

# Decentralized Clinical Trials (DCT) Adoption Playbook

December 2021: Complimentary Abstract / Table of Contents



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## Background and scope of the research

Decentralized Clinical Trials (DCTs), in which clinical trial data is collected through sensors or remote monitoring devices that are carried by a patient without the need to visit a site, can deliver many benefits to pharmaceutical companies including cost savings, better patient recruitment and retention, and improved data quality. COVID-19 had put the spotlight on DCTs that will last well beyond the pandemic-stricken years as the industry increasingly adopts digital solutions for conducting remote, virtualized, or decentralized trials. As enterprises grappled with regulatory uncertainties, there is need for upfront capital investment in sensors and products, and limited functionalities to decentralize clinical trials. In recent times, DCTs have proved to be a saving grace to restart paused clinical trials. Additionally, recent technological advances, the proliferation of wearables, and regulatory push to the industry to adopt DCTs following the COVID-19 situation have made the DCT landscape ripe for disruption.

Enterprises have accelerated their plans toward DCT adoption, looking to convert their piecemeal deployments into a comprehensive strategy aimed at enhancing the trial experience for patients, sponsors, and Contract Research Organizations (CROs). This report analyses DCT adoption across therapy areas and intends to guide enterprises towards a successful DCT adoption.

This report looks at:

- Current trends in DCT adoption
- Everest Group's framework for DCT adoption
- DCT use-case compendium

### Scope of this report:



**Geography**  
Global



**Industry**  
Life sciences (biopharmaceuticals, medical devices, and Contract Research Organizations)



**Vendor offering**  
Decentralized clinical trial products



**Use cases**  
Enterprise-stated and publicly available information (57 distinct use cases) has been analyzed for the purpose of this report

## Preface

Decentralization has enabled the shift toward remote patient trials, making trials more convenient and accessible for patients. Though DCTs have put patient experience at the forefront, yet enterprises need to overcome several challenges for a successful adoption.

The aim of this playbook is to make enterprises aware of the current trends, benefits, and challenges in DCT adoption across therapy areas and help them design a strategy for seamless adoption of decentralization in clinical trials.

The momentum toward decentralization will continue post the pandemic and a DCT adoption framework will enable enterprises to adopt and scale DCT solutions.



## Overview and summary of key messages

This playbook looks at 50+ DCT case studies across different therapy areas and informs enterprises about the trends, benefits, and challenges in DCT adoption to help them design a strategy for seamless DCT adoption.

Some of the findings in this report, among others, are:

### Benefits of DCT adoption

- DCTs have put patient experience at the forefront and enterprise buyers are looking for product solutions aimed at increasing patient satisfaction and driving patient enrollments
- Additional benefits include reduction in trial costs and timelines while increasing patient diversity, enabling real-time data collection and complex analysis

### DCT adoption trends

- Different therapy areas have different scope and implementation approaches toward decentralization, giving room for hybrid and completely decentralized trials. Highest DCT adoption is seen in the area of infectious diseases, led by the focus on vaccine development for COVID-19
- North America and Europe are at the top spots in terms of market priority; however, APAC countries have gained importance in recent times

### Challenges in DCT adoption

- DCTs bring in a unique set of challenges with respect to data integrity, security, and quality, along with challenges in the areas of patient engagement, site technology adoption, and stakeholder management
- Patient-intuitive DCT solution offering seamless integrations, coupled with robust data and network security can help enterprises overcome some of the challenges

### DCT Adoption framework

- For a successful DCT adoption, enterprises must prioritize on the therapy areas and carefully define their sourcing criteria. While large biopharma companies tend to prioritize end-to-end unified platforms, small and mid-sized companies focus on costs and vendor responsiveness
- It is critical to have commitment from top organizational leadership and cross-functional teams for successful DCT adoption

# This study offers distinct chapters providing a deep dive into key aspects of decentralized clinical trials adoption; below are four charts to illustrate the depth of the report

### Everest Group's view of an end-to-end DCT platform

Core modules			Auxiliary support services		
eConsent	Remote monitoring	TeleVisit	Patient screening	Drug/device provisioning	Remote CRA
eCOA/ePRO	Medication adherence		Patient enrollment	Patient concierge	
			Home nursing	Medical record review	

#### Patient experience

- Virtual enrollment and participation in clinical trials
- Electronic consent forms and virtual onboarding
- Patient engagement for a seamless experience
- Televisits and remote monitoring solutions
- Easy to report outcomes and fill in electronic records

#### CRO/sponsor experience

- Faster patient screening and document reviews
- Increased diversity and inclusivity in trials
- Reduced trial costs and trial timeliness significantly
- Standardized trial activities across multiple locations
- Real-time data gathering with complex scoring and analysis

### Benefits of DCT adoption

- Improved patient recruitment and retention**  
DCTs have increased patient enrollments by eliminating site visits, accelerating patient screening, and making the process patient-centric. With DCTs there is an ease of patient engagement and adherence, resulting in lower dropouts and higher retention rates.
- Reduced costs**  
DCTs help in reducing costs for both patients and caregivers. Patients are not burdened with travel costs while sponsors can cut down on sites, investigators, and related travel costs.
- Reduced trial timelines**  
Reduction in trial timelines has been a long-term industry imperative and DCTs have taken a step in that direction. With accelerated patient enrollment and data collection, the overall trial timelines are reduced to an extent with decentralized trials.
- More diverse patient population**  
DCTs can accommodate patients from around the world, irrespective of their location, creating a diverse patient pool for trials. This increases the efficacy of the drugs as they can be tested on a broader pool of patients.
- Getting real-time data**  
With DCTs, real-time data is now readily available. There is no dependency on bulk paperwork or third parties for data verification. DCTs enable real-time and precise data collection, increasing the efficiency of the entire process.

### Challenges with DCT adoption

- Data challenges**  
DCTs bring in risks related to data security, integrity, storage, and accessibility. It is a considerable challenge to maintain data privacy and compliance as sponsors and patients rely heavily on remote communication and data collection.
- Patient-facing challenges**  
Different levels of digital literacy, preference toward in-person physician visit, poor application design, and insufficient communication from sites and sponsors often lead to patient disengagement and a poor trial experience.
- Site adoption challenges**  
Sites lack professionals having sound knowledge about DCT products and operations. Most sites are not well-equipped with the latest technologies, raising concerns about protocol compliance, data security, and the readiness to conduct a decentralized trial.
- Regulatory challenges**  
When it comes to the adoption of digital tools and technologies, there is limited clarity on regulatory guidelines. The regulatory bodies support DCTs from a policy standpoint but certain challenges exist with the unclear regulatory guidelines.

### Everest Group's DCT adoption framework

- Portfolio prioritization**  
Determine the suitability of implementing decentralization in trials for each therapy area
- Organizational alignment**  
Plan stakeholder management for successful adoption of decentralization
- Sourcing criteria**  
Define the sourcing criteria for both DCT products and vendors



# Research calendar

## Life Sciences IT Services

■ Published
 ■ Planned
 ■ Current release

### Flagship reports

	Release date
Veeva Services PEAK Matrix® Assessment 2021	March 2021
Veeva Services Market Overview	July 2021
Decentralized Clinical Trial Products PEAK Matrix® Assessment 2021	July 2021
Decentralized Clinical Trial Products – Vendor Provider Profiles Compendium	August 2021
Decentralized Clinical Trial Products Market Overview	September 2021
Life Sciences Connected Medical Devices PEAK Matrix® Assessment 2021	Q4 2021
Life Sciences Commercial Services Specialists PEAK Matrix® Assessment 2021	Q4 2021
Life sciences Clinical Development Platform PEAK Matrix® Assessment 2022	Q1 2022
Life Sciences Digital Services PEAK Matrix® Assessment 2022	Q1 2022
Life Sciences Medical Devices Security Services PEAK Matrix® Assessment 2022	Q3 2022

### Thematic reports

	Release date
Connecting Life Sciences Manufacturing using Industrial IoT	March 2021
Evolution from Robotic Surgery to Digital Surgery	June 2021
<b>Decentralized Clinical Trials (DCT) Adoption Playbook</b>	<b>December 2021</b>
Sustainability in Life Sciences	Q1 2022
Reaping Success from an End-to-end Clinical Development Platform Landscape	Q1 2022

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