Everest Group®

Decentralized Clinical Trial Products – Market Overview

September 2021

Contents

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01

Introduction and overview

- Research methodology
- Key information on the report
- Background of the research
- Focus of the research

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

This report is based on four key sources of proprietary information

- Proprietary database of IT services contracts of major IT service providers with workplace services in scope of work (updated annually)
- The database tracks the following elements of each contract:
  - Buyer details including size and signing region
  - Contract details including service provider, contract type, TCV & ACV, service provider FTEs, start & end dates, duration, and delivery locations
  - Scope details including share of individual buyer locations being served in each contract, Line of Business (LOB) served, and pricing model employed

- Proprietary database of IT service providers (updated annually)
- The database tracks the following for each service provider:
  - Revenue and number of FTEs
  - Number of clients
  - FTE split by different lines of business
  - Revenue split by region
  - Location and size of delivery centers
  - Technology solutions developed

- **Service provider briefings**
  - Vision and strategy
  - Annual performance and future outlook
  - Key strengths and improvement areas
  - Emerging areas of investment

- **Buyer reference interviews, ongoing buyer surveys, and interactions**
  - Drivers and challenges for adopting workplace services
  - Assessment of service provider performance
  - Emerging priorities
  - Lessons learned and best practices

Product vendors assessed[1,2]

accenture, castor, Clinical Ink, COVANCE, DELVEHEALTH, ERT, eClinicalHealth, IQVIA, Jeeva INFORMATICS, Medable, MEDIDATA, ObvioHealth, SIGNANT HEALTH, Science 37, THREAD

1 Assessments for Covance, Delve Health, eClinicalHealth, ERT, and Signant Health excludes product vendor inputs and are based on Everest Group's proprietary Transaction Intelligence (TI) database, product vendor public disclosures, and Everest Group's interactions with DCT product buyers

2 Analysis for Signant Health is based on capabilities after its acquisition of Virtrial, analysis for ERT is based on capabilities after its merger with BioClinica, and analysis for Covance is based on capabilities after its acquisition with SnaploT

Source: The source of all content is Everest Group unless otherwise specified

Confidentiality: Everest Group takes its confidentiality pledge very seriously. Any information we collect that is contract specific will only be presented back to the industry in an aggregated fashion.

Background 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. Although the technology and literature to support DCTs existed even before the COVID-19 pandemic, there were only a few pilots being conducted, as enterprises grappled with regulatory uncertainties, the 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 FDA's push to the industry to adopt DCTs following the COVID-19 situation have made the DCT landscape ripe for disruption.

Numerous start-ups that address DCT requirements have emerged in recent times. The landscape has also experienced heavy fundraising and mergers and acquisition (M&A) activities. Through co-innovation, continuous product improvement, and market education, DCT vendors are focusing on increasing trust, expediting trial timelines, and delivering a smooth experience in running DCTs. Everest Group's Decentralized Clinical Trial Products PEAK Matrix® Assessment 2021 looks at the current vendor landscape offering such platforms and presents the executive sentiment and insights for such platforms.

This report looks at:

- DCT adoption
- Everest Group view of an end-to-end unified DCT platform
- DCT vendor landscape and key focus areas for enterprises from DCT vendors

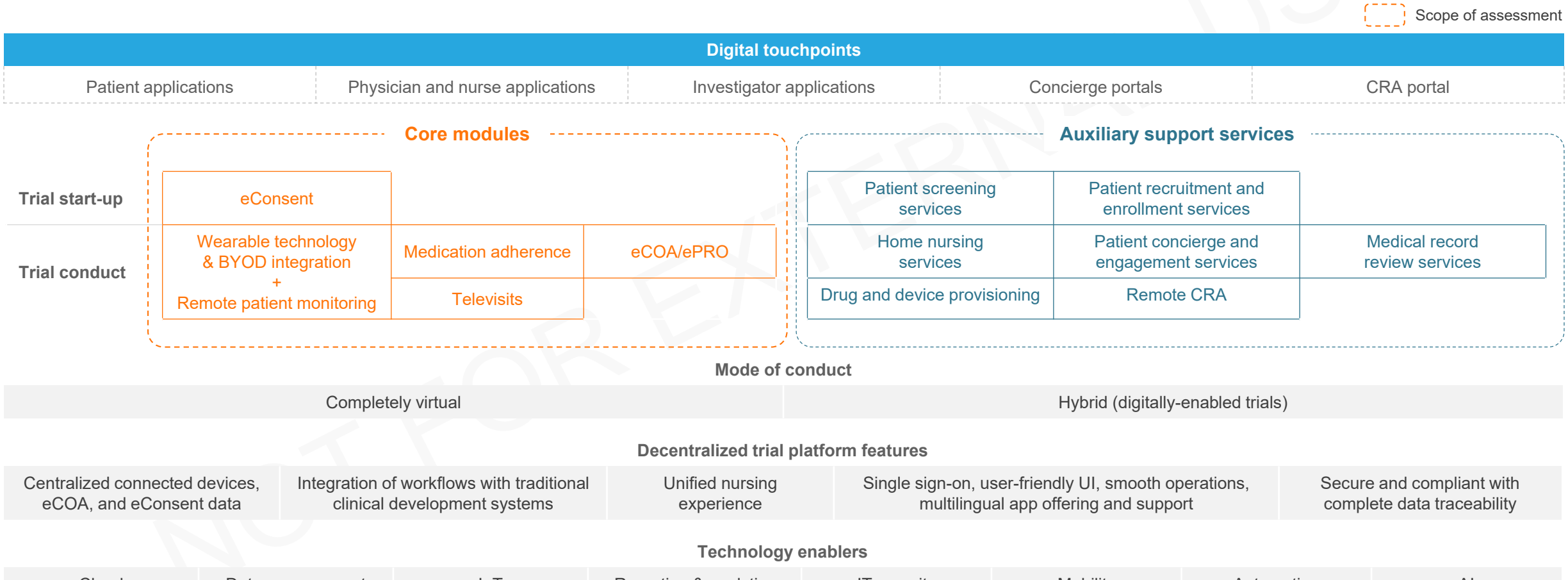
Scope of this report:

Geography
Global

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

Vendor offering
Decentralized clinical trial products

This report focuses on technology products and auxiliary services that enable DCT and offers insights into the key market trends



Source: Everest Group (2021)

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

02

DCT – trends and market dynamics

- DCT adoption
- DCT vendor landscape
- Enterprise view of DCT vendors
- Patient centricity and challenges in DCT adoption
- Future of DCTs

DCT: trends and market dynamics

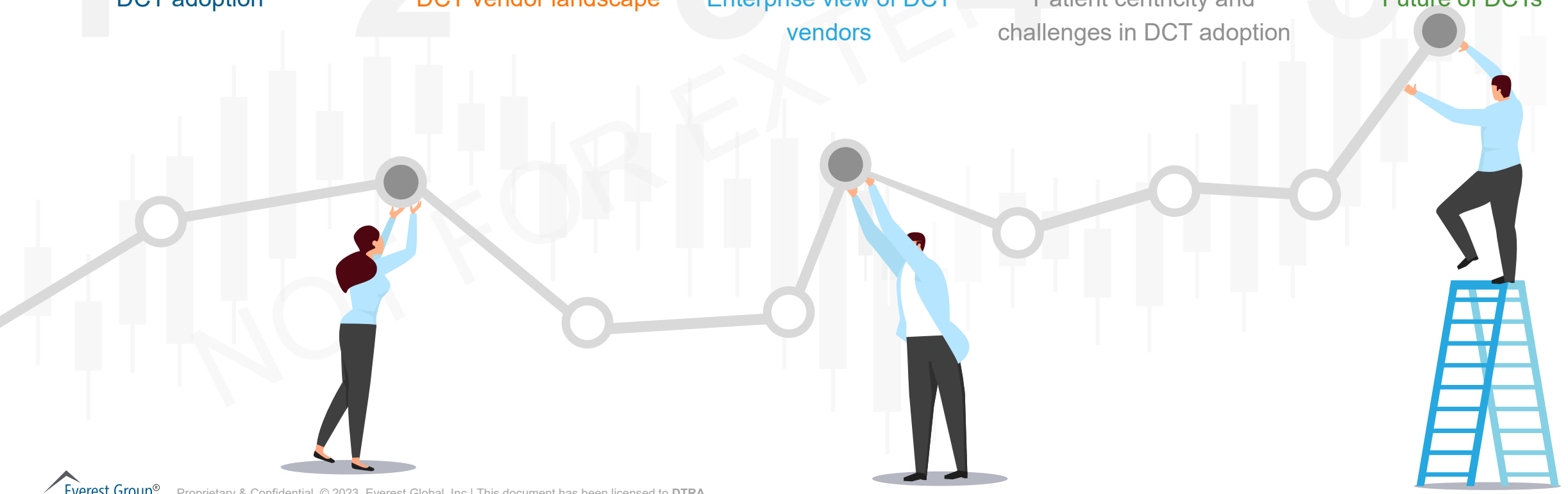
DCT adoption

DCT vendor landscape

Enterprise view of DCT vendors

Patient centricity and challenges in DCT adoption

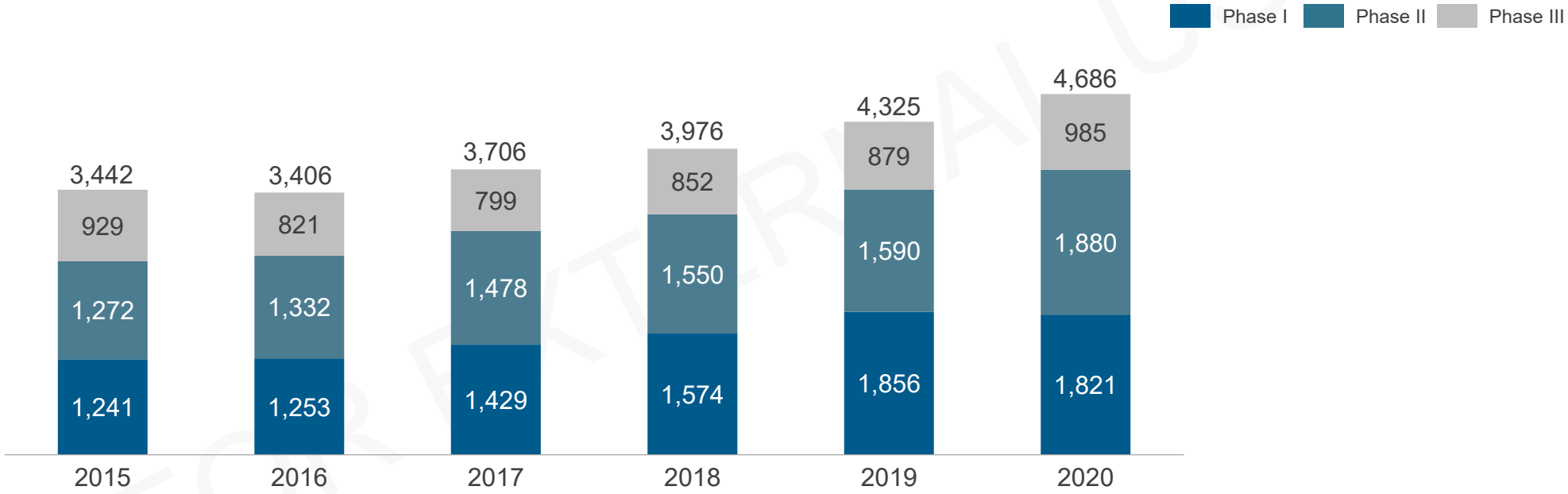
Future of DCTs



Clinical trial activities

Despite disruptions and hindrances resulting from the COVID-19 pandemic, the number of clinical trial starts saw significant growth in 2020

Number of clinical trials starts
2015-20



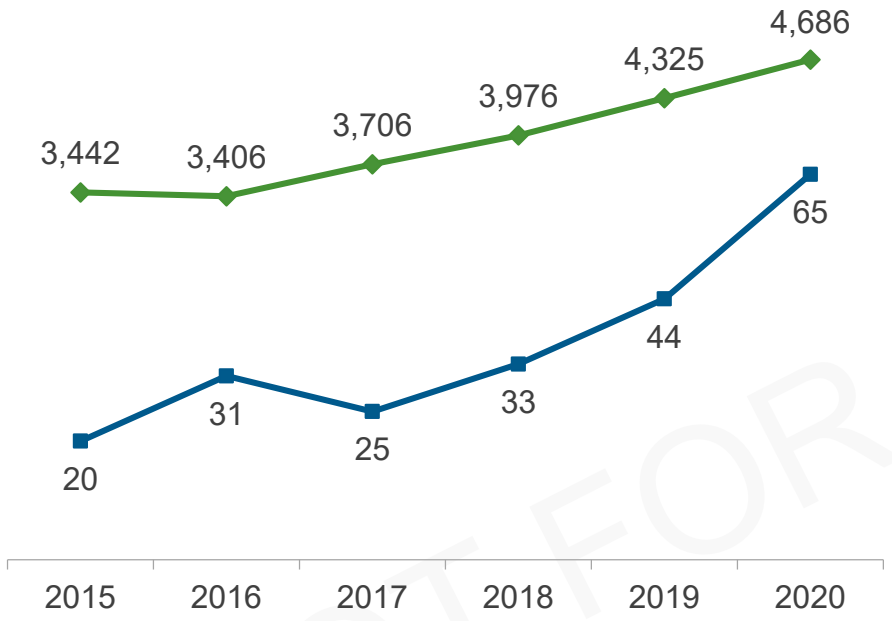
- Clinical trial starts saw an overall growth of ~8% in 2020, compared to the 2019 figures after the initial disruptions caused due to COVID-19. Non-COVID-19 industry-sponsored trials saw a massive dip in the first two quarters of 2020; however, recovery started from Q3 2020
- Oncology trial starts were at an all-time high since 2015 (60% growth as compared to the number of trial starts in 2015). This has been propelled by the movement towards rare oncology trials that account for more than 60% of the oncology trials
- The number of trial starts for infectious diseases have more than tripled as compared to the 2019 figures, driven by the COVID-19 related trials across the world. Besides infectious diseases and oncology, a majority of other therapy areas saw a slight dip in the number of trial starts, indicating that the priority of sponsors and enterprises were more towards the development of the COVID-19 vaccine

Source: Everest Group (2021); Citeline Trialtrove (2021); IQVIA Institute Report (2021)

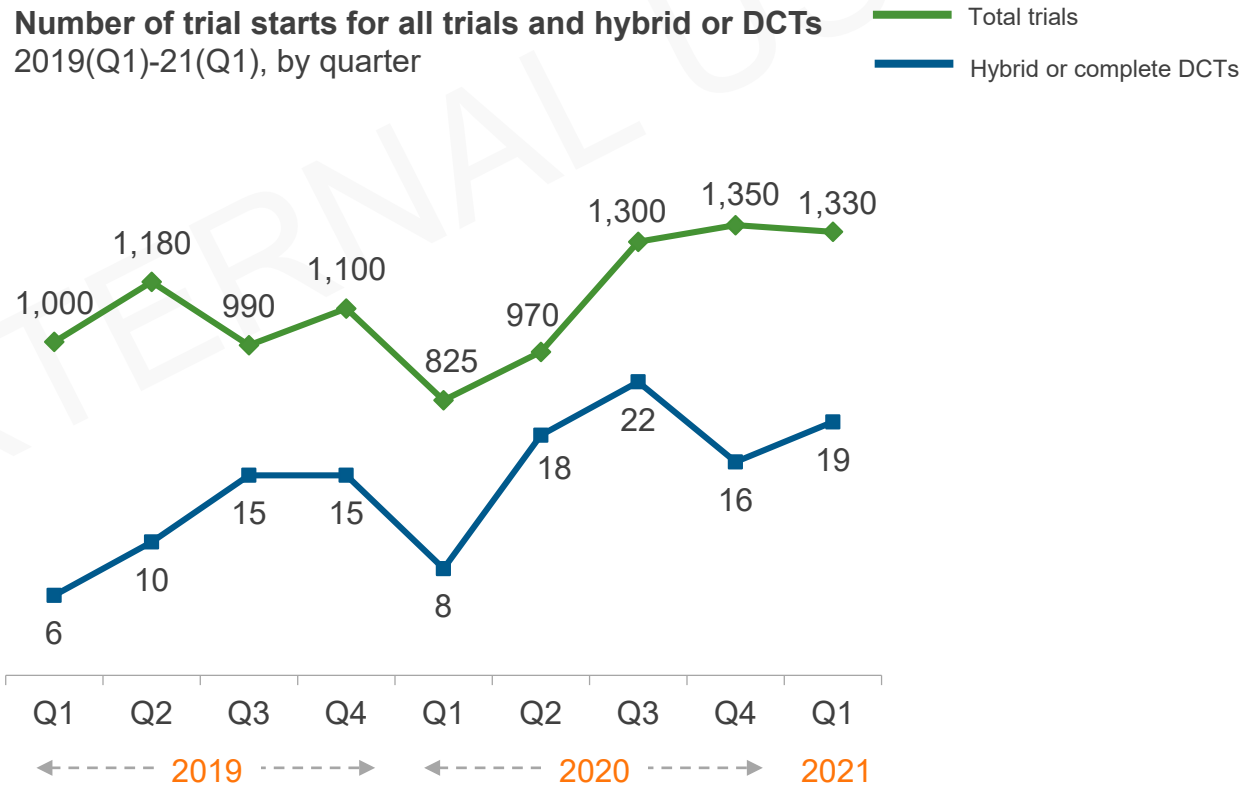
DCT adoption over the years

The life sciences industry has witnessed a gradual adoption of hybrid and DCT trials; however, the pandemic has catapulted them into the mainstream

Number of trial starts for all trials and hybrid or DCTs
2015-20



Number of trial starts for all trials and hybrid or DCTs
2019(Q1)-21(Q1), by quarter



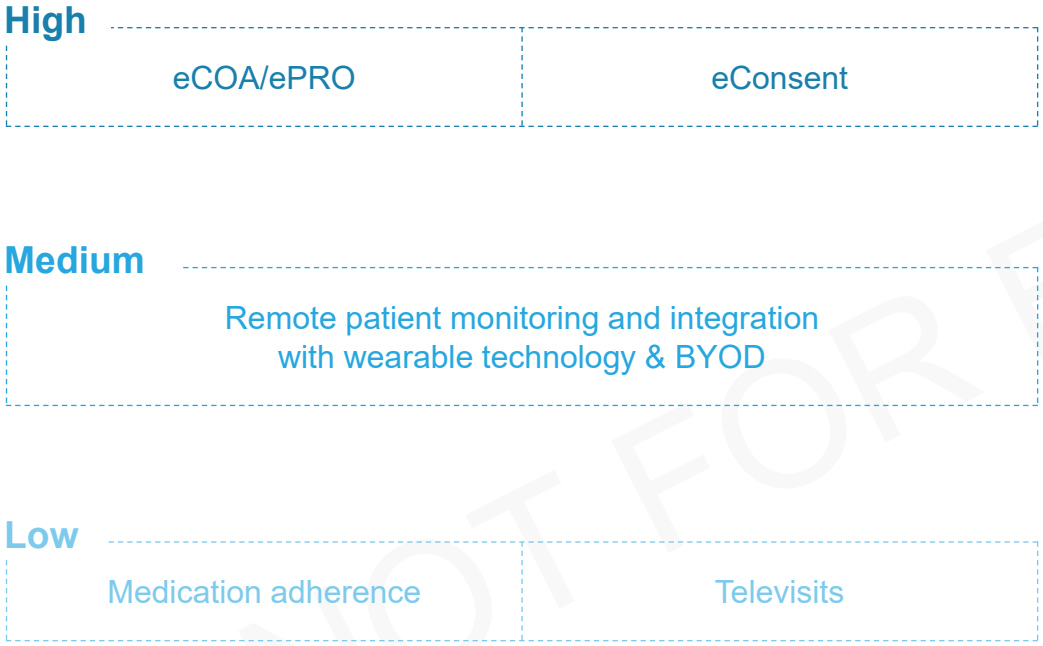
- The pandemic has proven to be the greatest accelerator for hybrid and decentralized trials with trial start numbers almost doubling the 2018 figures
- While the current adoption levels are still low, various developments, such as mergers, cross-industry alliances, investor financing, and partnerships, signal a rapid increase in adoption in the months and years to come

Source: Citeline Trialtrove (2021); IQVIA Institute Report (2021)

Demand trends for DCT products

eCOA/ePRO and eConsent experienced high demand as they helped to overcome the challenges of paper-based records, while medication adherence and televisits observed comparatively lower adoption

Core module adoption in decentralized trials



- The demand for eCOA/ePRO solutions is driven by the fact that eCOA/ePRO eliminates the challenges of paper-based records, increases data quality, compliance, and overcomes the risks of data challenges
- The pandemic, coupled with technology maturity, has increased the demand for eConsent solutions, thereby reducing site burden and audit risks, while improving patient experience and compliance
- The rise in the adoption of Remote Patient Monitoring (RPM) solutions is driven by the rise of wearable technology and medical-grade devices that can monitor patient vitals such as heart rate, blood pressure, and sleep patterns
- Adoption of medication adherence is low; however, 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

Source: Everest Group estimates as per RFI inputs (2021) and analysis of publicly available case studies

Buyer voices

Enterprises prefer to choose product vendors with both technology and clinical operations capabilities/partnerships

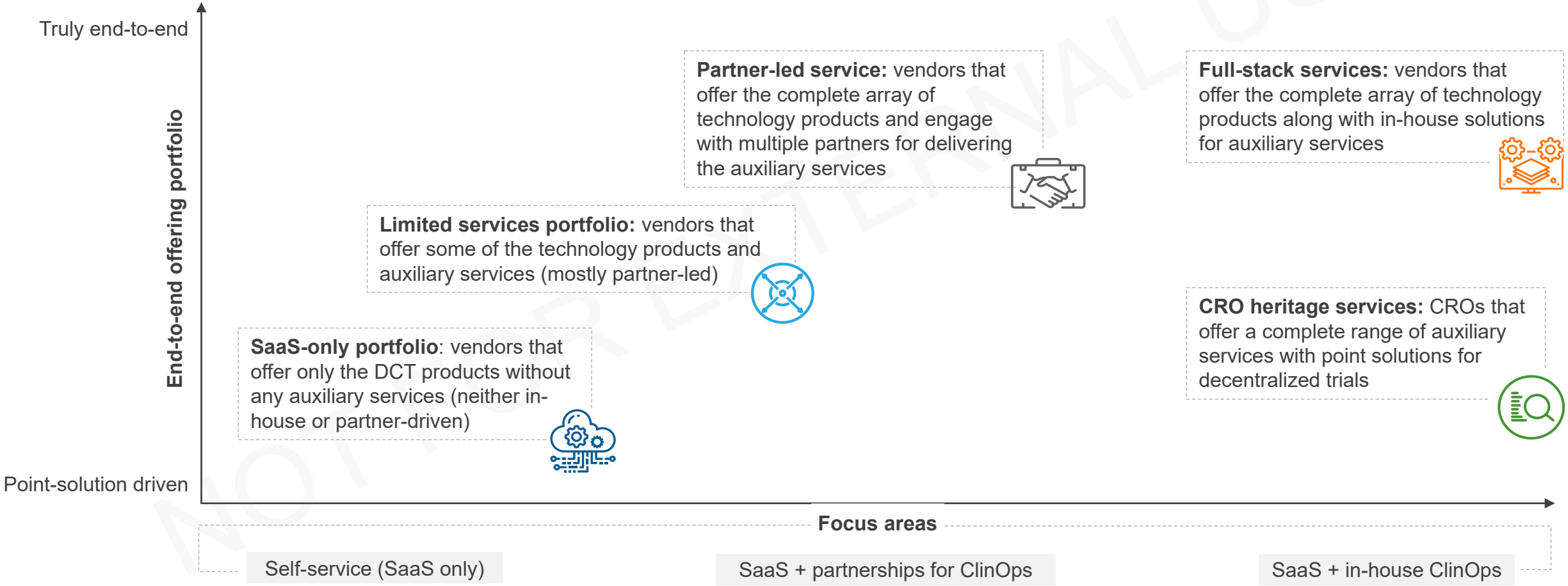
> This is not just a technology problem. Vendors who offer both the products as well as the services to operationalize DCTs will win in the long term.
>
> **– Head of Clinical Affairs, a top 20 biopharma company**

> The DCT vendor should not only have eConsent, Telemedicine, eCOA, and eSource capabilities but also remote monitoring (visits and wearables), direct-to-patient shipping, and home health nursing management capabilities.
>
> **– Head of Clinical Innovation, a top global biopharma company**

> We prefer a vendor who understands technology as well as clinical operations, someone with a good understanding of how tech meets business.
>
> **– Senior VP, Sites, patients and centralized solutions, a leading CRO**

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)

A closer look at the industry

Major players are focused on partnerships, acquisitions, human capital development, and enhancements to their DCT platform

Partnership

- Leaders are partnering with specialists for auxiliary services (home health nursing, remote diagnostics, and healthcare services, etc.)
- Partnerships are also seen with CRO vendors for consulting, clinical development, and commercialization services
- The other prominent areas where partnerships and acquisitions are rising include logistics, device provisioning, data analytics, and security (data, network, and devices)

Human capital development

- Leaders and top Major Contenders are hiring for roles such as Chief Scientific Officer, Chief Growth Officer, Chief Design Officer, Chief Product Officer, Chief Delivery Officer, Chief Strategy and Expansion Officer
- Investment in human capital is focused either on designing a simple unified platform for seamless patient experience during clinical trials or on expansion and marketing operations

Product design

- The focus is on innovation and next-generation technologies. There are certification programs to empower organizations to scale their DCT operations
- Vendors are aiming to provide customized solutions tailored to specific trials and protocols to maximize the research effectiveness
- Enterprise buyers are looking for an end-to-end, unified, secured platform that unifies data capture technology with study oversight and monitoring

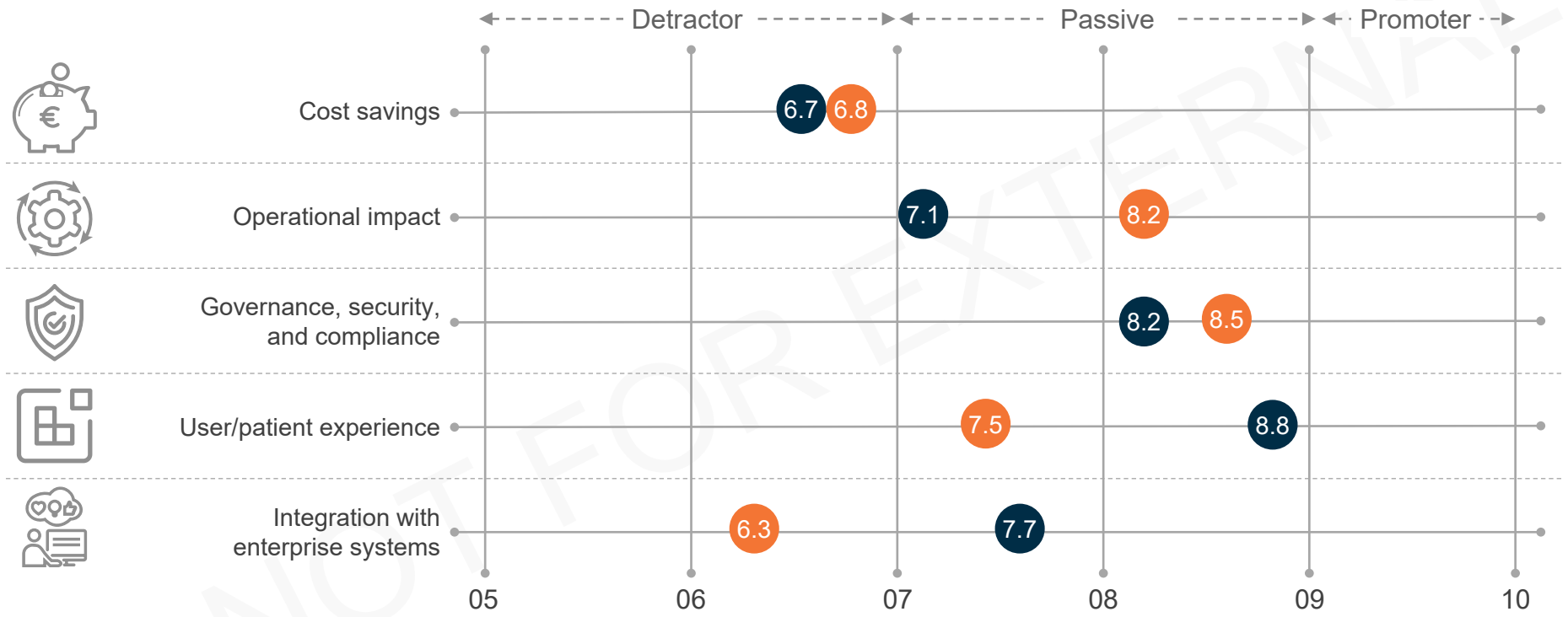
Funding and expansion

- Multiple vendors have raised significant funding to enhance their DCT program
- Start-ups have opted for public listings through mergers, allowing them to have high enterprise value, thereby making enough funds available for funding DCT expansion and growth
- Leaders are focusing on multiple geographies beyond their established territories (specially looking at Europe and the APAC region)

Source: Newsroom and public disclosures

Buyer reference feedback and scores | platform capabilities

Buyer perception of vendor's DCT platform capabilities
2020-21; ratings on a scale of 1 to 10

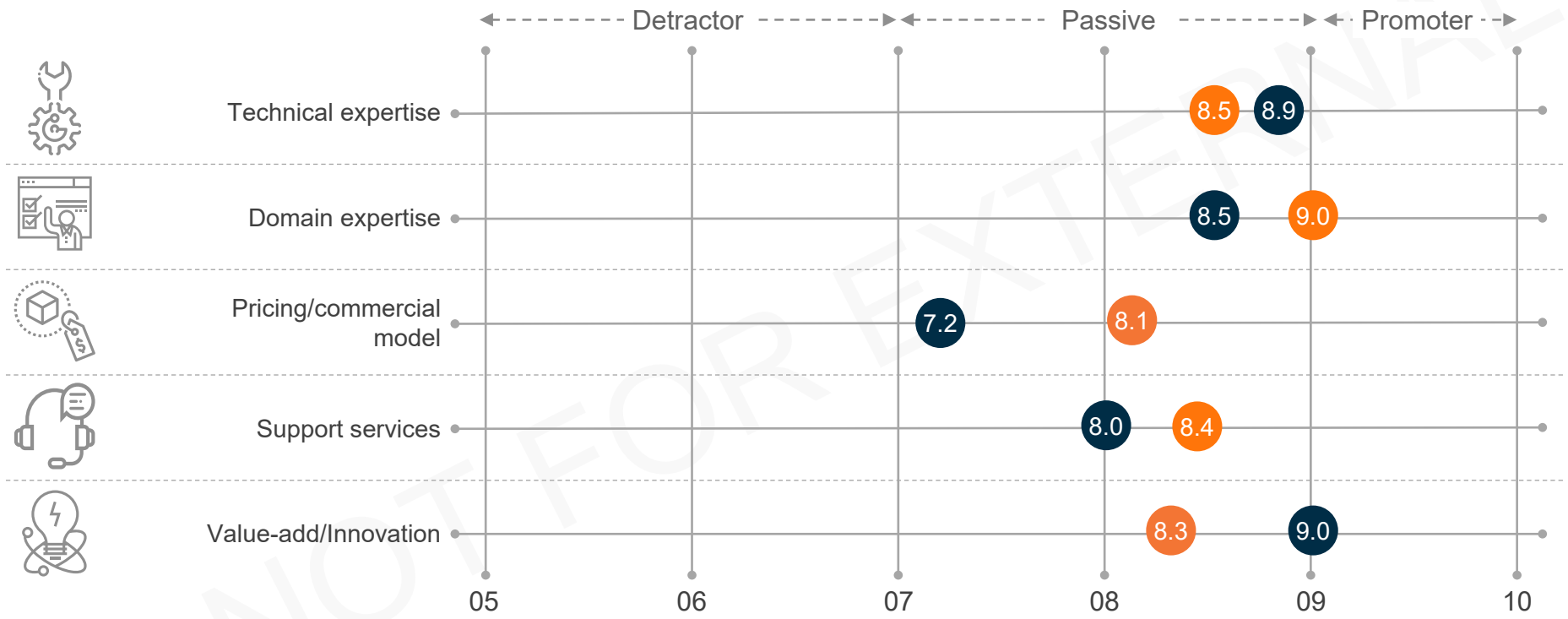


- Leaders offer an end-to-end modular platform with a unified data layer, providing better integration with existing systems
- Leaders also provide auxiliary services such as patient recruitment, patient concierge, device/drug provisioning, and remote CRA for the smooth execution of the DCTs
- Leaders are investing in hiring executives for designing patient-centric DCT solutions and strategy execution, leading to better rankings on patient experience

1 THREAD, Medable, Science 37
2 Castor, Clinical Ink, IQVIA, Medidata, ObvioHealth
Source: Everest Group (2021)

Buyer reference feedback and scores | participant capabilities

Buyer perception of existing DCT vendor capabilities
2020-21; ratings on a scale of 1 to 10



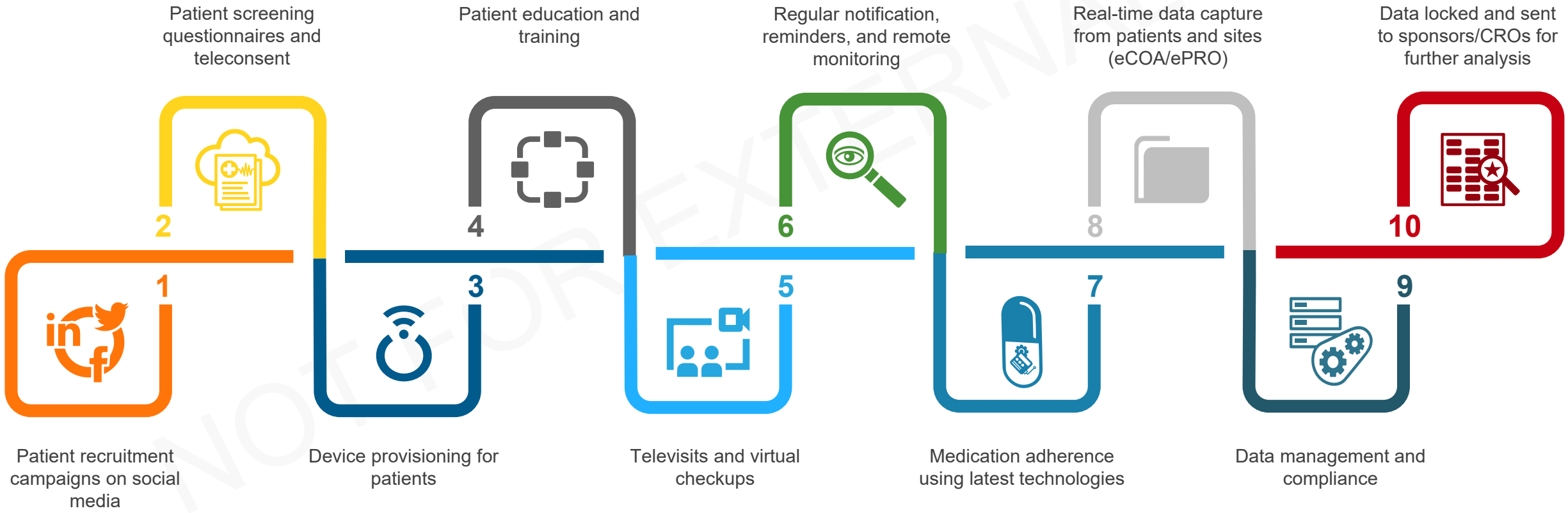
- DCT native vendors are focusing on enhancing their technical expertise, while the traditional CROs score high on domain knowledge due to their experience with clinical trials
- Existing CROs and SaaS providers can offer certain elements of the DCT suite at a lower price point as compared to the DCT native vendors who are perceived to be priced at a premium
- Leaders go for a consultative approach towards enterprises bringing in a lot of innovation and value addition to the table

1 THREAD, Medable, Science 37
2 Castor, Clinical Ink, IQVIA, Medidata, ObvioHealth
Source: Everest Group (2021)

Everest Group's view of an ideal patient journey in a decentralized trial

The activities are similar to the traditional trials; however, the journey becomes completely site-less

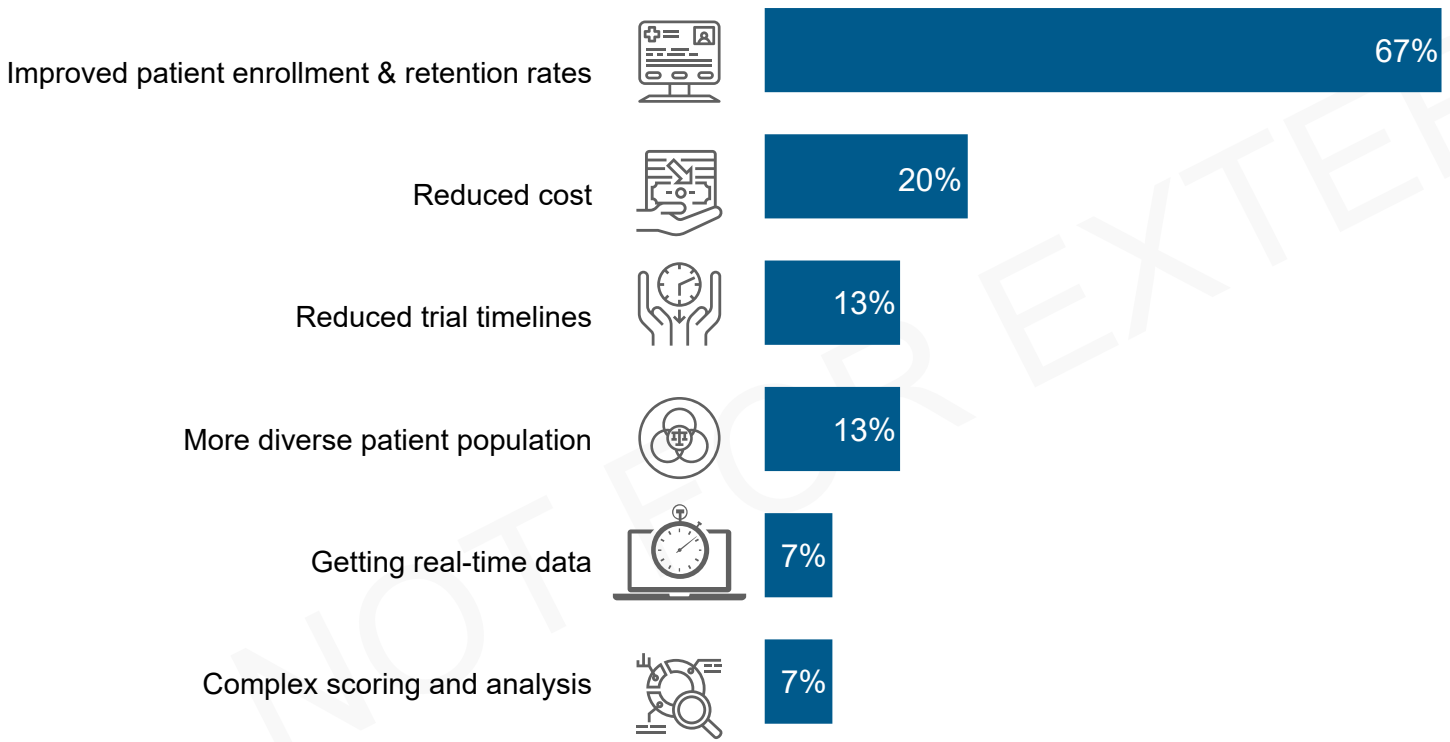
DCTs enhance patient experience



Perceived benefits of DCT adoption

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

Major benefits of DCT adoption according to buyers
2021, % 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)

Elements of a patient-centric DCT platform

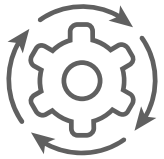
When enterprises say patient experience, there are multiple lenses. The underlying expectations are common – keep it simple for the patient

User-friendly interface

the User Interface (UI) of DCT applications and devices must be simple, yet effective. They must provide clear instructions and display only relevant and concise content.

Easy to set up

patients should have an easy time setting up a wearable, sensor, or application. It should be intuitive even to an average user with limited exposure to digital devices.



Smooth operation

the applications or devices should not pester patients with unnecessary notifications, malfunctions, or failures that would cause unwanted frustrations, resulting in reduced patient engagement.

Robust education and training

patients must be educated on how to enroll themselves for the trial, schedule appointments, feed in data, and get important information about their health and the trial.

Multilingual app and support

the devices or applications used should provide instructions and information in the commonly used languages across the world.

55% of enterprise buyers have stated that showcasing a patient-centric platform is their topmost expectation from a DCT vendor

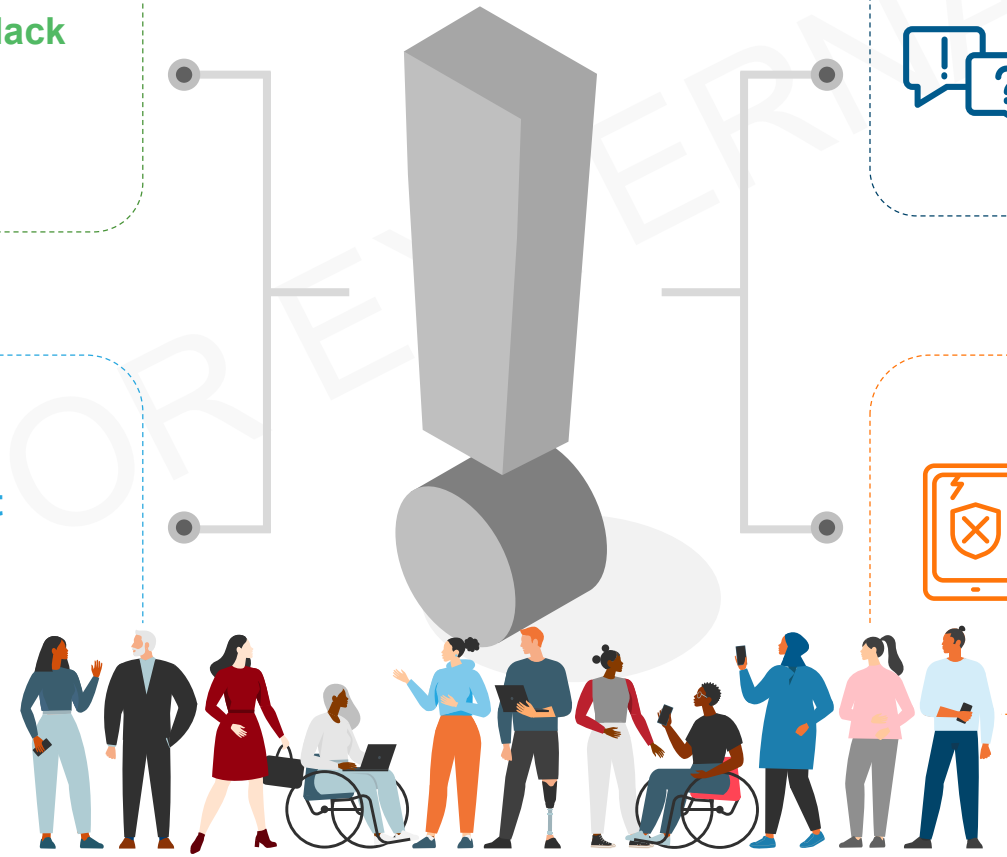
Source: Everest Group DCT buyer interviews (2021)

Patient-facing challenges

Patients face multiple challenges while using DCT apps, which result 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, unplanned user session logging out issues

Source: Everest Group (2021)

Initiatives aimed at improving the patient experience will result in improved engagement and retention rates for DCTs

Awareness

spread information about the ongoing and upcoming clinical trials and the ease of using digital technologies to participate in them (via social media, newsroom, public releases, etc.)

Increasing patient touchpoints

ensure monthly calls or visits by a home-care nurse/physician to motivate patients and give some scope for face-to-face interaction between patients and healthcare executives

Periodic updates and communication

provide regular updates about the research, drug performance, and rate of improvement in the form of lay summaries to enhance patient interest and engagement

Feedback from patients

take regular feedback from patients and include their inputs to improve the design of the patient-centric DCT platform

Education and training

educate the patients on how to use the technology, mobile application, devices, and wearables. Use follow-up calls or virtual connect options to ensure proper patient enablement

Data challenges with the DCT adoption

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

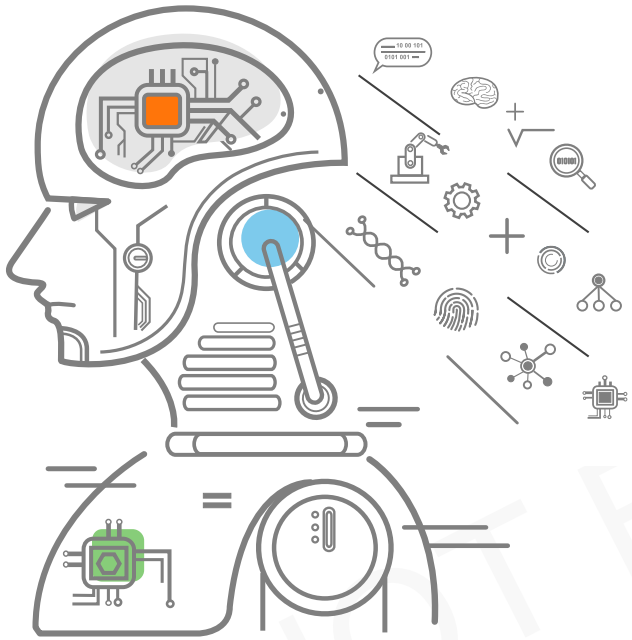
Challenges with managing data in DCTs

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

Source: Everest Group (2021)

Potential of Artificial Intelligence adoption in DCTs

AI has the potential to be used at all stages of clinical trials right from trial planning and design to patient engagement and medication adherence



Patient recruitment and enrollment: AI-enabled technologies can enhance patient selection and trial effectiveness, reducing heterogeneity in trials. Advanced digital technologies will allow data mining and analyze data coming from multiple sources, facilitating sponsors/CROs to select patients who would respond better and have measurable clinical endpoints

Patient monitoring: AI algorithms along with wearables and sensors can continuously monitor patients, automate data collection, and gather real-time data from patients

Medication adherence: AI technologies are helping CROs and sponsors to increase adherence (via video data capture, facial recognition, etc.) and compliance. AI can predict early drop out symptoms, giving opportunities for patient retention

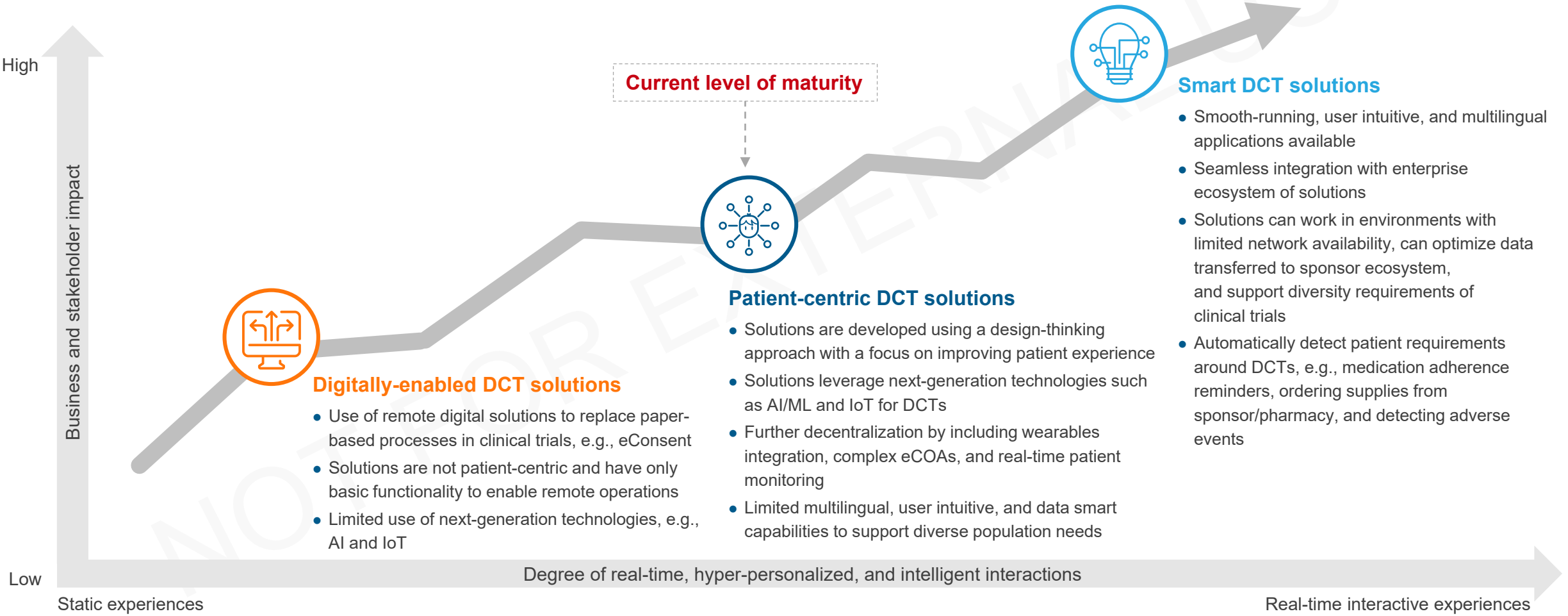
Patient engagement: AI-enabled chatbots can provide patients an omnichannel experience through a conversational application, thereby engaging effectively with patients. Chatbots can be used to collect data, allow patients to report health concerns, schedule appointments, and respond to queries

Clinical trial analytics: AI systems can help in translating and generating insights from the data generated during clinical trials. These can be used to design patient-centric solutions and to have informed conversation with patients. At the same time, powerful analytic tools and visualization would help sponsors get the best results from the trial activities

Source: Everest Group (2021)

Evolution of DCT

Current suite of solutions needs to evolve from being patient-centric to becoming smart DCT solutions



Source: Everest Group (2021)

03

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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