White Paper

DCTs Deliver Big ROI

New study proves that choosing decentralized clinical trials enables reduced time and cost, delivering measurable benefits for sponsors.

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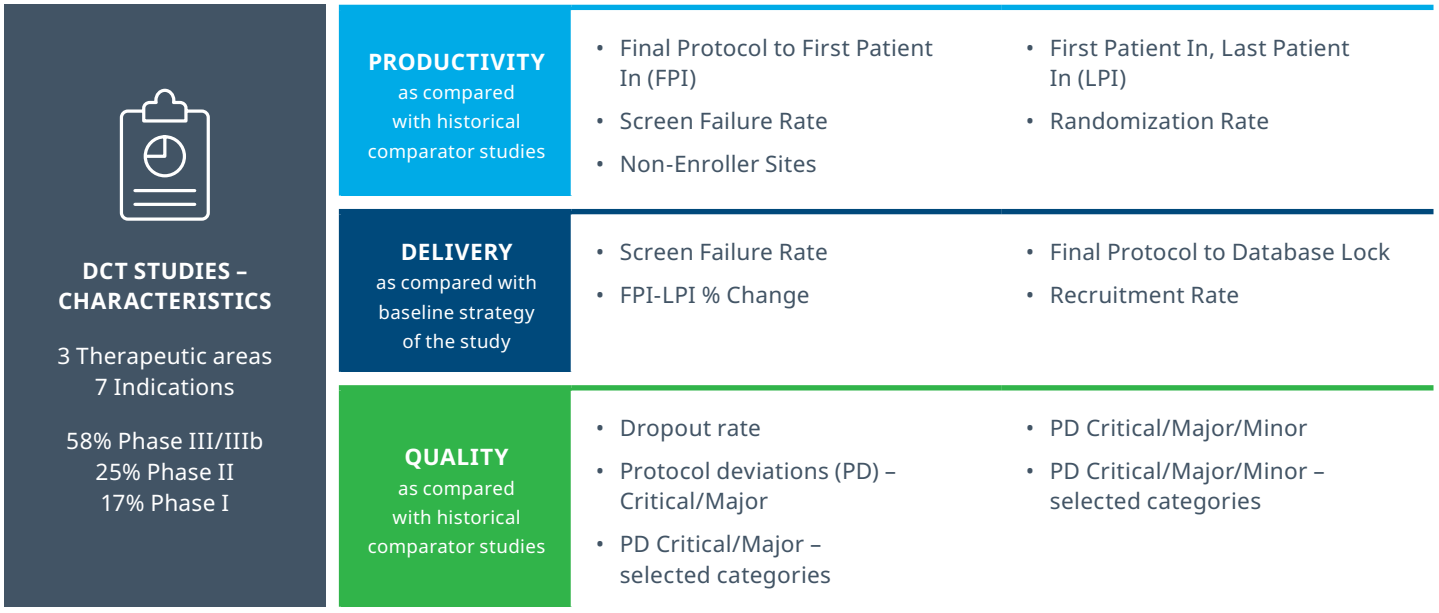
Table of contents

Executive summary

Decentralized clinical trials promise to be faster, less expensive, and more engaging than conventional trials – and we now have the data and initial trends to prove it.

IQVIA analysts recently completed an in-depth analysis of a dozen decentralized clinical trials,* using 14 value measures, to determine how this approach to research compares to traditional study models. The data shows that the DCTs delivered time and cost efficiencies at virtually every point in the clinical research journey.

DCT Proof Points: 14 Proof Points/study, 12 studies



* IQVIA currently manages 300+ clinical studies using DCT methodology; however, only those DCT studies which completed 100% recruitment were selected for this analysis. While DCT methodology did help in showing better improvement versus the historical comparator, there are other factors which influenced improvement (especially start-up timelines and recruitment), e.g., different regulatory environment that was instituted by regulatory agencies and IRBs during the pandemic that helped with expedited review and decision-making processes. Therefore, the initial analysis is an indication of positive trends and impacts that a DCT model could bring and cannot be attributed solely to DCT performance. As the number of studies adopting DCT methodology continues to grow, IQVIA has now established the methodology to compare performance of ongoing DCT studies with the historical comparator and will be reviewing this on an ongoing basis to refine the metrics.

KEY FINDINGS

The analysis shows multiple benefits including an average **49% reduction in time to first patient in, and a 54% reduction in protocol deviations**.

The trials also experienced:

- 78% reduction in recruiting time, measured by time from first patient in (FPI) to last patient in (LPI)
- 39% reduction in screen failure rates
- 15% reduction in dropout rates

When sponsors make decentralized models part of their clinical research strategy from the outset – rather than adopted midstream – the measurable returns are significant. This patient-centric approach to research streamlines and speeds recruiting, improves adherence, bolsters retention, opens participation to more diverse populations, and enables sites to deliver a better patient experience.

Measuring the impact of DCTs

The use of DCT platforms, telehealth applications, wearable devices, online patient portals, and other DCT technology soared during the pandemic as sponsors scrambled to keep trials moving forward after sites were shut down.

Initially, many sponsors were skeptical about whether this virtual approach to clinical research could engage patients and deliver consistent, quality data. But they soon discovered that these tools, along with mobile nursing units and home health options, freed patients to engage in trials with minimal site visits, creating a more engaging and inclusive trial experience.

When sponsors saw the potential of decentralized approaches to reduce patient burden, accelerate recruitment, and provide access to more diverse patient populations, it spurred their interest in making DCTs a more permanent part of the trial landscape.

Although some of the DCT elements have been in use in clinical trials (e.g. eCOA, eConsent) for years, a consolidated adoption of decentralized models into a single trial is a relatively new trend. Furthermore, there has been little historical data to verify savings and vet where and when such DCT models drive the most value.

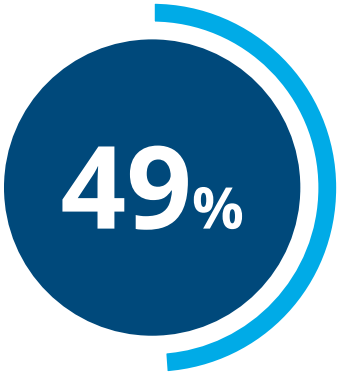
IQVIA has proven DCT benefits that are both tangible and measurable. The data from IQVIA's DCT analysis can help sponsors calculate the overall benefit of building trials around a decentralized model, and ensure they maximize the benefits of this approach for patients, sponsors, and their own bottom lines.

However, measuring the impact of DCTs is a complicated process. Hybrid trials, which combine site visits with technology-enabled data collection and home-based services, represent most decentralized clinical trials today. Each of these trials is required to be custom designed to meet the needs of the patients, sites, and sponsors, using a unique combination of technologies and strategies. Understanding the impact of these choices requires reviewing protocol design and analyzing available data to determine how each selection translates to time saved, better patient experiences, and demonstrable financial returns.

The analysis compared a dozen decentralized clinical trials for neurology, infectious disease, and dermatology treatments, to traditional studies in similar therapeutic areas, phases, and geographies. The results show the DCTs delivered time and cost savings, while reducing risks, improving quality, and enhancing the patient experience.

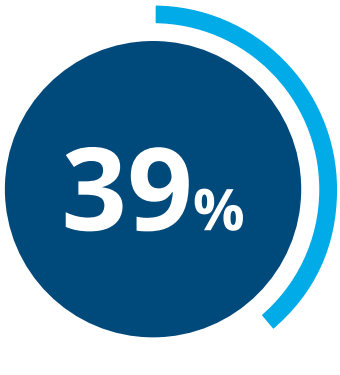
IQVIA's Decentralized Clinical Trial Performance

Demonstrating the value of Decentralized Trials through data-driven proof points



Reduction in **Final Protocol to First Patient In (FPI)** timelines

Reduction in **First Patient In (FPI) to Last Patient In (LPI)** timelines



Reduction in **Screen Failure Rate**

DCTs EXPERIENCE FASTER RECRUITMENT

Some of the most significant time savings uncovered in the analysis were related to patient recruitment by using of direct-to-patient services and providing flexibility to study patients with use of remote study visits.

Patient recruitment is one of the costliest and most complex elements of clinical research, with delays often adding months to a trial timeline. In some cases, trials are canceled due to a lack of study patients, a significant risk in rare disease trials.

Using decentralized approaches minimizes these risks by opening participation to a broader patient population, regardless of their location, by reducing or eliminating travel burdens, which can cause study patients and their caregivers to decline these opportunities. These benefits translate into significant time and cost savings.

The analysis found DCTs reduced the time to first patient in (FPI) by an average of 49%; and the time from FPI to last patient in (LPI) dropped a full 78%. The study also found that screen failure rates dropped by 39%, adding additional time savings.

The studied decentralized clinical trials also saw a 26% reduction of non-enrolling trial sites. This is considerable given the time and money that is often spent on these sites in traditional studies.

DEVIATIONS DROP

Protocol deviations dropped an average of 54% and reductions were seen across severities and categories, including those related to study procedures, consent forms, lab assessments, study visit schedules, and investigational product compliance. The reduction in protocol deviations in these categories indicates the DCT technology and site support also drove improvements in patient compliance and engagement.

This improvement is especially noteworthy given the steady rise in deviations in traditional trials. One 2022 report from Tufts found the mean number of protocol deviations has increased across all trial phases in recent years, with a typical Phase III study experiencing 119 deviations involving roughly one-third of patients. These events can add safety risks and lead to costly protocol amendments and weeks-long trial delays. Cutting their rate by more than half should translate to significant savings and an overall improvement in patient safety.

RETENTION RISES

The analysis shows decentralized clinical trials experience lower dropout rates (15%), likely due to the decreased time and travel burden experienced by study patients. This is also attributed to other factors as most trials leveraged decentralized technology to remind patients to complete online diary entries, attend telehealth visits, and complete treatment steps, thus promoting better study patient engagement and making adherence to study requirements easier.

Data from CenterWatch shows that dropout rates averaged nearly 20% in late stage trials, adding significant delays and added recruiting costs to trial budgets. Adopting a DCT model can cut those added costs considerably.

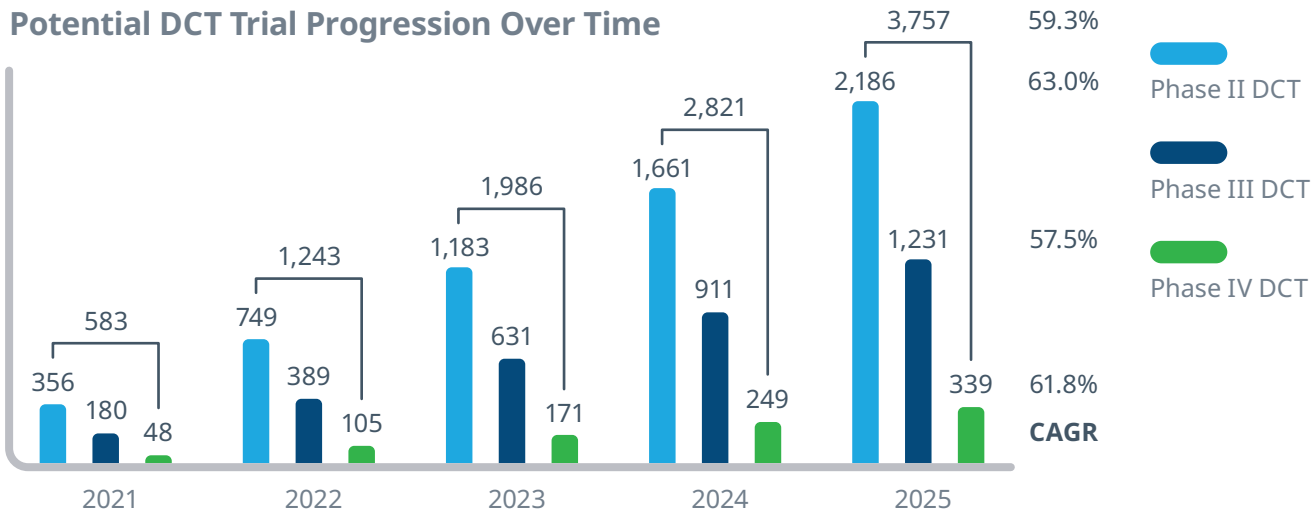
Results vary across studies

The analysis concluded that every DCT experienced some time and cost benefits by adopting DCT technologies and practices. Although each study saw different results based on the type of trial, size, location, and which decentralized elements were included, they all experienced benefits that delivered time and cost savings.

Understanding these variations will be critical to setting realistic expectations for future DCTs.

Industry Trends: Decentralized (& Hybrid) Clinical Trials

The DCT market is ready to explode to an estimated value of $1.63 billion by 2027, according to Precision Reports, with a CAGR of 14.8% during the 2021-2027 time period. Digital transformation allows for a better flow of information across participants, sites, sponsors and CROs to create a fully connected and collaborative trial environment.

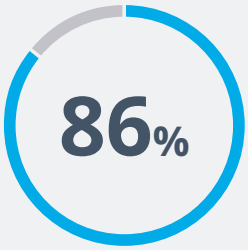


Source: Pulse Report: Decentralized Clinical Trials article from PharmaVoice, 10/1/2021, clinicaltrials.gov and Jefferies

Case studies: Decentralized models in action

Infectious disease study fast-tracks recruiting

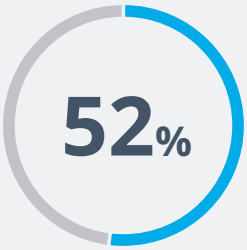
One Phase III DCT study for infectious disease, which recruited more than 23,000 patients, demonstrated major savings across all key recruiting measures. Given the massive scale of this study, the financial and time impact of these improvements was significant. Analysis vs. the historical comparator study shows:



Reduction in **Final Protocol to FPI**

Reduction in **FPI to LPI** timelines

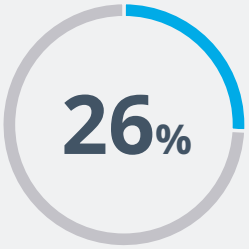
Reduction in **Non-Enrolling Sites**



Reduction in **Protocol Deviations**

Neurology study sees meaningful savings

Not all studies delivered such dramatic results because of the study scale. In another Phase III DCT that recruited 500 patients for a neurology study, the trial experienced:

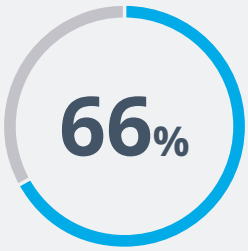


Reduction in **Protocol Deviations**

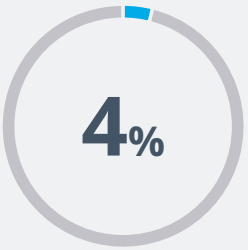
Reduction in **Patient Dropout Rate**

Screen failure rates slashed in dermatology study

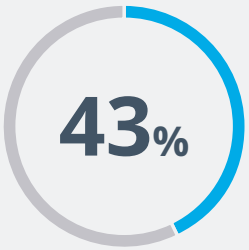
In a Phase II DCT for dermatology, analysts found screen failure rate dropped 66%, while patient dropout rate and protocol deviations fell by 4% and 43%, respectively.



Reduction in **Screen Failure Rate**



Reduction in **Patient Dropout Rate**



Reduction in **Protocol Deviations**

Planning ahead adds value

The adoption of decentralized approaches, technologies, and services has expanded considerably in the last few years. More than 34% of IQVIA's full-service projects now leverage one or more DCT elements, including IQVIA's Decentralized Clinical Trial (DCT) Platform and support services, research nursing & phlebotomy solutions (RNPS), direct-to-patient recruitment, risk-based monitoring, electronic clinical outcomes assessments (eCOA), e-diaries that allow patients to record data remotely, and other options.

We expect this rate of adoption to continue to grow, largely through hybrid trials that combine site visits with technology-enabled data collection and home-based services.

IQVIA is currently managing 300+ DCTs across 30+ indications in more than 50 countries, serving over 300,000 subjects which have generated over 14 million e-diary responses on IQVIA's DCT Platform. IQVIA also manages logistics for 850,000 lab kits and 19,000+ commissioned mobile devices and has a healthcare professional network of 2500+ nurses globally that provide study support to patients within their communities.

As sponsors make decentralized clinical trials part of their core trial planning process, they will need data and measurements tools to understand how different design choices can deliver variations in time and cost savings. As noted above, while overall savings are consistent, different trials experienced varying benefits.

These variations are driven by many factors, though the study found that one decision led to consistently better results: When sponsors planned for decentralized approaches from the beginning of the trial, they experienced bigger savings than those who retrofitted existing trials with DCT elements after the protocol was finalized. As more studies adopt a DCT model and if benefits associated with reduction in dropout rate and protocol deviations are seen in more ongoing studies, that could potentially help in having more valuable study patients at the end for statistical analysis. This could then help shape underlying assumptions, e.g., reduction in the required number of study patient populations for screening and randomization would still get the required number of participants due to better study patient engagement.

When sponsors planned for decentralized clinical trials from the outset, they were able to align study goals with DCT strategies and technologies, choosing elements that ensure the most value for patients, recruiters, and investigators in that trial. For example, in trials where speed to FPI was critical to trial success, IQVIA's direct-to-patient recruitment services accelerated recruiting and reduced leakage in the study patient pipeline.

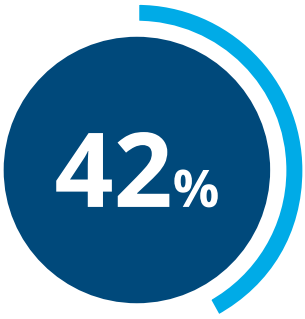
When sponsors planned for decentralized approaches from the beginning of the trial, they experienced bigger savings than those who retrofitted existing trials with DCT elements after the protocol was finalized.

The studies that included frequent data collection steps, using wearable devices, eCOAs, mobile nurses and telehealth options allowed trial designers to reduce the number of site visits. This made patient participation easier and increased the speed, quality, and consistency of data collection, while reducing the risk of attrition.

Retrospective application of a DCT strategy showed a 14% increase in screen failure rates over the historical comparator. But these trials did see reductions in first-to-last patient in (42%), non-enrolling sites (15%), and protocol deviations (41%).

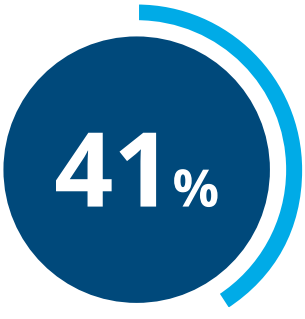
The later benefits suggest that even if a traditional trial is already planned, adding DCT technologies or support services later can positively impact results.

Retrospective application of DCT strategies showed some but not all benefits in improving delivery & quality
Compared to similar traditional study models:



Reduction in **First Patient In (FPI) to Last Patient In (LPI)** timelines

Reduction in **Non-Enrolling Sites**



Reduction in **Protocol Deviations**

How to plan your next DCT

All the measures in this analysis confirm the promise that embracing DCTs can drive measurable time and cost savings. But successfully executing DCTs is about more than selecting a technology platform. Every study will require a different combination of technologies, support services, and training to optimize results.

Most studies are not yet a perfect fit for a 100% remote model, but IQVIA has developed a process to identify when designs are a suitable choice, and what technologies and services will best serve the needs of patients, sites, and sponsors.

This process is based on a thorough review of the targeted patient population, the trials' inclusion/exclusion criteria, duration, patient expectations, protocols, endpoints, and other study requirements.

We also encourage sponsors to include key stakeholders in this process. Gathering feedback from regulators, technology experts, investigators, and patients, ensures the study is designed to enhance the patient experience while delivering financial benefits for sponsors.

Once sponsors go through this process, many are surprised to discover how much of a trial can be conducted remotely using recruiting platforms, telehealth, electronic documents, and mobile caregivers.

The future is decentralized

All the measures in this analysis confirm the belief that embracing decentralized clinical trials can drive measurable time and cost savings. Although each study saw different results based on the type of trial, size, location, and DCT elements included.

Choosing the right combination of DCT technologies and in-home support can help sponsors reduce study patient burden and streamline operational execution to capture cost and time savings in every trial.

To learn more about IQVIA's DCT platform and services, please visit iqvia.com/solutions/research-and-development/decentralized-trials.

About the author

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Bhausaheb Patil has over 25 years of experience in the clinical research industry, having held various local and global roles to promote patient safety, data integrity and regulatory compliance to bring new medicines to patients faster and more safely.

Bhausaheb has worked in a variety of functions such as clinical monitoring, clinical operations, project and resource management, and risk-based monitoring approaches. He is a seasoned manager at mid-to-senior levels within the clinical research industry.

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