WHITEPAPER

Operationalizing decentralized clinical trials

How to improve recruitment, retention, and diversity

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OPERATIONALIZING DECENTRALIZED CLINICAL TRIALS

How to improve recruitment, retention, and diversity

The era of decentralized clinical trials (DCTs) has begun. Validated in the crucible of the pandemic, DCTs have proven their ability to improve patient recruitment, retention, and diversity. The challenge now is to go from ad hoc approaches that kept trials going in a time of crisis to a rigorous, reproducible method. In rising to that challenge, sponsors will need to access diverse yet connected capabilities that span patient engagement, mobile phlebotomy, health data, and core lab testing.

Interest in DCTs, also known as virtual, remote, and hybrid clinical trials, dates back years but the approach had yet to become a routine part of drug development until the pandemic.[1] The need for sponsors to keep studies going amid COVID-19-related restrictions on travel and face-to-face interactions accelerated the switch to DCTs and, in doing so, created a range of benefits associated with the approach.[2]

"We aim to move the trial to the patient rather than the patient to the trial, and to start trial planning early on to reduce the burden of clinical trials and allow some of the standard of care work to happen close to patients as opposed to the clinical trial sites," said David Freeman, general manager, Healthcare Analytics Solutions at Quest.

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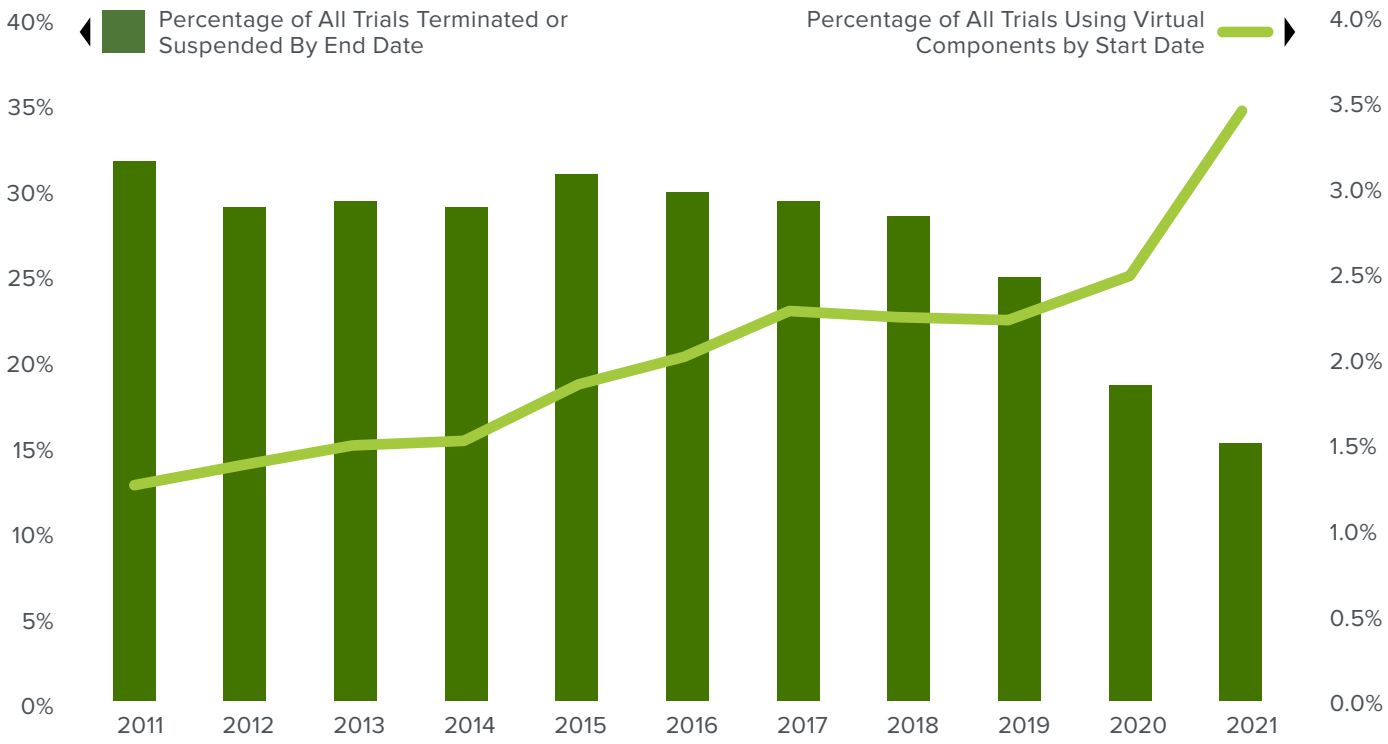
HOW DCTS IMPROVE DRUG DEVELOPMENT

Widespread adoption of DCTs can improve patient recruitment and retention and enhance the diversity of clinical trial populations. In the traditional, site-based model, clinical trials have geographic catchment areas, with 67% of oncologists saying they are unlikely to refer patients who live two hours or more from a study center.[3] The need for patients to travel frequently to trial sites prevents some people from joining studies, slows enrollment, and leads others to drop out because of participation burdens.

According to CTTI Recruitment Project Team, up to 86% of clinical trials do not reach recruitment targets within their specified time period and up to a third of participants drop out of trials (**Figure 1**).[4,5] DCTs address the problem by loosening and, in some cases, cutting the link between geography and study participation.

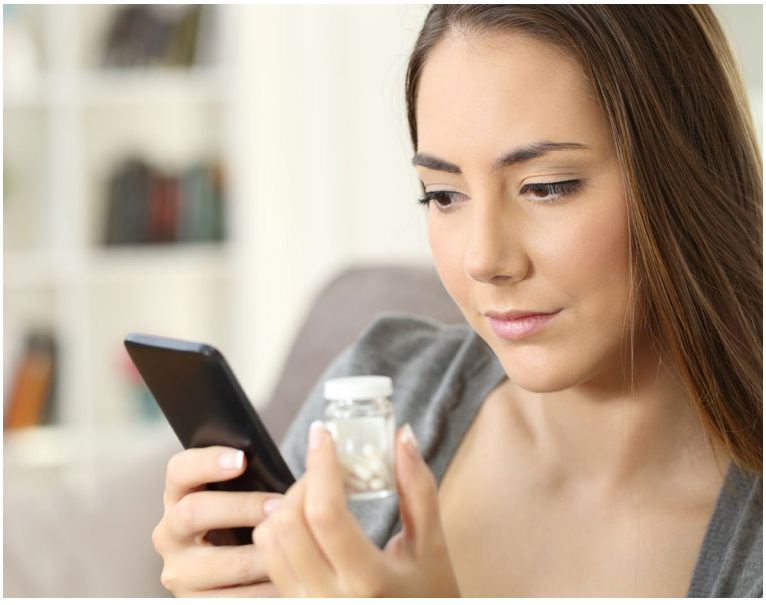
Figure 1: Proportion of trials impacted by low accrual rates 2011-2021



Source: GlobalData, Clinical Trials Intelligence Database, 2021

A 2020 study from Tufts Center for the Study of Drug Development showed patient recruitment rates increased from 47% to 77% between 2012 and 2019; this was largely due to the implementation of virtual trials, greater involvement of patients in the design of clinical trials, and the use of mobile technologies.[6] More recently, a report published by GlobalData showed that the proportion of trials that were stopped or suspended due to low accrual rates decreased from 32% in 2011 to 19% in 2020.[5]

At the same time, the DCT approach enables sponsors to cast the recruitment net wider and thereby enroll studies that are more diverse in terms of gender, ethnicity, race, and more. That is a key benefit for developers of precision medicines. “When taking a precision medicine approach, diversity is more than a moral imperative—it is a biological necessity,” said William Finger, General Manager of Quest Diagnostics’ Pharma Solutions. “Developers of rare disease drugs need access to patients with specific molecular or genetic differences. DCTs make it easier to get those patients into studies.”



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WHAT IT TAKES TO RUN SUCCESSFUL DCTS

Successful execution of DCTs requires close coordination of teams with distinct capabilities. Here, we look at the 4 elements that augment core central lab testing and are critical to successful patient recruitment and retention in DCTs.

Health data

The identification of a sufficient number of patients who meet the inclusion-exclusion criteria is a critical early step in the success of any clinical trial, be it physical, virtual, or hybrid. This step is more challenging for the developers of precision medicines because they need to zero in on smaller subpopulations of patients who have the specific markers targeted by the therapy trial.

Having tested more than half of the US population, Quest has the health data to solve this "needle in a haystack" problem. Each year the company touches the lives of one-third of American adults and serves nearly half of the physicians and hospitals in the US, giving it unprecedented insights into where sponsors can find patients who meet their enrollment criteria.[7]

"With the patient's HIPAA authorization, we can share information about clinical trial opportunities that the patient may be a match. By understanding and using lab-based Inclusion and Exclusion criteria, we hope to bring relevant trials to patients and relevant patients to trials", said Freeman

Mobile phlebotomy

The adoption of DCTs in response to the pandemic showed that this model benefits patients and sponsors alike. Yet, while some data can be captured remotely, most clinical trials still need to schedule in-person interactions with participants, notably to administer the investigational medicine and to collect the specimens that are critical to determining the safety and efficacy of drug candidates.

"Sponsors can retain the benefits of DCTs while performing required in-person interactions by bringing trials to patients, rather than making patients travel to trials," said Gene Stegeman, National Sales Director, Health and Life Sciences, ExamOne, a Quest company offering mobile phlebotomy services. "The ideal scenario is that the study comes to each patient's home to eliminate travel burdens." Quest Diagnostics is helping sponsors connect with patients through its mobile phlebotomy and clinical services groups, which can provide mobile specimen collection and mobile injection services in the home.

Quest Diagnostics has access to over 5,000 mobile phlebotomists, as well as mobile NPs, PAs, and MDs who routinely engage with patients and undertake sample collections and personalized assessments at home. The mobile team adapts and customizes its at-home services to meet the requirements of each trial—collecting blood, saliva, and urine samples while also taking physical measurements, monitoring vital signs, performing ECGs and functional tests, reporting adverse events, and administering therapy.

Patient Service Centers

While in-home services are convenient for most patients, some participants are uncomfortable with study staff coming into their homes. This means sponsors need to offer another option to deliver patient-centric clinical trials that maximize the benefits of the DCT model.

Sponsors that partner with Quest to run DCTs gain access to its more than 2,250 patient service centers and a test menu that spans over 5,000 assays, including routine biological tests, complex and specialized molecular and genetic tests, and anatomic pathology. Studies can be designed to allow participants to choose between scheduling an in-home appointment or visiting service centers in their communities to provide specimens and receive treatment. Wherever a specimen is taken, Quest properly prepares and routes it to the appropriate central lab.

"Quest provides a sample integrity process ensuring there is traceability of the sample; delivery to the lab and processing within the lab is controlled and standardized, all of which is incredibly valuable to pharma," said Greg Baschkopf, Quest's senior director Clinical Trials and IVD Services.

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In addition to breaking down logistical barriers and improving the patient and sample journey, local and at-home testing can help to build deeper relationships to better understand patient needs throughout the clinical trials process.[8] This enhanced understanding opens the door to a more personalized medicine approach. Relationships established during a trial can extend beyond the study itself to provide longitudinal patient data and insights, all of which can be translated back into planning to align research with the needs of the patient and the program.

Patient engagement

The need to frequently visit study sites during working hours makes it impossible for some people to participate or stay in clinical trials. By lowering the barriers to clinical trial participation, DCTs enable a larger pool of subjects to participate regardless of gender, socioeconomic status, and ethnicity.

"It's not enough to have access to patients. We need to keep them engaged to keep them on study," said Director, Medical Affairs, Kelly Brassil, PhD. "We focus on the holistic experience of the patient and how best to support them, beyond the lab or clinical trial parameters."

Recognizing the importance of adherence, Quest acquired the patient engagement capabilities of a software development company called Pack Health. Combining the company's patient platform with Quest's health data and testing capabilities empowers the lab to support DCTs with e-signatures, text messaging, Adobe forms, and other technologies that are familiar to patients, thereby minimizing the user learning curve.

The patient engagement platform can facilitate electronic consenting and recruiting of participants and the administration of patient-reported outcomes.[9] In addition, a team of health advisors engage with patients in a meaningful way to provide support and education around the trial design and ensure they remain protocol adherent. Patient insights are fed back to ensure the patient voice remains at the center of clinical drug development.[10]

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CONCLUSION

"The pandemic catalyzed how we conduct clinical trials," Brassil said. "We already used a digital platform for e-consenting and e-recruiting of individuals and the administration of patient reported outcomes and other data but it catalyzed us to explore other types of data and specimen collection at home or at patient service centers. We can go out into the community and engage meaningfully with participants during specimen collection and patient support, and expand diversity, equity, and enrollment in trials."

All the pieces are now in place for a new, more efficient era of drug development that will advance the promise of life-changing medicines. The pandemic has proven decentralization can improve patient recruitment, retention, and diversity, with existing technologies and capabilities needed to operationalize the model.

Leading biopharma companies are now recognizing that the best results are achieved by working with partners that hold multiple pieces of the DCT puzzle—specifically, the data to identify and the tools to retain trial participants, and the capacity to bring trials to participants. Quest is a rare example of a company with the full suite of integrated capabilities.

"We can provide bespoke services that can be adapted to the clients' needs," said Baschkopf "We can help to identify patients; engage, and support them through the trial journey and beyond; and have the analytical, logistical, medical, and technical expertise in diagnostics and companion diagnostics. We can function as an enabler for pharma, improving their chances of success both pre- and post-approval,"

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Quest Diagnostics empowers people to take action to improve health outcomes. Derived from the world's largest database of clinical lab results, our diagnostic insights reveal new avenues to identify and treat disease, inspire healthy behaviors, and improve health care management. Quest annually serves one in three adult Americans and half the physicians and hospitals in the United States, and our nearly 50,000 employees understand that, in the right hands and with the right context, our diagnostic insights can inspire actions that transform lives. www.QuestDiagnostics.com.

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