in via online outreach and/or in person at their homes, rather than requiring visits to a physical trial location. These hybrid protocols not only enhance diversity across clinical trial populations, they also improve recruitment and enrollment time.

"We all understand what this means when we're testing the efficacy and safety of therapies. To think that any drug, any indication would be developed without an understanding of its broad impact across as many races and ethnicities is absolutely insane for science, as well as the health of the planet."

- Jason Feldman CEO at Vault Health