Everest Group®

Decentralized Clinical Trials (DCT) Adoption Playbook

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Contents

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Introduction and overview

- Research methodology
- Background of the research
- Objective of the playbook
- Summary of key messages

Our research methodology is based on four pillars of strength to produce actionable and insightful research for the industry

01

Robust definitions and frameworks

PEAK Matrix®, market maturity, and technology adoption/investment

02

Primary sources of information

Annual contractual and operational RFIs, service provider briefings and buyer interviews, web-based surveys

03

Diverse set of market touchpoints

Ongoing interactions across key stakeholders, input from a mix of perspectives and interests, supports both data analysis and thought leadership

04

Fact-based research

Data-driven analysis with expert perspectives, trend-analysis across market adoption, contracting, and service providers

Proprietary contractual database of life sciences IT Services (ITS) contracts (updated annually)

Year-round tracking of all major life sciences IT service providers

Dedicated team for life sciences outsourcing research, spread over three continents

Over 30 years of experience advising clients on strategic IT, business services, engineering services, and sourcing

Executive-level relationships with buyers, service providers, technology providers, and industry associations

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

Scope of this report:

Geography
Global

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

Vendor offering
Decentralized clinical trial products

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.

A summary of findings from the DCT adoption story so far in the life sciences industry

Patient experience

DCTs have put patient experience at the forefront. Enterprise buyers are looking for product solutions aimed at increasing patient satisfaction and driving patient enrollments.

Varying adoption levels

Different therapy areas have different scope and implementation approaches toward decentralization, giving room for hybrid and completely decentralized trials.

Challenges to overcome

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.

Successful adoption

Enterprises need to focus on their therapy area portfolio, be diligent with product and vendor selection, and manage internal change to be successful with DCT adoption.

02

DCT adoption and market trends

- Everest Group's view of an end-to-end DCT platform
- Benefits of DCT adoption
- Trends in DCT adoption
- Challenges with DCT adoption

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

An end-to-end DCT platform provides a consistent and improved trial experience for all participants (patients, CROs, and sponsors) while enhancing diversity and reducing trial timelines

End-to-end DCT platform – a single, unified platform that brings in complete decentralization to the clinical trial continuum. It enables patients to enroll, register, and participate in a clinical trial from their homes while allowing sponsors and CROs to virtualize trial oversight, manage patient monitoring, as well as maintain data integrity and compliance. It includes all the core technology modules aided by the auxiliary services for the smooth execution of a decentralized trial

Core modules		
eConsent	Remote monitoring	TeleVisit
eCOA/ePRO	Medication adherence	

Auxiliary support services		
Patient screening	Drug/device provisioning	Remote CRA
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

DCTs have enhanced the trial experience for both patients and healthcare professionals, enabling remote participation, centralized data collection, and facilitating efficient drug research

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.

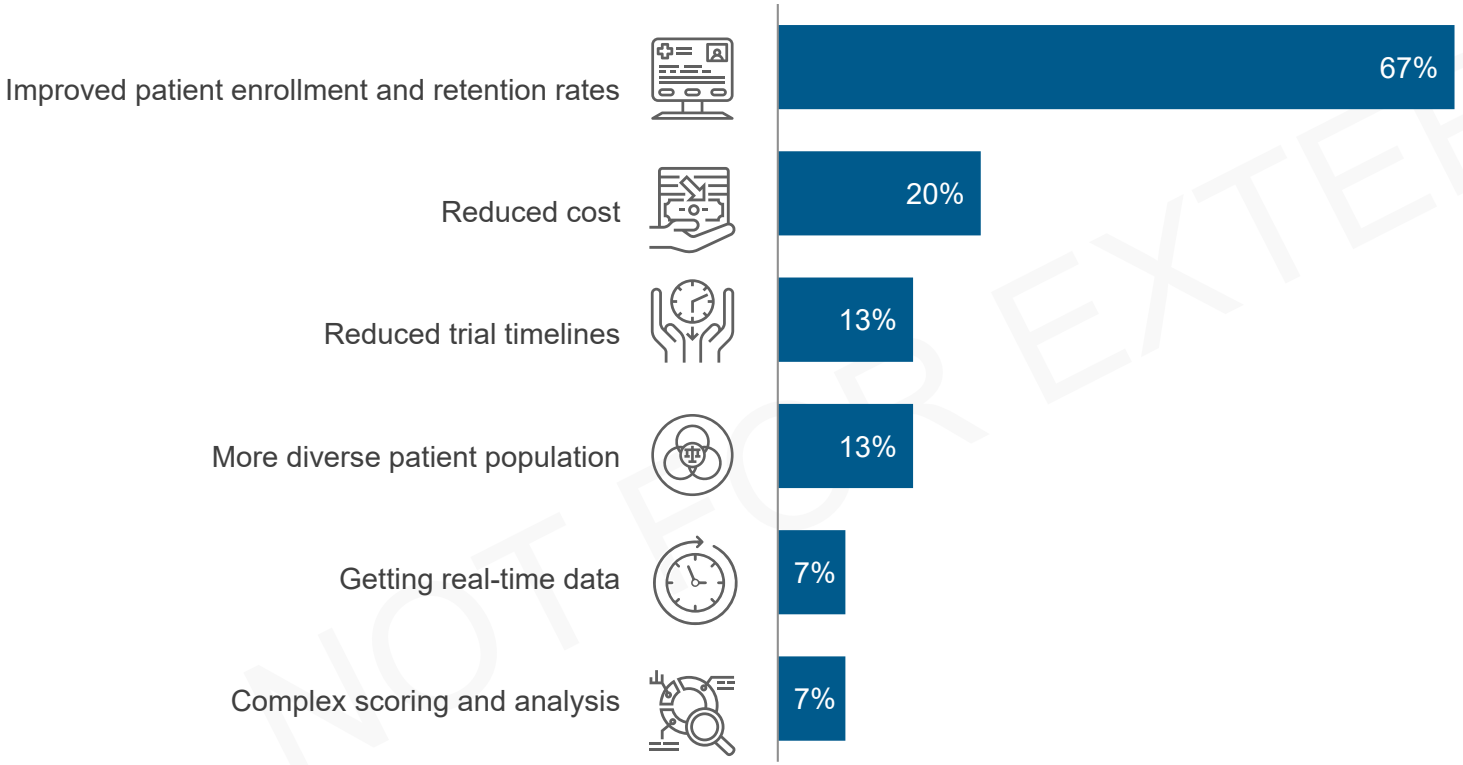
More diverse patient population
DCTs can accommodate patients from around the world, irrespective of their location, creating a diverse patient pool for trials. This increases the efficacy of the drugs as they can be tested on a broader pool of patients.

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.

DCTs have put patient-centricity at the forefront

Two out of the three enterprise clients that were interviewed stated that the biggest perceived benefit from adopting DCTs was improved patient enrollment and retention rates

Major benefits of DCT adoption according to buyers
2021, percentage of respondents citing specified benefits



Buyer quotes

DCTs have enabled direct patient recruitment from 40+ health centers, identified using EHD data.
– Interventional Cardiologist, a leading academic institution

The main reason for using the new model was to change the patient experience and be able to reach more diverse patient population for trials.
– Head, Clinical Trial Innovation, a top biopharma company

We saw 95% retention rates and the vendor was able to use technology to message trial participants directly on their phones/laptops and that had a huge impact.
– Vice President, Clinical Operations, a top biotechnology company

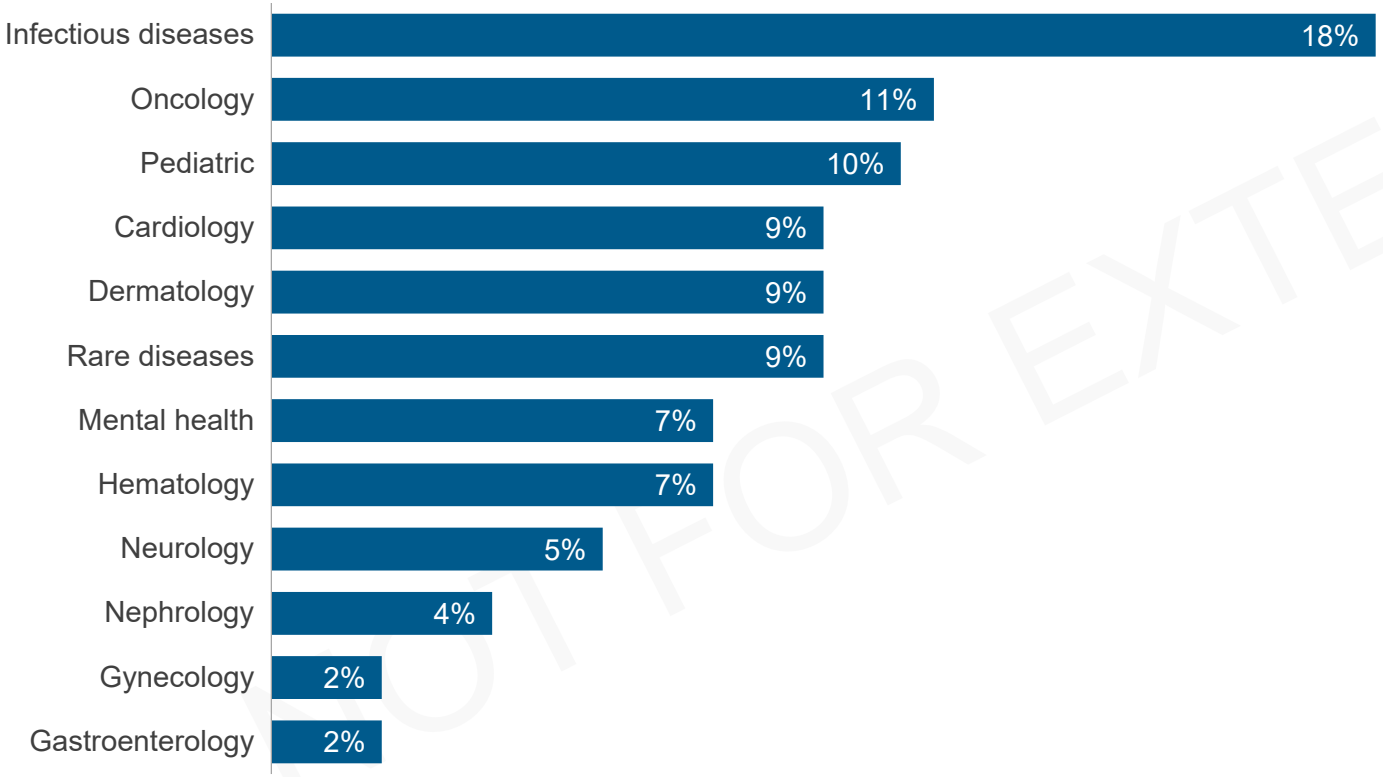
Patient enrollment and retention rates improved by ~25% as compared to traditional studies.
– Senior Director, Innovation and Digital Operations, a global CRO

Source: Everest Group DCT buyer interviews (2021)

DCT adoption across therapy areas

Infectious diseases and oncology trials have seen the maximum adoption of decentralization

Industry sponsored decentralized trials[1] by therapy area
2021; percentage of trials



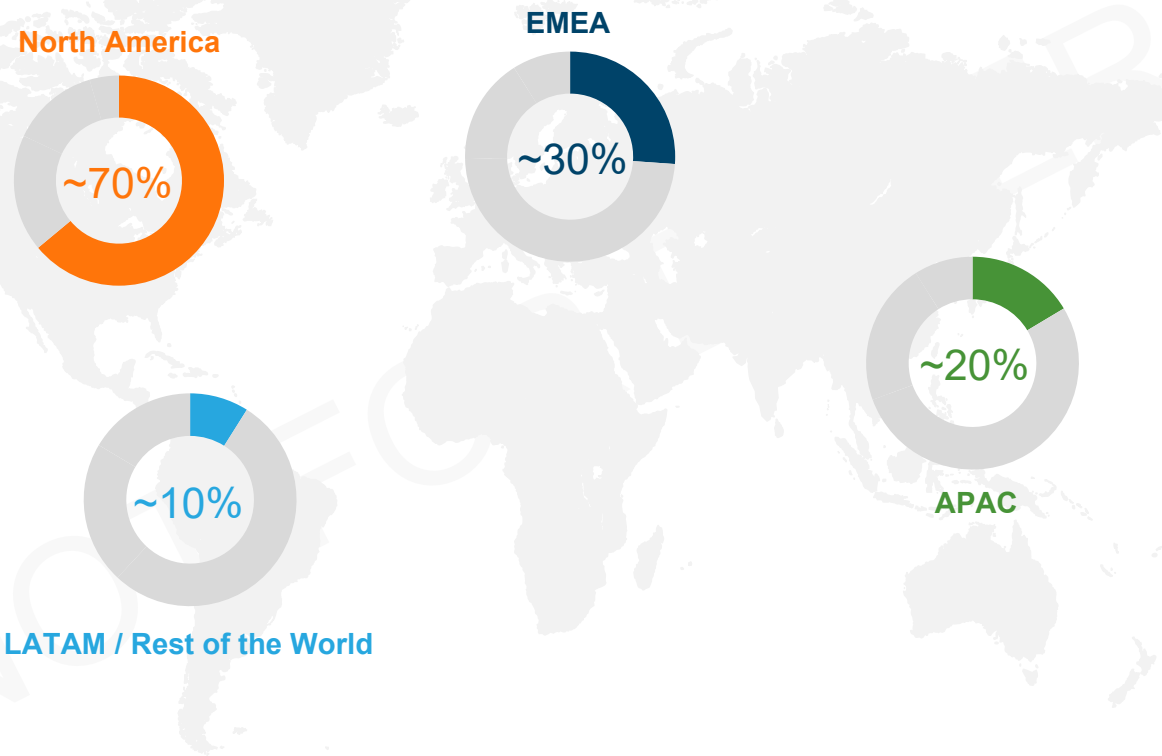
- The surge in the number of infectious diseases trials was driven by the focus on developing vaccines for COVID-19. From 2020 till April 2021, almost 60% (815)[2] of infectious disease trials were related to COVID-19 and remote trial solutions were the major enablers for these studies
- Oncology is a therapy area that sees large number of trials start every year. The pandemic halted multiple trials as patient movement got restricted. Decentralization introduced innovative channels to gather patient consent and insights
- Decentralization in Pediatric trials reduced overall study timelines, while reducing burden for kids and their families and contributing to accurate dosing and medical adherence
- The other therapy areas saw a decline in trial initiations. Most of the decline was seen in Phase I trials, because initiating a new trial in the middle of the pandemic proved to be difficult for the sponsors and investigators and their primary focus was toward developing vaccines for COVID-19

1 Based on Everest Group's analysis of 57 publicly available and enterprise-stated case studies
2 Citeline Trialtrove (2021); IQVIA Institute Report (2021)

DCT adoption across geographies

It is no surprise that North America and Europe are at the top spots in terms of market priority; however, APAC countries have gained importance in recent times

Industry sponsored decentralized trials by geography (patient locations)[1]
2021; percentage of trials



North America and Europe
Technological advancements, high levels of digital literacy, proliferation of wearables, and the regulatory support from FDA, EMA, along with regulators of individual European countries are responsible for higher adoption of DCTs in North America and Europe.

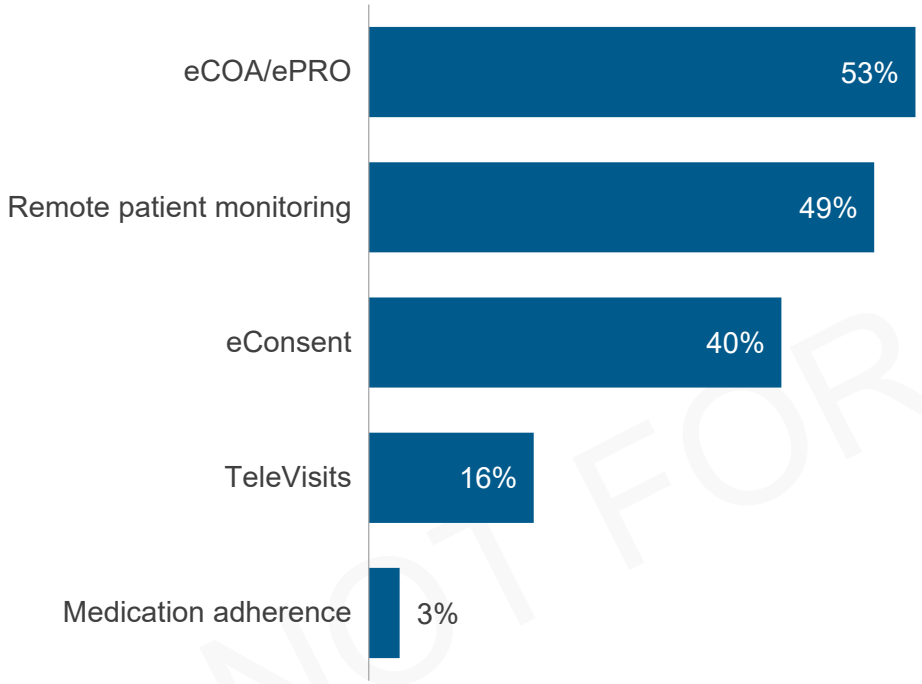
APAC
Increase in healthcare spending (forecasted to reach US$2.3 trillion by 2026) and the rise in Non-communicable Diseases (NCDs) namely cardiovascular diseases, cancer, and diabetes have increased the demand for pharmaceutical products and medical devices in the APAC region.

1 Multiple trials are global in nature or have more than one region from where patients were recruited

Demand trends | core modules

eCOA/ePRO and remote monitoring experience high demand as they enable remote care and real-time data collection from patients irrespective of their locations

Technology products used in decentralized trials[1]
2021; percentage of adoption



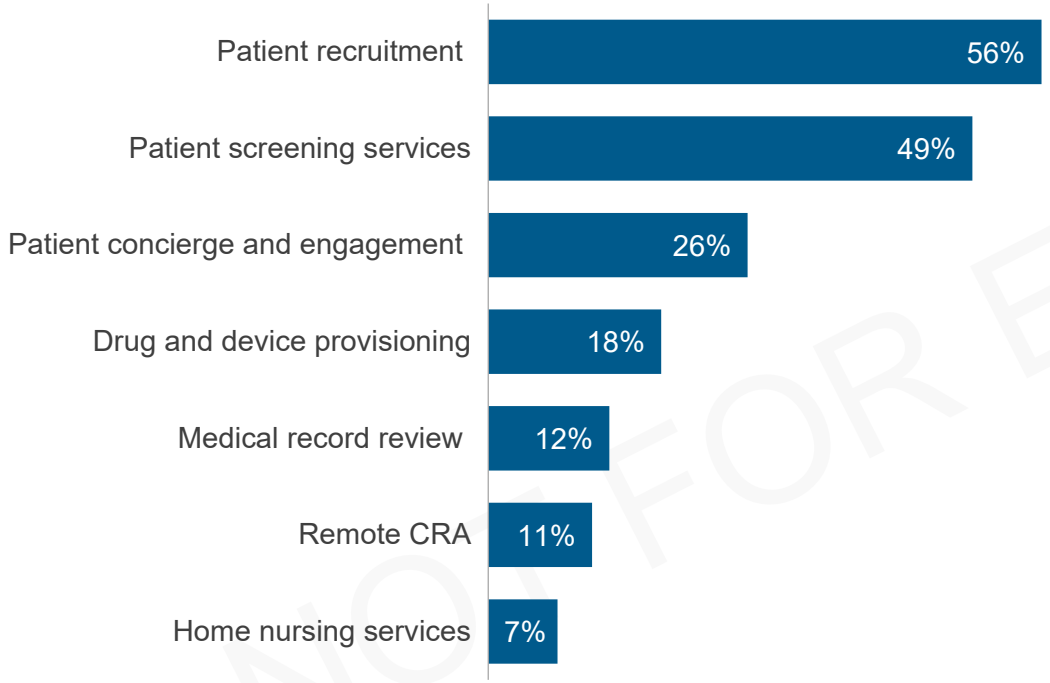
- The demand for eCOA/ePRO solutions is driven by the fact that eCOA/ePRO allows remote data collection, eliminates the challenges of paper-based records, and enables real-time data collection, thereby increasing convenience for patients
- The adoption of wearables and medical-grade devices has enabled remote patient monitoring. Augmented Reality (AR) and Virtual Reality (VR) technologies show early indications of providing an immersive experience, bringing patients closer to a clinic-like setting from the comforts of their homes, trying to get closer to the in-person experience
- The pandemic, coupled with technology maturity, has increased the demand for eConsent solutions, resulting in accelerated patient enrollment, reduced consent errors and site burden, and improved patient experience
- Adoption of medication adherence is low, and the present adherence monitoring is limited to push notifications to check whether patients have taken their medicines or not. The demand for personalized care, and the aging population, will gradually push for higher adoption
- The adoption of the TeleVisits solution is currently low. This is due to video conferencing capabilities also being embedded into eCOA and eConsent solutions

1 A single trial might require multiple technology products
Source: Everest Group analysis (2021) of publicly available and enterprise stated case studies

Demand trends | auxiliary support services

Remote patient recruitment and screening have seen high adoption across trials, while lack of offerings from vendors limits the adoption of other services

Auxiliary support services used in decentralized trials[1]
2021; percentage of adoption



- Decentralized trials have helped to overcome the traditional challenges of under-enrollment and patient dropout by accelerating patient recruitment and broadening the reach to a global pool of patients. Nearly 60% of decentralized and hybrid trials see the adoption of remote patient recruitment and screening services
- DCTs are evolving and only the leading DCT product vendors offer auxiliary services such as patient concierge and device/drug provisioning (in-house or through partnerships). Most DCT vendors do not have the capabilities or the partnership ecosystem to deliver these auxiliary services
- Less than 10% of decentralized and hybrid trials see the adoption of medical record review, home nursing, and remote CRA services. These services will experience a rise in demand and adoption as decentralized trials become more mainstream and product vendors mitigate the existing challenges with DCT adoption

1 A single trial might require multiple auxiliary services
Source: Everest Group analysis (2021) of publicly available and enterprise stated case studies

Challenges with DCT adoption

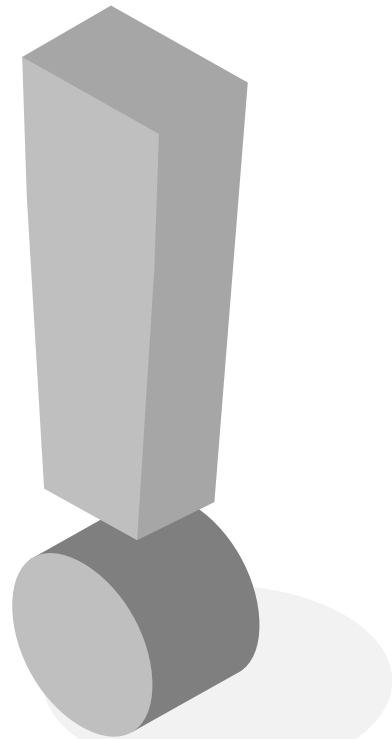
Decentralization in trials brings in challenges with data integrity, patient engagement, site technology adoption, and regulatory compliance

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.



Data challenges

The industry needs to address the challenges of data collection and consumption, and figure out the best ways to increase reliability and accuracy with each step

Data security	Data accuracy and device integrity	Operation and process integration	Data interpretation/tracking	Data storage and access
Vulnerabilities may arise when sponsors work with large, well-respected CROs, and rely on them to collect, maintain, and transfer data to sponsors securely.	Apps, ePRO tools, and wearable devices require technical and clinical validation. There should be appropriate mechanisms in place to detect if sensors are faulty and if patients are being non-compliant in a study.	DCT solutions pose their own integration and data transfer challenges, resulting in a frustrating site/sponsor experience. Data ownership is another grey area that can become a major challenge.	DCTs will require new tools that integrate data collection and data management and offer the ability to collect data from new sources and in non-conventional formats.	Decentralized methods allow clinical trial staff to collect patient data frequently and in a variety of environments. If the staff must spend hours sifting through data points or transferring them among different systems, DCTs could become more complicated and time-consuming than the traditional ones.

Patient-facing challenges

Patients face multiple challenges while using DCT products and applications, resulting in an inferior trial participation experience

Non-intuitive user interface; lack of functionality to manage settings and notifications

Limited know-how on usage of application; lack of patient education and training capabilities

Insufficient communication from sites and sponsors, resulting in confusion and reduced patient engagement and motivation

Poor application design and testing, resulting in slow applications, crashing, and unplanned user session logging out issues

Site adoption challenges

Sites are not ready to adopt the new DCT solutions with multiple challenges holding them back

Technical know-how

There is a clear dearth of professionals having sound knowledge and understanding of decentralized operations. The majority of sites have not received training for DCT solutions from vendors, leaving staff with half-baked knowledge about the new model of clinical trials.

Regulatory support

Site staff do not have enough information on the regulatory aspects of the decentralized solutions. Regulations become even more complicated as these vary across nations in Europe, and it is difficult to establish a standard procedure for consistent experience.

Protocol compliance

Site personnel or trial leaders cannot monitor each patient to ensure that protocols are being followed. Protocols vary with trial phases and patient conditions and a breach can pose to be a threat for the success of the trial.

Digital resources

DCTs have increased the dependency on technology and digital resources, but all sites are not well-equipped and have not invested significantly in the latest technologies, raising questions on the readiness to conduct a decentralized trial.

Source: SCRS White Paper: Impact Assessment of DCTs (2020), DCT Site Selection: key factors (Anju Software 2021)

Regulatory challenges

Site personnel and sponsors voice challenges in aligning decentralized trials with regulatory requirements

88%

Respondents[1] cite difficulties in complying with regulations

Top regulatory challenges
Complying with regulations related to new data collection methods
Aligning data accessibility and security with regulatory norms
Maintaining the safety and reliability of remote monitoring tools and devices
Achieving homogeneity for cross-border trials
Understanding when, where, and how a protocol deviation can occur
Keeping site personnel and investigators updated with the regulatory guidelines

1 Informa Engage research (respondents include professionals in biopharmaceuticals, CROs, and medical device companies) on behalf of Oracle (2021)

03

DCT adoption framework

- Portfolio prioritization
- Sourcing criteria
- Organizational alignment

Everest Group's DCT adoption framework

It is a three-step structured process to guide enterprises in their DCT adoption journey

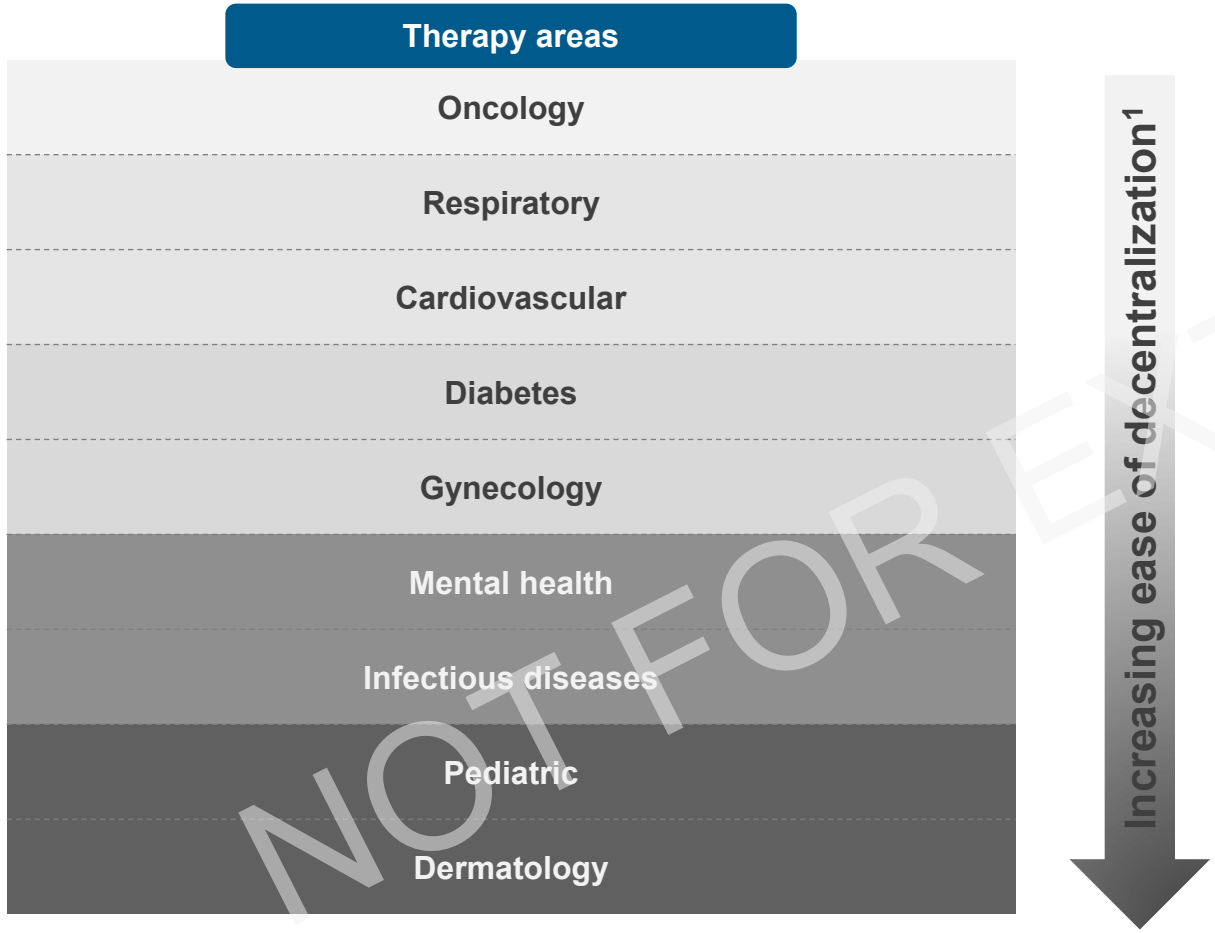
Portfolio prioritization
Determine the suitability of implementing decentralization in trials for each therapy area

Organizational alignment
Plan stakeholder management for successful adoption of decentralization

Sourcing criteria
Define the sourcing criteria for both DCT products and vendors

Portfolio prioritization

Different therapy areas require different decentralization approaches, resulting in the need for portfolio prioritization



- Trial setups, procedures, and data collection methods vary across therapy areas. Some trials can be completed without any site visits while others can adopt a hybrid approach, for e.g., complex procedures to be performed in a clinical setting while simple monitoring of the patient vitals can be performed remotely
- Sponsors need to identify therapy areas where DCT adoption would bring most value addition for patients, site investigators, and physicians
- Based on the portfolio prioritization, sponsors can identify their internal capabilities that needs to be strengthened and the technologies that need to be deployed. Such an approach would help in selecting product vendors and service providers for successful DCT implementation

1 Indicates fully decentralized trials (no site visits or completely remote)
Source: Everest Group (2021)

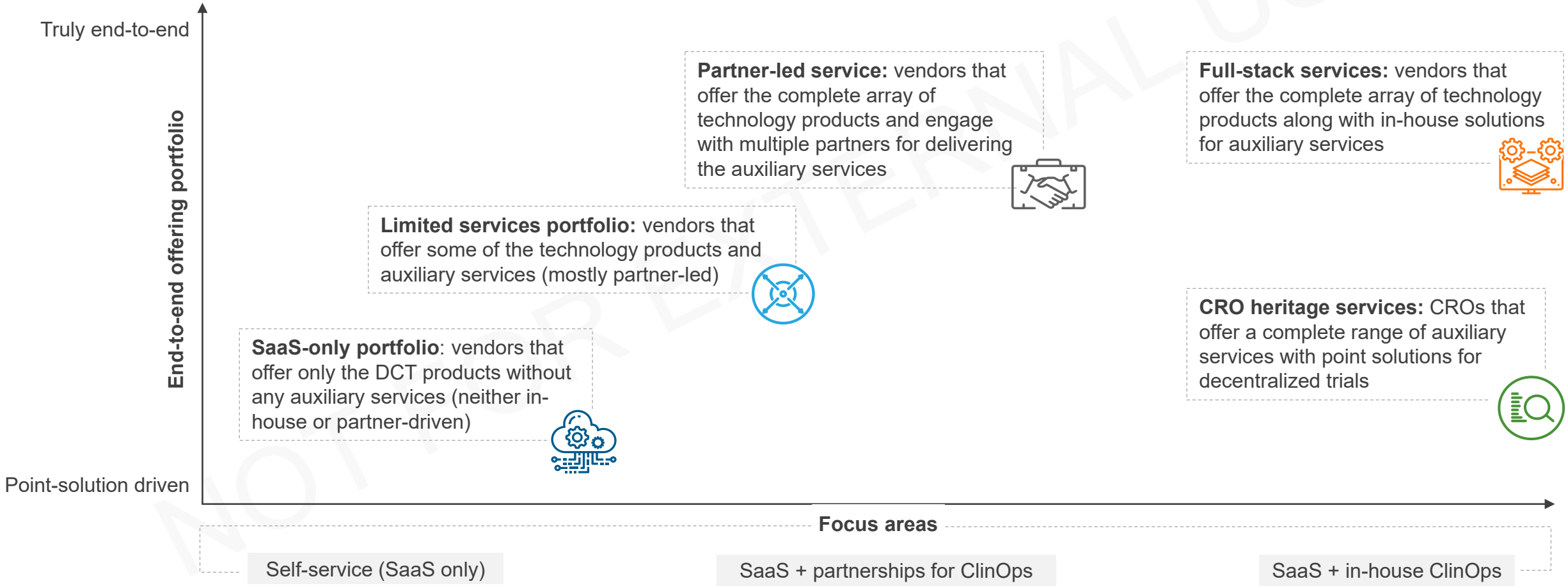
Portfolio prioritization

Multiple parameters would help sponsors in prioritizing therapy areas for DCT adoption

Toward site-based approach	Parameters	Toward decentralized approach
Patient groups with low levels of digital literacy (aged patient, some minority groups, etc.)	**Patient demographics**	Young population with moderate to high levels of digital literacy
Patients are localized or the trial needs to be conducted in a hospital setting	**Patient location**	Patients located across the globe
Trials involving diagnosis that requires heavy equipment and complicated setups	**Diagnostic procedures**	Trials that do not require complex procedures such as scans and imaging
Trials requiring continuous monitoring and attention to medication adherence	**Monitoring and intervention**	Trials that require limited monitoring and intervention
Not well-versed with the new tools and technologies	**Skill levels of professionals**	Tech savvy and high digital literacy, with good understanding of regulations

DCT vendor landscape

To run DCTs holistically, enterprises prefer to opt for both products and auxiliary services during the DCT deal solutioning, which is best fulfilled by full-stack and partner-led vendors



Source: Everest Group (2021)

Sourcing criteria for selecting DCT products

It is no surprise that patient-centricity of the DCT products is central to enterprises during sourcing decisions

Technology maturity

- User and patient experience
- Technology capabilities
- Experience with large studies

Innovation

- Investments toward designing more patient-centric solutions
- Future developments & investments in their solutions

Reviews

- Top rankings on search engines
- Good reviews from other buyers

Decreasing order of importance (similar trend is observed for large, mid-sized, and small biopharma companies)

Source: Everest Group (2021)

Sourcing criteria for selecting DCT vendors

Different enterprise segments have different priorities, resulting in a need for contextualized deal solutioning approach

Annual revenue: small: < US$1 billion, mid: US$1-5 billion, large: > US$5 billion

Large biopharma companies	Mid & small biopharma companies
Unified platform	Cost
Past case studies	Responsiveness
Scalability	Flexibility
Leadership team	Setup time
Geographic footprint	Transparency

Source: Everest Group (2021)

Organizational alignment

Limited knowledge, lack of well-defined KPIs, and cost pressures result in the need for stakeholder alignment

Why is stakeholder alignment necessary?
Life sciences industry has been a traditional laggard when it comes to digital adoption
Absence of established/fixed operating model for running DCTs
Lack of well-defined metrics/KPIs to measure the success of DCT adoption
Very limited business cases/success stories to justify the new investments and cost pressures

~59%

Respondents[1] state that stakeholder alignment caused difficulties in DCT adoption

1 Veeva report on DCT adoption (2021)

Strategies to drive organizational alignment

Increasing know-how about DCTs and having well-defined processes with diligent financial planning will be the hallmark for successful organization alignment

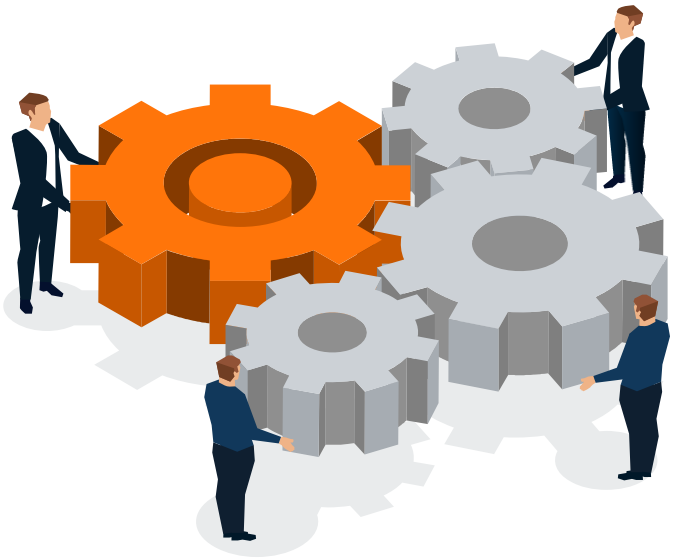
Training of research associates and relevant personnel on the configuration and usage of the new devices/sensors/applications along with the new processes and operations related to decentralization of trials must be done.

Business cases that clearly highlight quantifiable impact generated due to the adoption of DCTs, should be present. These should highlight patient/user experience along with financial numbers.

KPIs, such as cost per patient, enrollment duration per patient, and patient retention/dropout rate, should be defined and benchmarked against traditional figures to define success for decentralized trials.

Budget plans should be made for decentralized trials. This includes budget for training, improving digital capabilities, strengthening in-house capabilities, and implementing DCTs smoothly.

Support should come down from the top leadership for the adoption and execution of DCTs. It is imperative to have commitment from leadership and cross-functional teams for successful DCT adoption.



04

Appendix

- Glossary

Glossary of key terms used in this report

AI	Artificial Intelligence is the simulation of human intelligence and decision-making capability by machines
BYOD	Bring Your Own Device. Refers to being allowed to use one's personally-owned device, rather than being required to use an officially provided device
CRA	A Clinical Research Associate manages and oversees multiple aspects of a trial to ensure that they are safe and effective
CRO	A Contract Research Organization is an organization that provides research services to firms in the life sciences industry on a contract basis
DCT	Decentralized Clinical Trial. DCTs are defined as studies executed through telemedicine and mobile/local healthcare providers, using processes and technologies differing from the traditional clinical trial model
eConsent	It is the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive web sites, biological recognition devices, and card readers, to convey information related to the study to obtain and document informed consent
eCOA	Electronic Clinical Outcomes Assessment. eCOAs are a method of capturing outcomes data electronically in clinical trials. eCOA employs technologies such as handheld devices, tablets, or the web to allow trial participants, physicians, and caregivers to directly report information related to healthcare outcomes
ePRO	Electronic patient-reported outcome. ePROs allow patients to answer questions and report on their health through an electronic device, such as a smartphone or tablet
IoT	Internet of Things refers to a system or a network and connected devices such as computers and sensors, which can interact through data exchange and use analytics algorithms to make decisions
ITS	Information Technology Services is the transfer of ownership of some, or all information technology processes or functions to a service provider. This could include core, administrative, delivery, or management-related processes or functions
Leaders	Leaders are the highest rated service providers/vendors, according to Everest Group's proprietary scoring methodology, with top quartile performance across market success and capability
LS	Life Sciences – Everest Group defines the life sciences industry to include organizations in the fields of pharmaceuticals, biotechnology, and medical devices
Major Contenders	Major Contenders are the second-highest rated service providers / vendors, according to Everest Group's proprietary scoring methodology, with second or third quartile performance across market success and capability
Televisits	Televisits are a safe and secure way for you to connect to a doctor remotely, via video and audio connection either on a smartphone or a computer

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With you on the journey

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