

A Closer Look at Implementation Timelines for Decentralized Clinical Trials (DCTs)

Decentralized clinical trial (DCT) models provide operational efficiencies and promote patient-centric considerations previously impossible in traditional, site-based clinical trials.

Before the advent of the COVID-19 pandemic, DCTs remained in a growth phase, with wide adoption of some elements, like electronic clinical outcome assessments (eCOAs), and increasing utilization in trials investigating rare diseases with geographically dispersed populations, but less comprehensive application by sponsors across the full spectrum of clinical studies. The challenges to conducting traditional, site-based trials in the context of the pandemic, however, significantly accelerated adoption of DCT models. While DCTs enabled res-

cue of trials that otherwise would be challenging during the pandemic, further adoption can be applied through the goal of developing DCT protocols from inception.

Challenges to Implementation Time

In 2020, PPD commissioned an industry survey exploring trends in the clinical trials market, including the threat COVID-19 presented to trials, patients, and data. Among the answers provided by respondents, one figure stood out: when asked about the typical implementation time for a DCT during COVID-19 (from protocol redesign to

first TeleVisit), the average answer was 7.5 months.

Surprisingly, this average answer is longer than a standard timeline, and many of those delays were likely the result of a lack of standardization across countries with their approach to DCTs, regulatory delays, and protocol amendments to retrospectively implement DCT solutions in trials originally designed with traditional protocols. Additional explanations for challenges in rapid implementation can be found in respondents' wish list for how to improve DCTs, which included creating more user-friendly interfaces for investigator sites, patients, and families; more robust education and training; better regulatory support; and more effective preparation of sites for DCT implementation, and is underlined by the most critical factor cited for evaluating CROs for DCT support: delivery timelines.

With the urgency of clinical research and ever-tightening expectations for

efficiency throughout the clinical cycle, a 7.5-month timeline to implement a DCT trial design is a major barrier. This underscores the need to partner with a CRO that possesses not only all of the capabilities and resources to offer end-to-end DCT support, but also the nimbleness and focus to do so with unprecedented speed.

The Benefits of a True Focus on DCTs

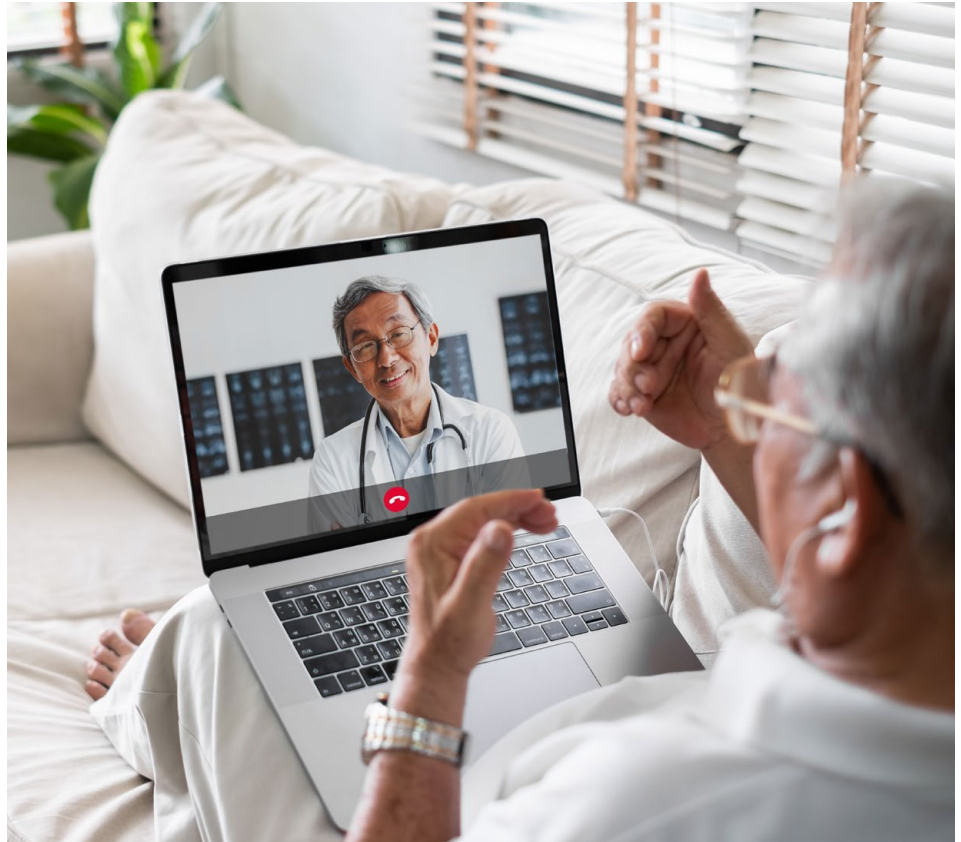
PPD made DCT operationalization a primary focus well before the pandemic, and as such is well positioned to develop DCT solutions — whether from inception via providing DCT consultancy and strategy for the application of the trial or to rescue a conventional, site-based trial — in a fraction of this time.

Building DCT strategies into the protocol from the start will further increase efficiencies when deploying a decentralized trial design; as such, with more sponsors seeking DCT strategies in the first version of the protocol, we anticipate even greater benefits will be possible. As these models are increasingly utilized, ethics committees and regulatory authorities will be able to perform more rapid reviews to expedite the review and approval periods.

At PPD, DCT strategies have been incorporated into our core strategy and processes, rather than merely existing as a bolt-on capability. Our deep DCT strategy experience and our knowledge of technical innovation allows us to select the solutions best suited for a given protocol rather than merely applying a one-size-fits-all strategy.

The best way that sponsors can accelerate implementation is to find a partner like PPD who is fully invested and focused on DCTs and can support all of the strategy, operational, technology, regulatory, and design support needed to streamline and simplify launching DCT trials.

Want to see more industry feedback regarding decentralized trials? [Read the full report.](#)



At PPD, the average time from protocol finalization to the first TeleVisit is a mere 2.5 months, and, with accelerated regulatory guidance, we have even been able to deploy a DCT solution in as little as five days.



PPD is a leading global contract research organization providing comprehensive, integrated drug development, laboratory and lifecycle management services. Our customers include pharmaceutical, biotechnology, medical device, academic and government organizations. With offices in 46 countries and approximately 24,000 professionals worldwide, PPD applies innovative technologies, therapeutic expertise and a firm commitment to quality to help customers bend the cost and time curve of drug development and optimize value in delivering life-changing therapies to improve health.

PPD continues to pioneer digital capabilities and deploy solutions to streamline protocols, putting patient experience at the center of every design. Our team continues to offer our customers more trial delivery options through innovative technology and collaborations, selecting the right digital approach that can drive recruitment, engagement, retention, and data quality to further decentralized clinical trials.

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