VIEW POINT

THE WAY FORWARD FOR CLINICAL TRIALS: DECENTRALIZED AND HYBRID

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Over the years, the rising cost and time taken to bring a new drug to the market have led to a growing interest in alternatives to the traditional, on-site model of clinical trials. The outbreak of the pandemic accelerated the adoption like never imagined before, setting a new standard on how trials are conducted. Sponsors and CROs began exploring ways to increase patient recruitment, engagement, and retention while improving efficacy, and ensuring continuity of trials.

Today, the clinical trials market size is an estimated USD 45 billion1 and it is expected to grow, making it ripe for advanced digital solutions. Going by the latest numbers, approximately 1,000 virtual trials are registered at Clinicaltrials.gov, out of the 320K*. Many of these are sponsored by academia or medical councils, pointing to the fact that it is a long way to go before widespread industry adoption.

While virtual trials mean going completely site-less, a decentralized hybrid approach can boost patient participation from the comfort of homes. In fact, it is the hybrid approach that is believed to overtake traditional models. A hybrid clinical trial model offers the best of both worlds. It means trials executed through digital technologies.

Before we delve deeper into understanding what's the best fit for pharma companies, let's look at what has been driving this change.

Challenges in Traditional Models

The drug development lifecycle has been remarkably complex. It takes 10 to 15 years or even more and billions to develop one successful drug. Despite these significant investments in time and money, 90% of drug candidates in clinical trials have been known to fail.2

Hurdles in Patient participation

Patient Recruitment and Retention: Patient recruitment and retention are critical to the success of a clinical trial. In a typical on-site model, participants need to make at least 10-15 visits to the site in a trial that lasts around 120 days. As per the study, 70% of the patients live more than 2 to 3 hours away from the nearest clinical sites spending hours travelling, resulting in 50% of patients dropping out before the completion of the study.3

Awareness & Trust: General public is usually unaware of clinical trials and participation opportunities. Less than 5% of the population participates in clinical trials due to a lack of awareness and trust deficit.

Rising Costs: According to the Tufts report, the cost of bringing a new drug to market has gone up over the years to around 2.9 billion USD.4 Legacy systems and outdated approaches drive the clinical trial costs northwards, for instance, phase 3 of a trial costs as much as 50 million USD. Moreover, clinical protocols have been increasingly complex, with costs per study volunteer visit growing by 34%.5

Decentralized Clinical Trial (DCT): Benefits & Barriers

Decentralized is more about taking the trial to the patient and making participation easy. It breaks the geographical barriers, ensuring access to truly interested participants, belonging to diverse groups and socio-economic backgrounds. It allows sponsors and investigators to analyze the continuous flow of information in real-time. Ultimately, providing a holistic view of data from all sources that helps derive actionable insights and make informed decisions. It is also believed to be further suited for phase 4 and post-marketing activities.

With more people willing to share personal data, the sensors and remote data capture devices in clinical trials make remote participation easier and less burdensome. Industry experts predict that about 50% of clinical trials will include wearables and sensors by 2025.5

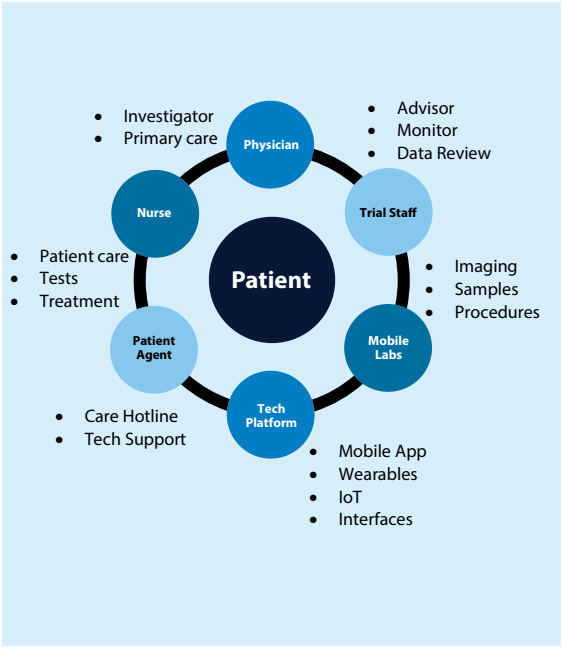
Despite these benefits, the adoption of decentralized trials has been rather slow. CROs focusing on DCT do not have an E2E model that covers the entire lifecycle. Startups too are focusing on a specific aspect of the value chain and do not seem to have a full solution in place.

The shift to the DCT model cannot happen overnight and require sponsors to approach this holistically and ensure organizational barriers are broken through a centralized CoE based approach. Some other challenges include lack of expertise, data security, complex drug regimen, pediatric studies, and complex regulatory practices followed across the world. Moreover, it requires the availability of validated demonstrated equivalence of in-home alternatives for required diagnostics, treatment procedures, and assessments.

The Way Forward – Some of the Key Considerations for Successful DCT

We've put together some of the considerations for the sponsors and CROs:

Reaping the benefits of a decentralized approach will require an integrative platform that connects all aspects of the trial. A cross-functional team with the right digital tools and technologies in its arsenal. Setting up a digital trial Center of Excellence (CoE) can serve as an epicenter that cuts across all therapeutics, departments and participants, helping analyze markets, finding products that are the best fit, and understanding data regulatory rules across the globe.



Current Virtual Trials Market Solutions Tend to Focus Only on a Part of the Value Chain

Patient Engagement	Patient Treatment	Data Acquisition
Recruitment	TeleHealth	Digital Health
eConsent	Drug Supply	ePRO / eCOA
	Aherence	EDC
		DDC

Other capabilities that may be required

Medical writers for writing CSR
Biostatisticians for statistical analysis
Medical scientific team for protocols, eICF
Recruitment/Monitoring
Data analysis
Study report writing
Multiple language

For making the shift from the traditional approach, an organizational approach must start top-down and bottom-up by breaking the problem into byte sizes. The focus should be on recruitment, eConsent and gradually building an ePRO, monitoring, and data capture using wearables and other IoT technologies and building additional capabilities as it progresses.

The approach taken for a clinical trial will also depend upon the characteristics of the drug being developed like topical, oral, subcutaneous, and intravenous. If it requires the participants to undergo imaging scans like X-ray, MRI, CT-scan, or biopsies and other assessments, then that will require clinical settings. Among the key considerations is also the phase of the clinical trial, for instance, DCT is best suited for phase 4 and post-marketing.

With gradual acceptance, DCT is slowly entering the mainstream, but it is essential for sponsors to understand how and where to benefit from the alternate models. Essentially, what aspects are amenable for virtual enablement, and which ones will still need some human intervention to ensure the best outcomes. In the future, clinical trials will be hybrid technology solutions that will cut down the round trips made to sites drastically, thereby enhancing the patient experience. To put it simply, the future of clinical trials is hybrid.

About the Author

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Rajan Dalawai is a Senior Client Partner with Infosys, responsible for managing a portfolio of Lifesciences Businesses for Infosys in the DACH region. He has well over 24+ years of IT Industry experience and in the last 12+ years has been advising and partnering with Pharmaceutical clients in solving their Business problems through transformative Technology solutions. He has a deep understanding of the challenges that the Pharmaceutical Industry is going through and has delivered several cutting edge Data & Digital solutions for the Industry.

Sources

1 Clinical Trials Market Size, Share & Trends Analysis

2 Parsing clinical success rates

3 Decentralized Clinical Trials

4 Reshaping Clinical Trials in 2022

5 Wearables & Big Data In Clinical Trials — Where Do We Stand?

*Total registered since 2000 & 25-30K studies are registered per year

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