Everest Group®

Life Sciences Decentralized Clinical Trial Platforms State of the Market 2023

March 2023

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Introduction and overview

- Research methodology
- Introduction
- Objective of the SOTM report
- Summary of key message

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

01

Robust definitions and frameworks

Function specific pyramid, Total Value Equation (TVE), PEAK Matrix®, and market maturity

02

Primary sources of information

Annual contractual and operational RFIs, 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 providers

Proprietary contractual database of IT services (ITS) contract (updated annually)

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

Dedicated team for healthcare 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, providers, technology providers, and industry associations

Introduction

Decentralized Clinical Trials (DCTs) include collecting data through a patient's sensors or remote monitoring devices without the need to visit a site. These trials can deliver many benefits to pharmaceutical companies including cost savings, better patient recruitment and retention, flexibility in operation, and improved data quality. Before the COVID-19 pandemic, although the technology and literature to support DCTs existed, there were only a few pilots being conducted as enterprises grappled with regulatory uncertainties, upfront capital investment in sensors and products, and limited functionalities to decentralize clinical trials. The increasing need for remote patient- and site-centric trials increased the investments in DCTs. Desired patient experience, smooth onboarding of the diverse patient population, seamless technological execution during trials, and hassle-free logistics at the site have been the focus for enterprises. The momentum is expected to accelerate as we move beyond 2022, indicating that DCTs are here for the long term. Technological advancements (cloud, AI/ML, NLP, etc.), innovative business models, increased wearables support, FDA's push to the industry to adopt DCT, and a holistic approach to clinical trials have proliferated the landscape.

Enterprises have accelerated their plans toward DCT adoption by investing in enterprise-level deals, 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 looks at:

- DCT adoption trends and market dynamics
- DCT platform provider landscape
- Enterprise view of DCT providers
- ESG initiatives and emerging technology opportunities in the industry

Scope of this report

Geography
Global

Industry
Life sciences (biopharmaceuticals, medical devices, and contract research organizations)

Provider Offerings
Decentralized clinical trial platform

Summary of key messages

DCT adoption trends and market dynamics	• eCOA/ePRO, eConsent, and telemedicine experience high demand as they enable remote care and real-time data collection from patients • Patient concierge and engagement with drug and device provisioning have seen high adoption across trials, while other services are picking up at a lower rate due to a lack of offerings from the providers • North America and Europe are witnessing the maximum adoption of DCT; however, APAC countries have gained importance in recent times • Neurology, Oncology, and infectious diseases trials have seen the maximum adoption of decentralization
DCT platform provider landscape	• Enterprises tend to prefer a partner-led approach over full-stack solutions as the former offers a comprehensive suite of matured technology solutions along with auxiliary services • Leadership development, product enhancement, enterprise deals, geographic expansion, and inorganic growth have been the focus of DCT platform providers
Enterprise view of DCT providers	• Demand-side interactions indicate an increasing preference to adopt an end-to-end DCT solution • Large enterprises look at the unified platform experience, and leadership team while small & midsize enterprises consider cost and flexibility as important KPIs for platform selection • Clinical data captured during trials used for subsequent analytics and patient recruitment speed see high value in terms of measuring the return on investment made in DCT solution
ESG initiatives and emerging technology opportunities in the industry	• DCT is a boon for platform providers who need not spend an extra penny on the carbon footprint, improve diversity in clinical trials, and comply with regulations • Voice analytics and behavioral analytics including medication identification and facial recognition seem to modernize clinical trials; study feasibility, compliance, and predictive analytics remain as the matured opportunities • Retail pharmacy, wearable technology for connected devices, and diversity inclusion are some of the emerging themes of the decentralized clinical trials industry • Current suite of solutions needs to evolve from being patient-centric to becoming broader stakeholder-centric

02

Everest Group DCT PEAK Matrix® Assessment 2022

- Everest Group's view of end-to-end DCT platform
- DCT PEAK Matrix Result
- Buyer perception of DCT platform providers capabilities

Scope of Decentralized Clinical Trials Platforms PEAK Matrix® Assessment 2022

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 costs and timeline

Scope of assessment

Mode of conduct	
Completely virtual	Hybrid (digitally-enabled trials)

Core modules (technology products)					
Trial participant recruitment (screening and enrollment)	eConsent	Wearable technology with BYOD integration + Remote patient monitoring	Medication adherence	Televisit	eCOA/ePRO

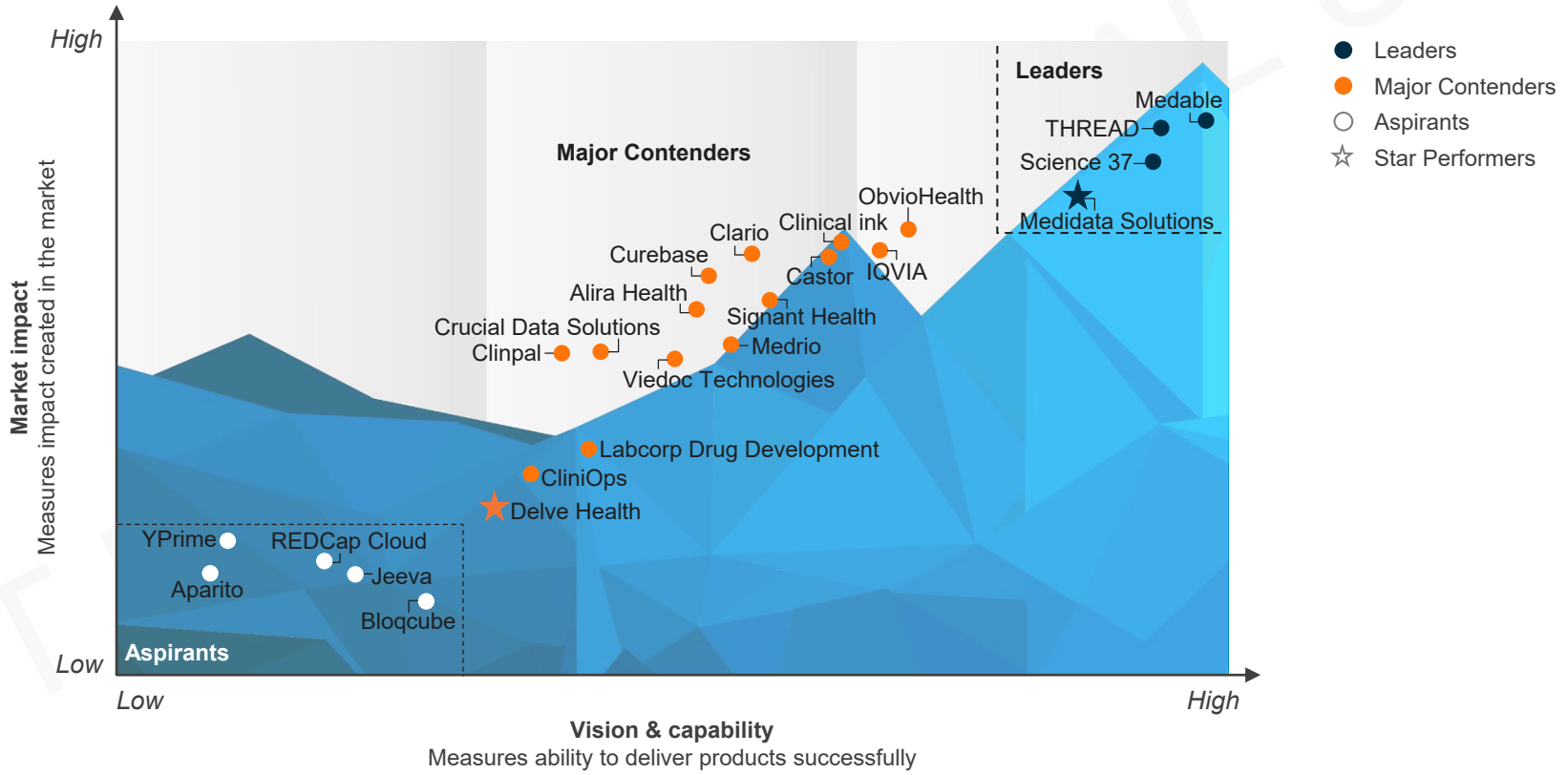
DCT platform capabilities				
Unified data platform	Integration of devices and workflows with existing clinical development systems	User training and support	Data security, privacy, and compliance	RWD collection and analysis
Site support and enablement	Single sign-on, user-friendly UI, smooth operations, multilingual offering, and support	Collaboration workflows for all stakeholders	Enterprise-wide scalability (geography and therapeutic areas)	DCT analytics (KPIs, next-best actions, and actionable insights)
Patient engagement (information exchange, feedback, training, and support)				

Enabling services (in-house/partnerships)				
Home nursing services	Patient concierge services	Medical record review services	Drug and device provisioning	Remote CRA

Inclusion criteria for the assessment: Platform providers offering at least **eCOA/ePRO, eConsent, and televisit capabilities** (out of the core modules) will qualify for this assessment

Everest Group DCT PEAK Matrix Assessment Result

Everest Group Decentralized Clinical Trial Platforms PEAK Matrix® Assessment 2022[1,2]



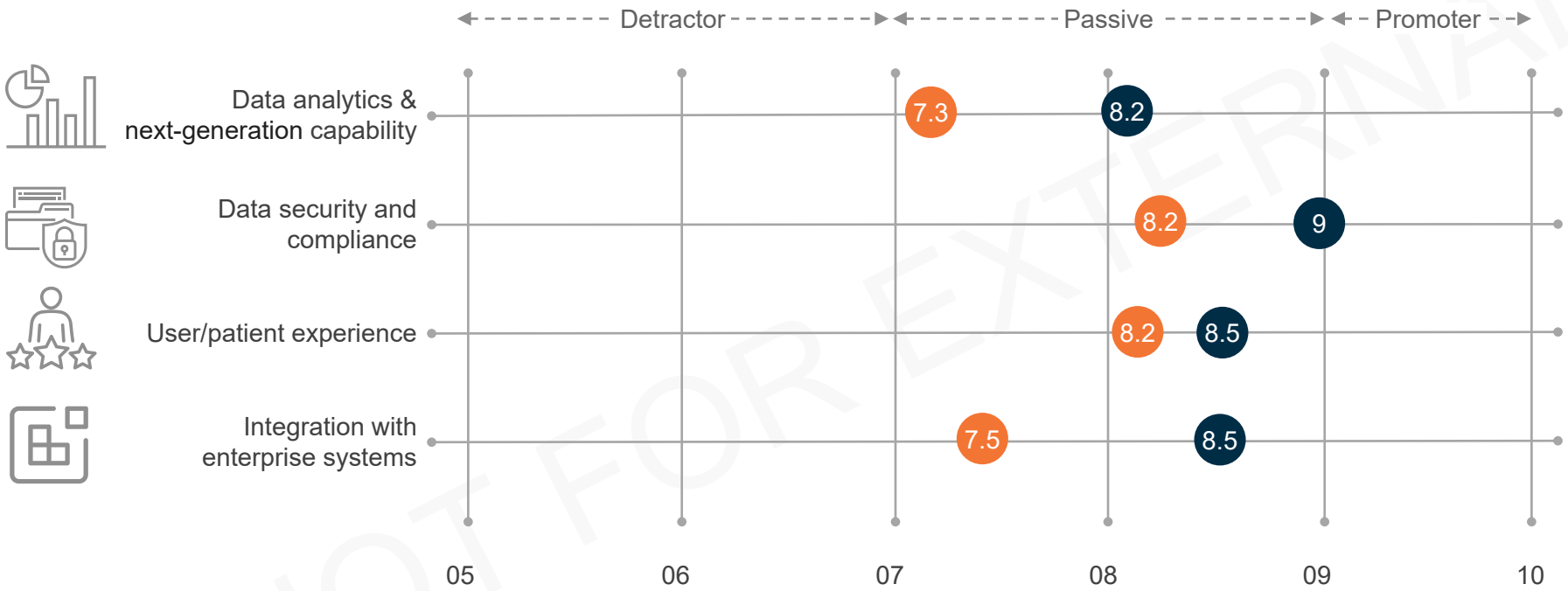
1 Assessments for Aparito, IQVIA, REDCap Cloud, and YPrime excludes platform provider inputs and are based on Everest Group's proprietary Transaction Intelligence (TI) database, platform providers' public disclosures, and Everest Group's interactions with decentralized clinical trial platform buyers

2 Analysis for Clinpal is based on capabilities before eClinicalHealth got acquired by Cambridge Cognition

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

Buyer reference feedback and scores | platform capabilities (page 1 of 2)

Buyer perception of provider's DCT platform capabilities
2022-23; ratings on a scale of 1 to 10

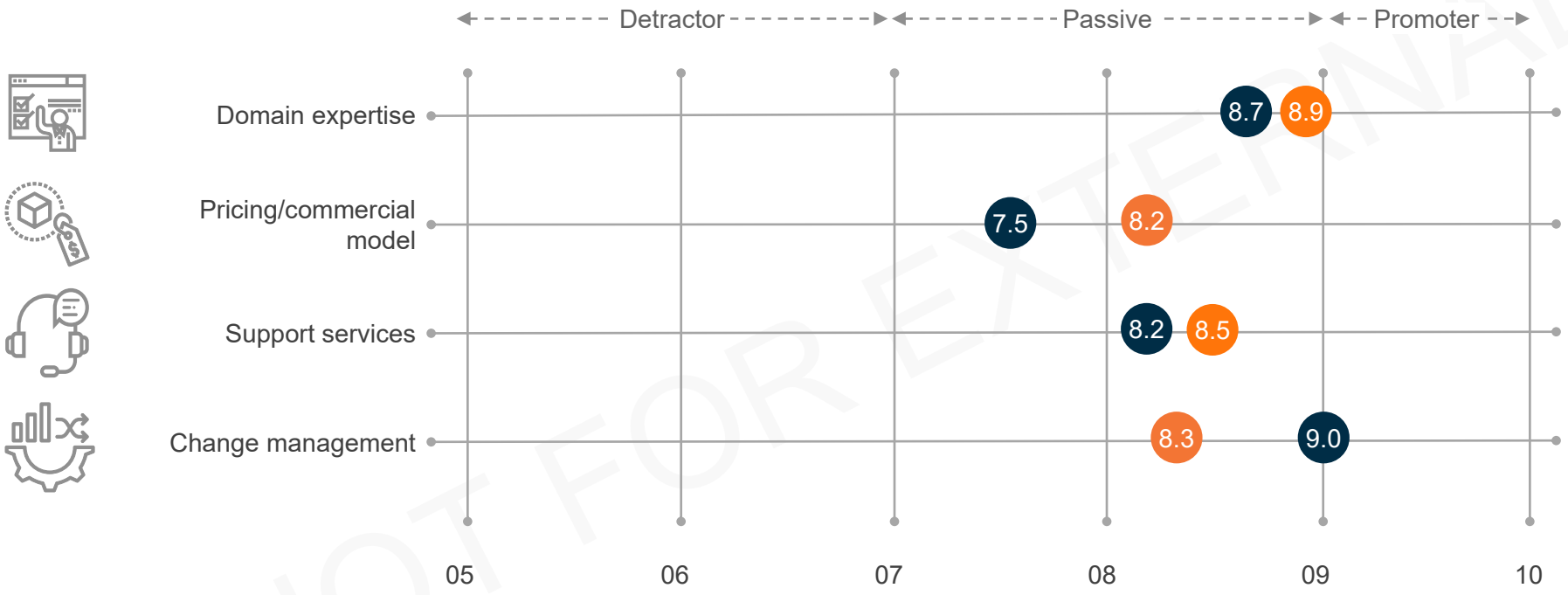


- Leaders take an ecosystem approach to offer a complete suite of DCT solutions both core platform modules and auxiliary services (both in-house and via partnerships) such as patient concierge & engagement, home nursing, and drug and device provisioning
- Leaders focus on holistic DCT consulting (market education, change management, trainings, and certifications)
- Leaders focus on RWD collection and compliance with data security and state-specific regulations
- Leaders provide inbuilt APIs for integrating with existing clinical development platforms and solutions

1 THREAD, Medable, Science 37, Medidata Solutions
2 Castor, Clinical Ink, IQVIA, ObvioHealth
Source: Everest Group (2023)

Buyer reference feedback and scores | platform capabilities (page 2 of 2)

Buyer perception of provider's DCT platform capabilities
2022-23; ratings on a scale of 1 to 10



- DCT platform providers are prioritizing the improvement of their technical skills, whereas traditional CROs excel in domain expertise as a result of their extensive involvement in clinical trials
- Major contenders and some of the eCOA/ePRO heritage providers offer offers modular solutions and price their products separately
- Leaders enable DCT solutions by providing the training, video content, and all the required implementation assistance throughout the process

1 THREAD, Medable, Science 37, Medidata Solutions
2 Castor, Clinical Ink, IQVIA, ObvioHealth
Source: Everest Group (2023)

03

DCT market trends and dynamics

- DCT adoption trends
  - Core module adoption
  - Auxiliary services adoption
  - Geographic region wise adoption
  - Therapeutic area (TA) wise adoption
- DCT deal sizes
- Drivers and challenges with DCT adoption
- Regulators' role in DCT adoption

Enhancing patient experience might be the major benefit of DCTs; however, patients are not the only stakeholder in the game

Elements of consideration for respective categories of audience

Human

- Enhanced patient engagement
- Improved drop-out rates
- Enrolled diverse patient population into the trials

Sites

- Hassle-free site engagement
- Unified platform experience for running the DCT
- Augmenting patient-physician interactions through technology

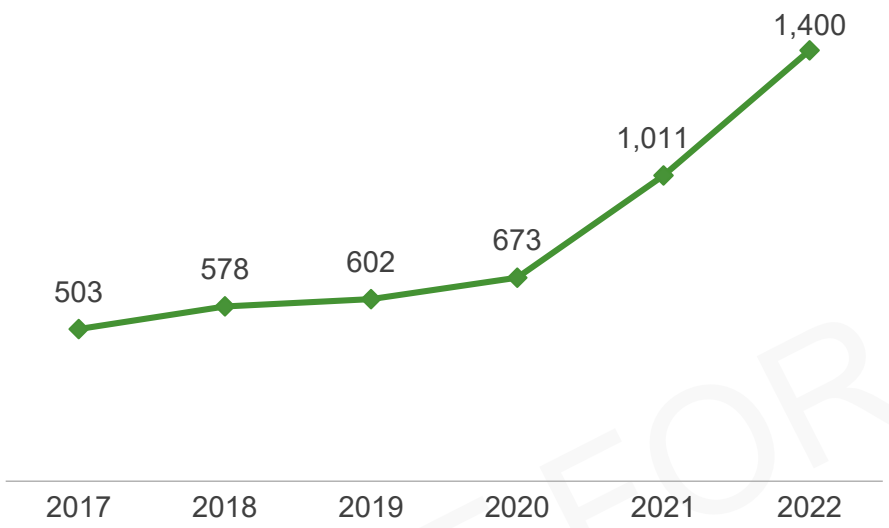
Sponsors

- DCT performance on various KPIs
- Trials timelines and efficiency
- Implementation across TAs and geographies

DCT adoption over the years

DCT adoption is seeing an uptick as a greater number of trials are having some component of decentralization; use of eCOA/ePRO and eConsent have been widely used in recent time

Initiated drug trials involving virtual or decentralized components[1]
2017-22, number of trials



A significant number of trials with a decentralized and/or virtual component were conducted in 2022, representing over 38% increase from 2021

What percentage of your trial portfolio is/will be decentralized/hybrid in nature?[2]

Present day	In the coming two years	In the next five years
20-25%	~ 40%	80-90%

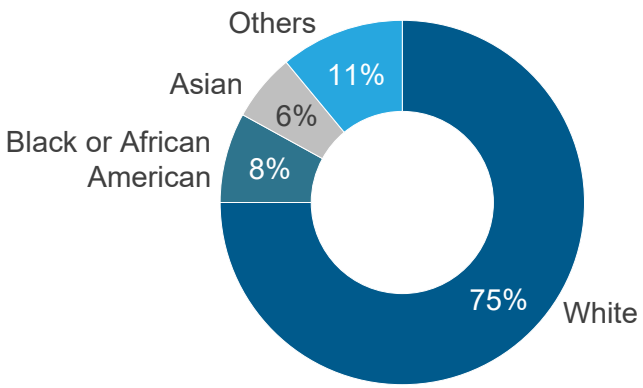
- Almost 80-90% of buyers mention that every trial in the future will have some decentralized component such as eCOA/ePROs and eConsent
- Enterprises look at digitizing the trials and reducing burdens on site and patients, pushing trials to be decentralized

1 GlobalData (2022), & Clinical Trials Arena (2022), includes trials identified as mentioning decentralized/virtual components in clinical registry protocols
2 Everest Group DCT buyer interviews (2022)

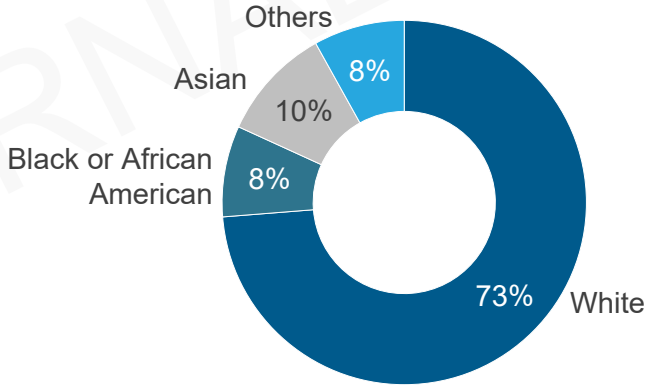
Trial participation by population group

Diversity inclusion seems to be a major challenge in clinical trials due physical, technological and cultural barriers

Participation in clinical trials by subpopulation
2020 (Jan 1, 2020 – Dec 31, 2020); percentage
100% = 32,000



Participation in clinical trials by subpopulation
2021 (Jan 1, 2021 – Dec 31, 2021); percentage
100% = 30,000



Diversity challenge

Diversity in the patient population is still a challenge DCT providers need to solve. There are certain barriers that are to be overcome clinical trials:

- Physical barrier – Lack of transportation, inability to take time off work and lack of insurance coverage for trial-related costs are some of the access barriers faced by many individuals
- Technology barrier – Underrepresented communities don't have knowledge about operating digital tools and devices due to digital illiteracy
- Cultural Barriers – Cultural barriers, such as language differences, beliefs, and values, can also make it difficult to recruit and retain diverse populations

Source: FDA Drug Trials Snapshots Report 2019, 2020, and 2021. The report for 2022 is yet to be published

The government's push by mandating the representation of diverse patient populations and DCT providers' initiatives help tackle the diversity inclusion challenge in clinical trials

Regulatory bodies taking positive steps

U.S. FOOD & DRUG ADMINISTRATION

DEPICT act 2022:

This acts requires Investigational New Drug (IND) and Investigational Device Exemption (IDE) applicants to report clinical trial enrollment targets by demographic subgroup, including age, race, ethnicity, and sex, and provide a rationale for those targets

DIVERSE trials act 2021:

This act pushes drug or device manufacturers to provide, subject to some limits, free digital health technologies and other remuneration to patients in approved clinical trials, community education support

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Recommendation paper:

This recommendation paper scope out decentralized elements in clinical trials including diversity of the patient population

Clinical trial regulation act:

This act explicitly asks for justification of any non-representative procedures in the clinical trials, and non-represented sub-groups of the population

DCT platform providers help reach a diverse population

MEDIDATA

- Site selection with diverse backgrounds using analytics
- Partnership with Circuit Clinical for the diverse site network

Medable

- Extensive collaboration with site network for site requirements feedback
- Invested in site network council to elevate diversity in DCT trials

DCT providers addressing diversity challenge

THREAD

Onboarded patient ambassadors, advocates, and community leaders through a partnership with CureClick for diver patient population outsourcing

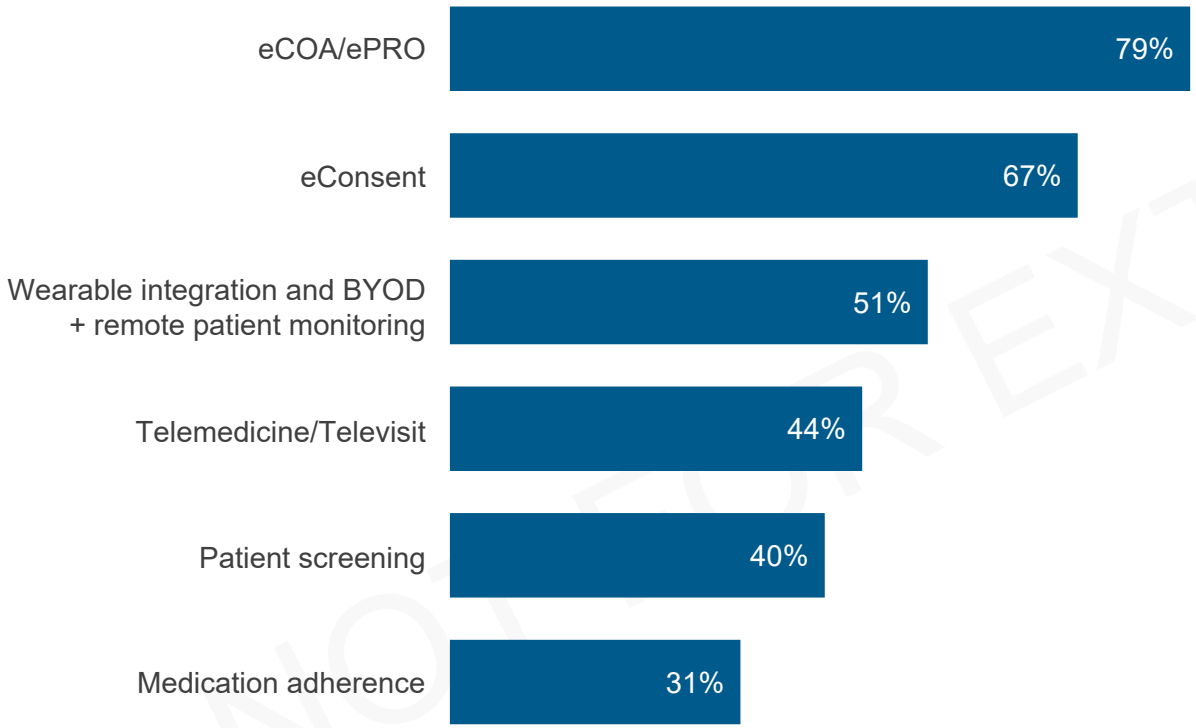
Other initiatives

- DCT providers adopting targeted social media campaigns for reaching a diverse population
- Educational content in various languages

Demand trends | core modules

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

Core modules used in decentralized trials[1]
2023; percentage of adoption



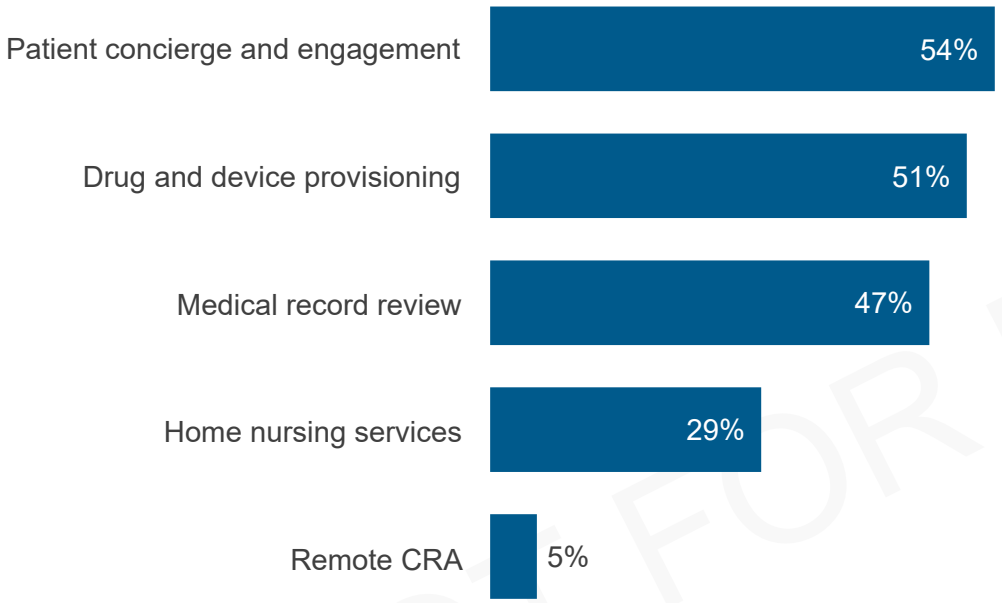
- Ease of data capture, easy-to-track and monitor trials, and keeping a tab on patient progress are driving the growth of the eCOA/ePRO segment enabling paperless record-keeping, and real-time data collection
- The pandemic, coupled with technology maturity, and increased adoption of digital consenting has increased the demand for eConsent solutions at a higher rate, resulting in accelerated patient enrolment, reduced consent errors and site burden, and improved patient experience
- The adoption of wearables and medical-grade devices has enabled remote patient monitoring with real-time data capture. Coupled with AR/VR technology, patients are given clinic-like experience from the comfort of their homes
- With factors such as increasing access to patients for sponsors and CROs, reducing site visits, and improving data quality with real-time data collection, telemedicine has gained traction in recent years
- Currently, medication adherence adoption rates are low, and the most popular form of monitoring is through push notifications that remind patients to take their medication. However, as the demand for personalized care increases and the population continues to age, there is a growing need to improve medication adherence, which is likely to lead to higher adoption rates

1 A single trial might require multiple technology products
Source: Everest Group analysis (2023) of publicly available and enterprise-stated case studies

Demand trends | auxiliary support services

Patient concierge and engagement with drug and device provisioning have seen high adoption across trials, while other services are picking up at lower rates due to lack of offerings from the providers

Auxiliary support services used in decentralized trials[1]
2023; percentage of adoption



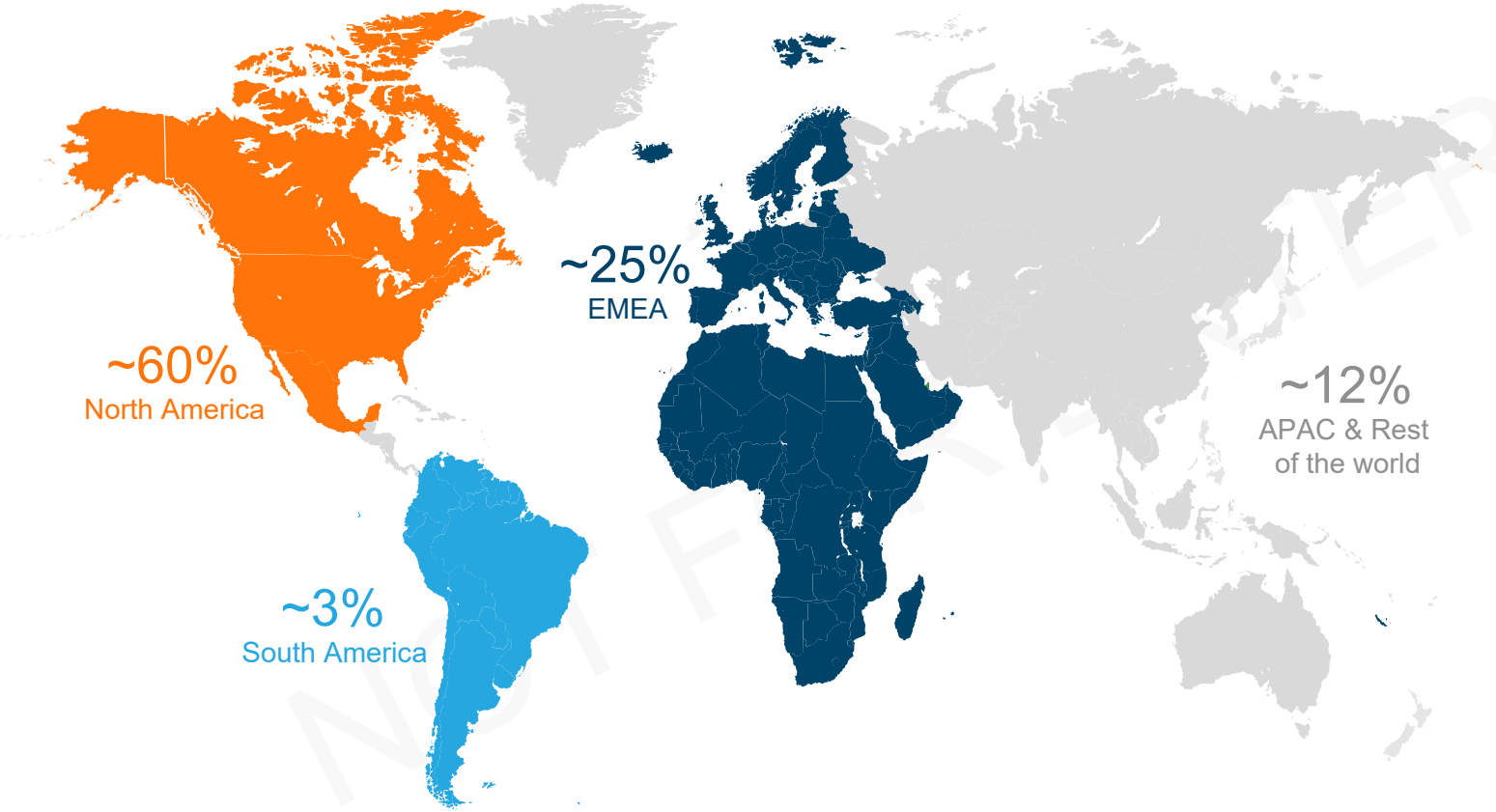
- Patient concierge services along with voice-activated devices, gamification, and rewards, help in improving patient engagement resulting in retaining them; They also aids in reducing the burden on nurses on site and are hence adopted by many DCT providers as an auxiliary service to offer
- DCT platforms allow managing drug and device inventory, dispensing, and tracking, as well as tools for ensuring participant safety and data integrity pushing the adoption
- DCT providers are partnering with various entities such as CROs and training institutes to offer these auxiliary services along with technical capabilities of the platform to provide end-to-end solutions
- Medical record review is growing for improving the quality of data collected from the patients and enhancing the patient experience but at a lower rate

1 A single trial might require multiple technology products
Source: Everest Group analysis (2023) of publicly available and enterprise-stated case studies

DCT adoption across geographies

North America and Europe are witnessing maximum adoption of DCT; however, APAC countries have gained importance in recent times

Industry sponsored decentralized trials by geography (patient locations)[1]
2023; percentage of adoption



North America and Europe
The increased usage of digital clinical trials in North America and Europe can be attributed to technological progress, widespread digital skills, the widespread use of wearables, and the support of regulatory bodies such as the FDA, EMA, and country-specific regulators.

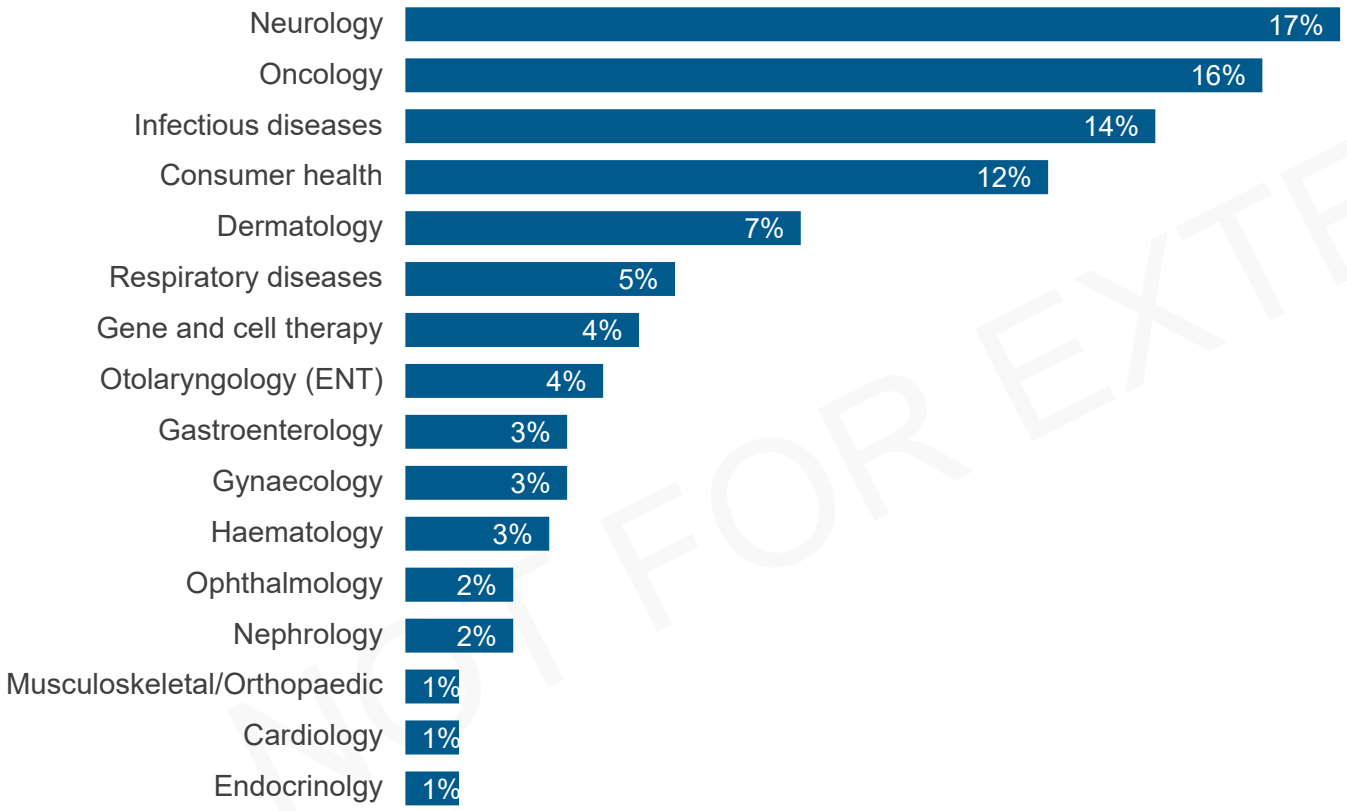
APAC
The APAC region is conservative and highly cost sensitive. The DCT paradigm is new, and as a result, there is hesitancy owing to a lack of knowledge on how to effectively and ethically implement decentralized trials. But it is seeing an increase in healthcare spending (forecasted to reach US$2.3 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. DCT providers such as Sciences 37, ObvioHealth are expanding their APAC presence by partnering with CROs and investors.

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

DCT adoption across therapy areas

Neurology, Oncology, and Infectious diseases trials have seen the maximum adoption of decentralization

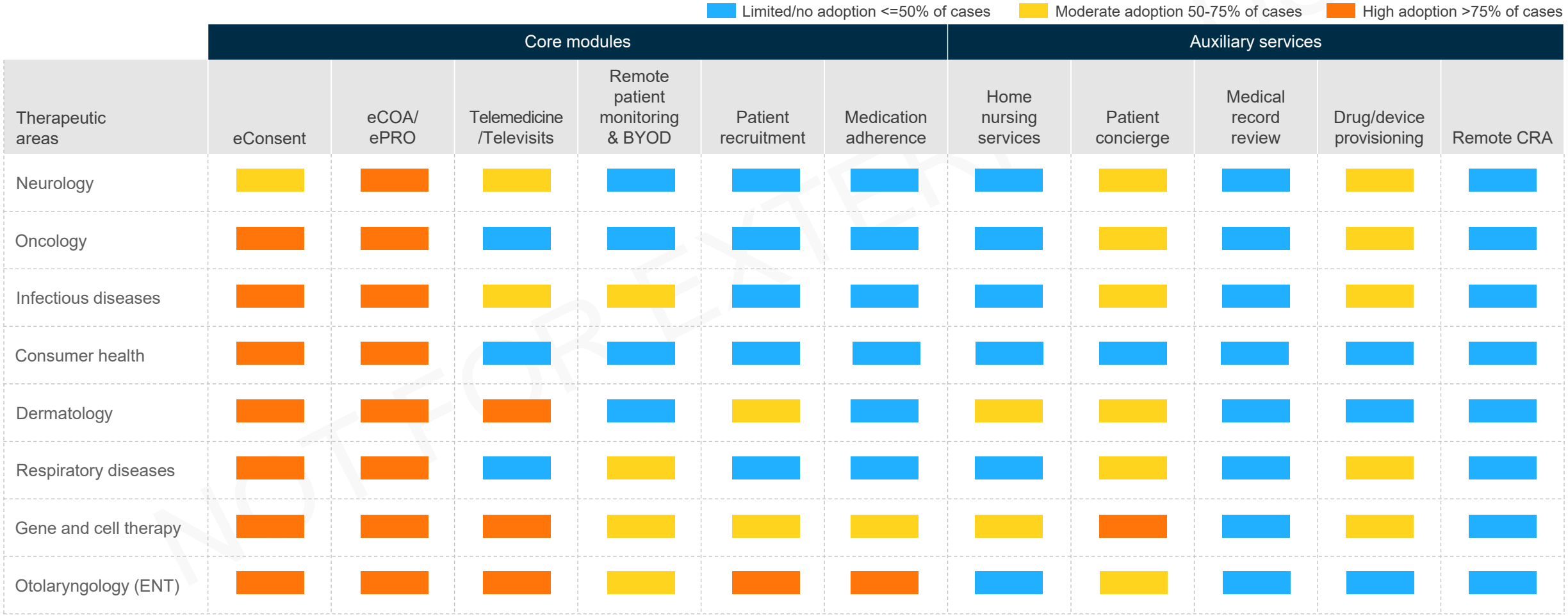
Industry sponsored decentralized trials[1] by therapy area
2023; percentage of adoption



- There has been a surge in depressive disorders, followed by Alzheimer's and other dementias, Parkinson's disease, and multiple sclerosis in developed and developing countries causing a greater number of trials
- Decentralized clinical trials have reduced the complexity of Oncology trials and are able to reduce the prolonged duration of these trials encouraging more studies to adopt DCT
- 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
- Consumer Health challenges containing children, men, and women's health-related areas have been addressed by DCT in recent times. The decentralization of pediatric clinical trials has helped to streamline the overall duration of studies, while also easing the burden on children and their families. Additionally, it has improved the accuracy of dosing and increased medical adherence
- The other therapy areas are now seeing inclination in trial initiations. Trials that were difficult to be initiated in the middle of the pandemic due to focus on creating a vaccine for COVID-19, see attention-from sponsors and investigators

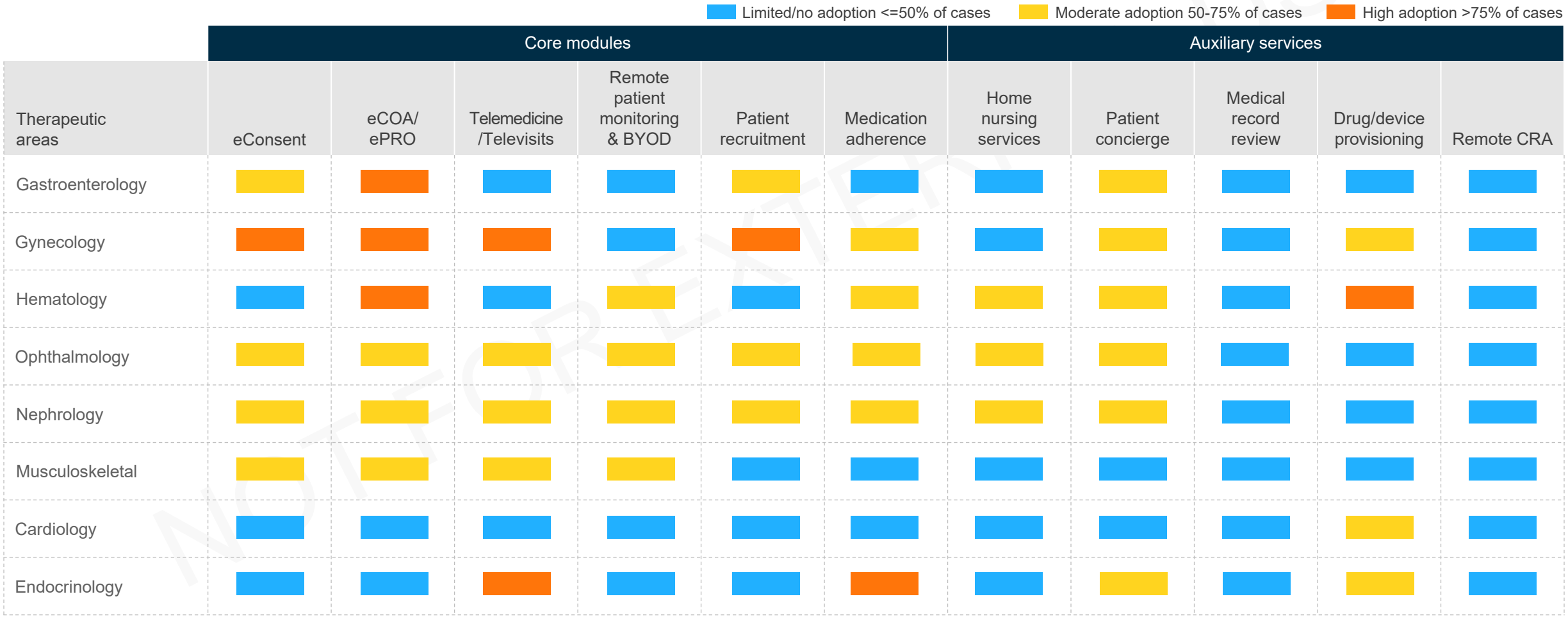
1 Based on Everest Group's analysis of 134 publicly available and enterprise-stated case studies
2 Citeline Trailtrove (2021); IQVIA Institute Report (2021)

DCT core modules and auxiliary services adoption across therapeutic areas (page 1 of 2)



Source: Everest Group's analysis of 134 publicly available and enterprise-stated case studies

DCT core modules and auxiliary services adoption across therapeutic areas (page 2 of 2)



Source: Everest Group's analysis of 134 publicly available and enterprise-stated case studies

Deal sizes for DCTs have increased along with the duration

Deal size for DCTs (in US$ million)

	Minimum	Average	Maximum
2021	0.3	1	>10
2022	0.6	1.4	>10

DCT deals sizes have increased due to:

Complete technology and auxiliary services solution

Capability to conduct global trials, advanced analytics, & change management

Domain expertise, improved stakeholder experience, & enterprise-level deals

Country-specific regulations such as EMA and FDA will push the adoption of DCTs driving the deal sizes up while DCT platform providers need to develop a unified experience for all the stakeholders across geographies.

Source: Everest Group estimates as per RFI inputs (2021 and 2022)

Drivers for growth of decentralized clinical trials

Enhanced stakeholder experience, improved data quality, and a favorable regulatory landscape are driving the growth of the industry

- Regulatory activities – EMA and FDA's positive stance on DCTs encouraging higher adoption
- Improved data quality – focus on real-time data versus point-in-time data bringing valuable insights into clinical trials with applied analytics
- Increased focus on holistic DCT consulting – market education, change management, and training
- Increased push from industry associations (such as DTRA) to focus on standardization and socialization of best practices in DCTs
- DCTs have increased access to clinical trials for patients from underrepresented communities and geographies

Ongoing challenges the industry needs to solve for

Inadequate training, complicated regional regulations, and lack of site readiness pose challenges for the life sciences enterprises to adopt DCTs

Confusion around operationalizing DCTs and lack of training for patient and sponsor education

Increasing scrutiny on patient data protection and privacy mandates

Complicated state-specific regulations regarding the acceptability and validity

Challenges around site readiness and site experience with lack of business case and proven RoI

Financial stability of suppliers – increased scrutiny from investors

Regulators' roles in DCT adoption

Regulatory bodies across the world have taken positive steps; encouraging the adoption of DCTs

U.S. FOOD & DRUG ADMINISTRATION

The FDA has encouraged the use of DCTs since the pandemic and has issued several guidance documents including –

- Diversity plans to improve enrollment of participants from underrepresented racial and ethnic populations in clinical trials
- Advancing oncology decentralized trials
- Advancing efficient and inclusive clinical trials
- Conduct of clinical trials of medical products during the COVID-19 public health emergency

EUROPEAN MEDICINES AGENCY

The EMA has shown positive intent and has supported DCTs for several years –

- Recommendation paper on decentralized elements in clinical trials
- Launched Accelerating Clinical Trials in the EU (ACT EU) initiative in January 2022
- Guidance on clinical trial management during the COVID-19 pandemic

Australian Government – National Health and Medical Research Council

The Australian statutory authority encouraged the use of digital strategies in clinical trials, right since the pandemic –

- COVID-19: guidance on clinical trials for institutions, HRECs, researchers, and sponsors (strongly encourages the use of digital technologies – virtual visits, telehealth, eConsent, and remote monitoring in clinical trials)

PMDA 独立行政法人 医薬品医療機器総合機構 Pharmaceuticals and Medical Devices Agency

The PMDA in Japan hosted a conference in October 2022 on digital tools and methods to facilitate clinical trials in Japan –

- The conference highlighted the benefits and research methodology for DCTs
- There was a mention that highlighted that eConsent will soon become an option in clinical trials
- Discussions on the responsibilities of stakeholders to ensure data reliability

NATIONAL MEDICAL PRODUCTS ADMINISTRATION 国家药品监督管理局

Chinese regulatory landscape started becoming favorable after National Medical Products Administration (NMPA), China joined the ICH.

- The NMPA encourages sponsors to conduct early clinical trials in China or include China early in multiregional clinical trials
- In 2022, the number of Investigational New Drug applications (IND) and New Drug Applications (NDA) approvals in China was the highest in five years

Decentralized trials from regulators' lens

Sponsors, platform providers, and technology providers need to work in cohesion to address challenges faced by regulators before they can further encourage the adoption and simplify guidelines for DCTs

Challenges for the implementation of DCTs

- Insufficient justification for the decentralized elements in the trial protocol (reduction of cost is not considered sufficient)
- Inability of investigators to monitor all outsourced activities – chances of non-compliance by third parties (like home nursing services)
- Recruitment of a skewed patient population – tech-savvy patients with sufficient digital literacy
- Limited validation of novel digital outcome measures
- Concerns regarding data safety, data validation, and data quality

Steps to mitigate the challenges

- Case-by-case justification for the decentralized elements used in trials with their anticipated risks and mitigation measures
- Comprehensive training for patients and third-party associates to ensure adherence to all standards and compliance
- Innovative patient engagement measures to compensate for the face-to-face interactions
- User-intuitive apps and devices to be used for trials so that patients with limited or no tech knowledge can easily operate them
- Investigators should take responsibility and ensure that all personal and sensitive data is secured, all data flow workflows are monitored, and all data collected is stored in a structured manner

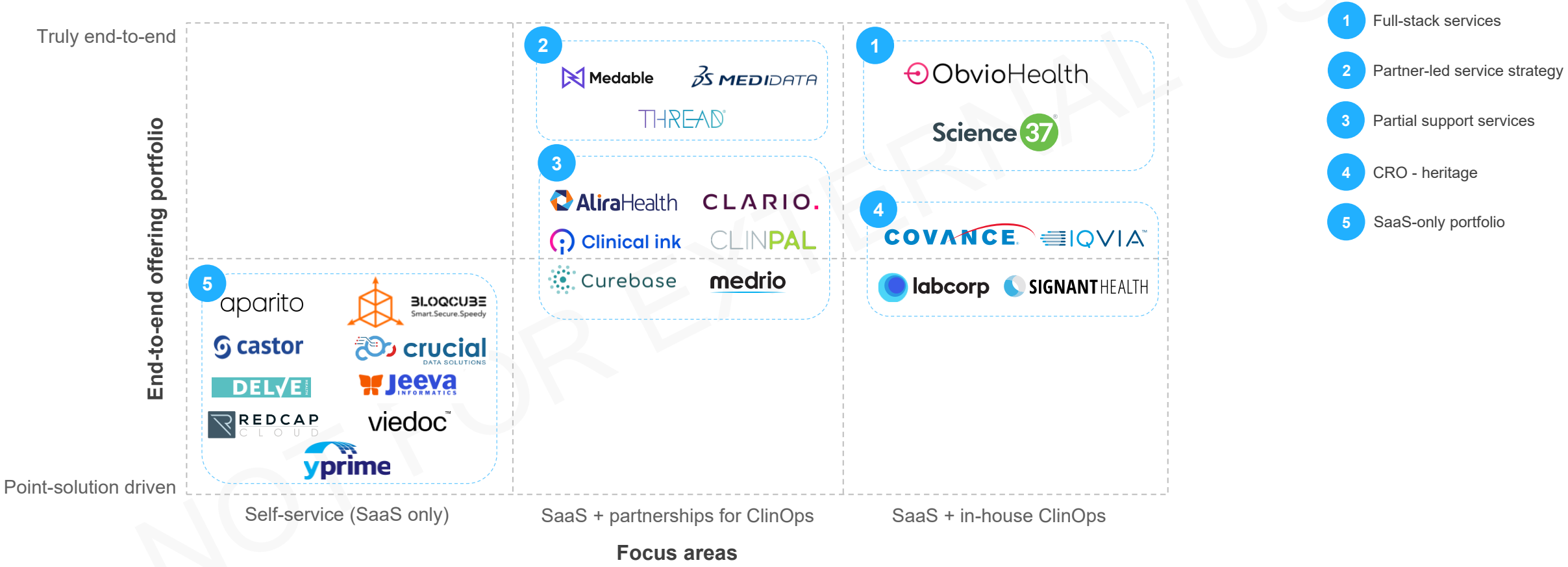
04

DCT platform provider landscape

- DCT platform provider landscape
- Investment priorities for DCT providers
- Shifting focus areas for DCT deployments

DCT platform provider landscape

The DCT provider landscape hosts various categories of providers who bring in different value propositions for running decentralized trials



Source: The providers in each category are randomly placed and do not indicate any relative positioning

DCTs are approaching a partnership strategy

Enterprises tend to prefer a partner-led approach over full-stack solutions as the former offers a comprehensive suite of matured technology solutions along with auxiliary services

Strengths		Areas of improvement
The entire product and services suite (technology products and auxiliary services) under one roof	Full-stack offering 	There exist certain gaps in the delivery of the auxiliary services; pharma enterprises are also curious if scalability can be met based on in-house resources (e.g., home nursing)
Technology maturity and a strong partner ecosystem to offer exhaustive auxiliary support services	Partner-led services 	The solutions are not competitively priced, and are perceived to be priced at a premium; need to focus on regional and local partnerships to solve for client needs
Some of the point solutions/capabilities are technologically superior	Limited services 	There is a clear lack of an end-to-end platform view and a complete set of auxiliary services
The focus is completely on innovation and platform-based approach	SaaS-only offering 	The complete absence of clinical operation services creates unmet needs for buyers
Superior clinical operations services due to years of experience in conducting trials	CRO heritage services 	They charge higher prices as their overall pricing structure includes high program management fees

Investment priorities for DCT providers

Leadership development, product enhancement, enterprise deals, and geographic expansion

Human capital development

- Domain expertise
- Product strategy (design, development, and management)
- User engagement and experience
- Diversity and inclusion

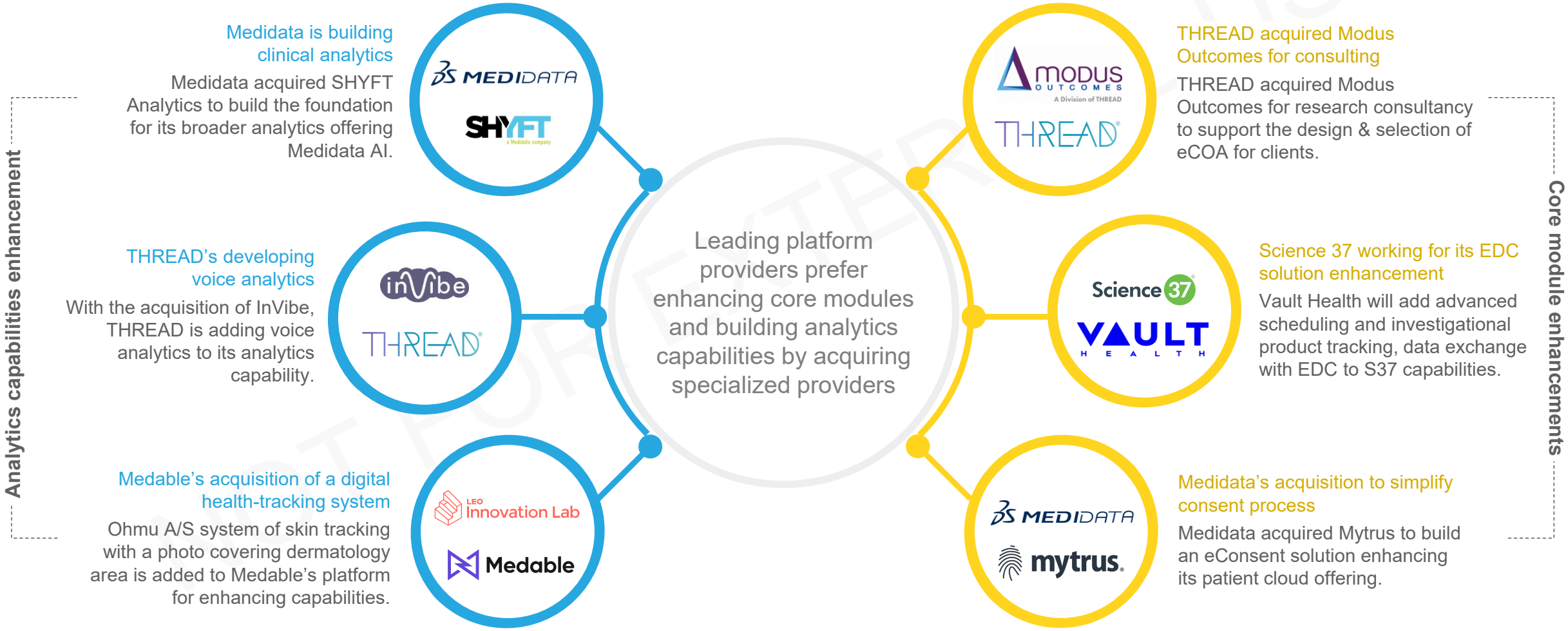
Increase market adoption

- Product enhancement
- Sponsor education and support
- Talent management
- Site network
- Operational efficiency
- Provide a personal site liaison

Scale and expand

- Enterprise-level deals
- Europe and APAC market
- Inorganic growth
- Portfolio of services with a consultative approach by building change management resources (Medable academy and THREAD Design)

Inorganic growth for enhancing capabilities is an approach preferred by most of the platform providers



Shifting focus areas of DCT deployments over the last two years

2021 focus	VS	2022 focus
Piecemeal deployments	**DCT deployments**	Increased focus on enterprise-level deals
Patient centricity	**Major focus**	Stakeholder centricity – patients, sites, and sponsors
Scattered approach – mostly auxiliary services	**Partnerships**	Ecosystem approach – services, technology, and data
Lower focus on data quality	**KPIs**	Higher focus on quality of RWD collected in real-time
Major focus on market education but limited scale around user training	**Consulting**	Increased focus on holistic DCT consulting (market education, change management, and training)

05

Enterprise view of DCT providers

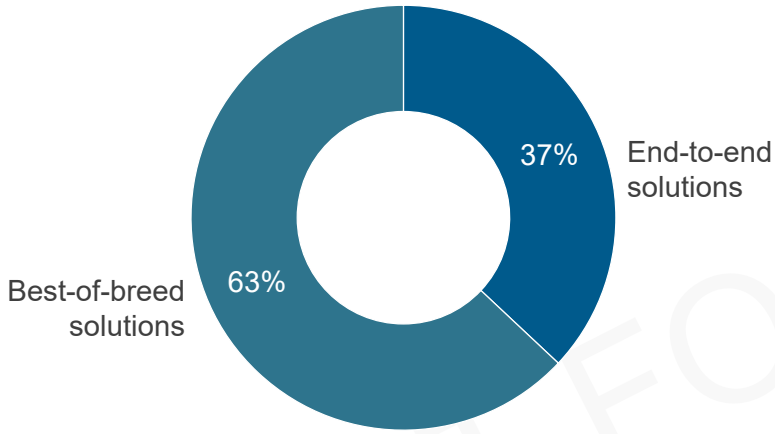
- Enterprise preference for DCT solutions
- Sourcing criteria for DCT solutions
- KPIs to measure RoI in DCTs

End-to-end DCT solutions vs. best-of-breed DCT solutions

Demand-side interactions indicate an increasing preference to adopt an end-to-end DCT solution

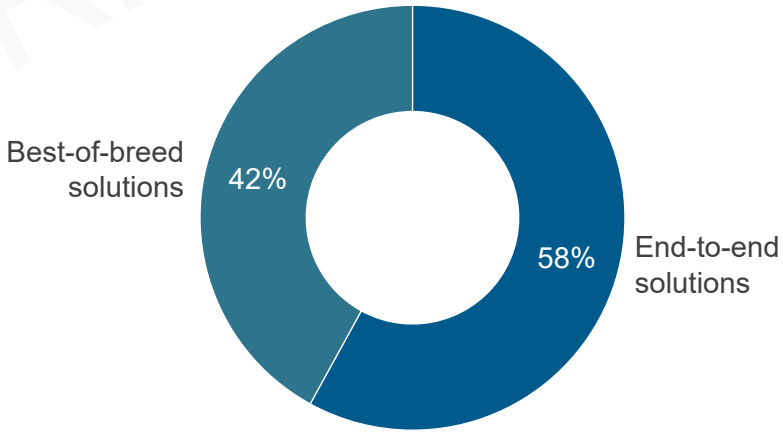
Type of DCT solution opted by clients
2021; N = 27

Assessment 2021



Type of DCT solution opted by clients
2021; N = 40

Assessment 2022



Enterprise-level deals with DCT providers among top pharma companies show the push for the adoption of end-to-end DCT solutions

gsk sanofi

Source: Everest Group estimates as per buyer reference interviews (2021 and 2022)

Buyer voices

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

> We prefer an end-to-end platform approach rather than point solutions or a glorified eCOA. The need of the hour is to realize the value of technology and auxiliary services together.
>
> – Senior Director, Digital Health R&D, a top 10 biopharma company

> The ideal clinical trial provider should possess a comprehensive range of capabilities, including eConsent, Telemedicine, eCOA, and eSource, as well as additional features such as remote monitoring through visits and wearable devices, direct-to-patient shipping services, and the ability to manage home health nursing.
>
> – Head of Clinical Innovation, a top global biopharma company

> DCT platform providers that were previously stand-alone, are now building product suites and becoming an end-to-end platform providers with added support services through partnerships and acquisitions.
>
> – Head of Clinical Operations, a midsize CRO

Sourcing criteria for selecting DCT providers

Large enterprises look at the unified platform experience, and solution maturity while small & midsize enterprises consider cost and responsiveness as important KPIs for platform selection

Key focus areas for biopharma companies from DCT providers
Annual revenue: small: <US$1 billion, mid: US$1-5 billion, large: >US$5 billion

Large biopharma companies	Midsize & small biopharma companies
Unified platform experience	Cost
Solution maturity	Responsiveness
Integration with devices	Flexibility
Leadership team	Ease of use
Data & analytics	Customer support

Source: Everest Group (2023)

KPIs to measure the return on investment in DCTs

Quality of data captured in DCTs, and patient recruitment speed see high value in terms of measuring the return on investment made in DCT solutions

Order of priority for KPIs used to measure the RoI in DCT

1. Quality of clinical trials data captured
2. Patient recruitment speed
3. Patient retention rate
4. Trial timeline and completion
5. Patient and sponsor satisfaction

- With DCT, real-time data cleaning and data validation checks improve the quality of clinical data and are considered the most important KPI to look at the safety and efficacy of the trial and for subsequent analytics for clinical decision-making
- With the arrival of COVID-19, trials needed to be completed in record time, demanding an acceleration in the patient recruitment process
- Patient retention rate becomes an important parameter to evaluate the success of clinical trials as before DCTs, drop-out rates were high, indicating trials did not complete on time or got stopped

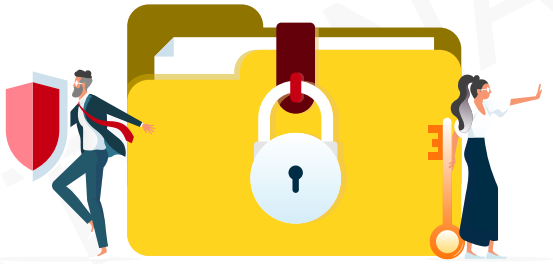
Source: Everest Group (2023)

06

ESG initiatives and emerging technology opportunities in the industry

- ESG initiatives adopted by DCT platform providers
- Technology and analytics themes
- Future of DCTs

DCT allows reducing the carbon footprint of traditional trials, improving access for underserved populations, and enhancing transparency and accountability



Environmental initiatives

- Targeted source data verification for reducing on-site monitoring
- Focus on remote patient monitoring to reduce site-visit saving fuel and travel cost
- Organization with no office space providing a complete virtual solution, BYOD, and direct data capture technology

Social initiatives

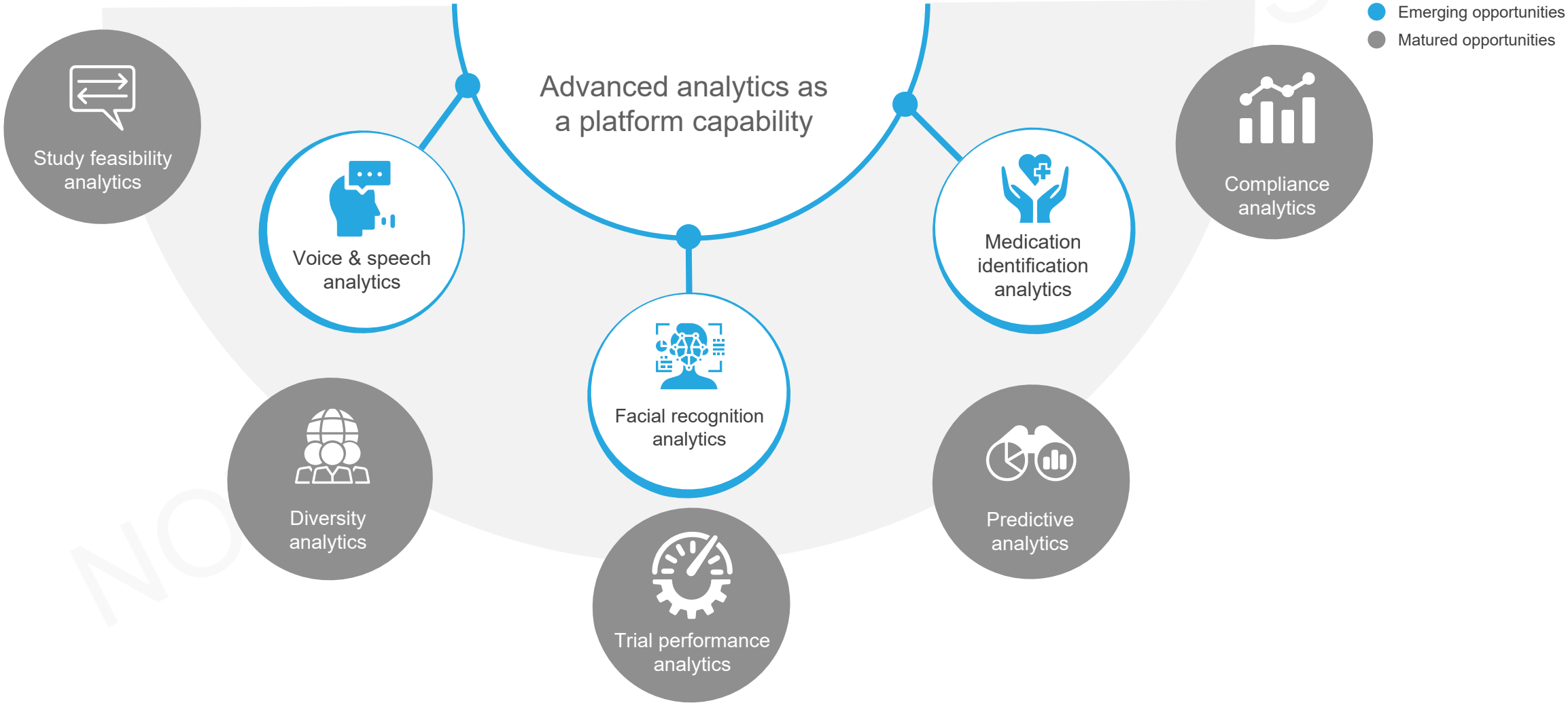
- Establish a committee working for diversity in clinical trials
- Social innovation center for learning & development of stakeholders
- Partnerships with non-profit organizations to provide free access to healthcare advice and support

Governance initiatives

- Unified data protection strategy and dashboarding for governance
- Blockchain-based system with data immutability, integrity, reporting transparency, and disclosures

- Enterprises, CROs, and platform providers are working toward access to care, equality, and data governance with the reduction in patients visits, and the elimination of paper-based systems around operationalizing the DCTs
- DCT providers go completely virtual in terms of administrating the DCTs and enabling solutions for a diverse set of patient populations with established committees looking at inclusion criteria and leveraging reporting transparency disclosures for the governance side of things

Voice analytics and behavioral analytics including medication identification and facial recognition seem to modernize clinical trials; study feasibility, compliance, and predictive analytics remain as the matured opportunities



Emerging themes

Retail pharmacy, wearable technology for connected devices, and diversity inclusion are some of the emerging themes of the decentralized clinical trials industry

Emerging themes in decentralization of care

Wearable technology for connected devices in clinical trials

- Continuous real-time monitoring of patient health
- Increased patient compliance and retention
- Increased patient outcomes with improved data quality

Retail pharmacy is expanding patient access to clinical research

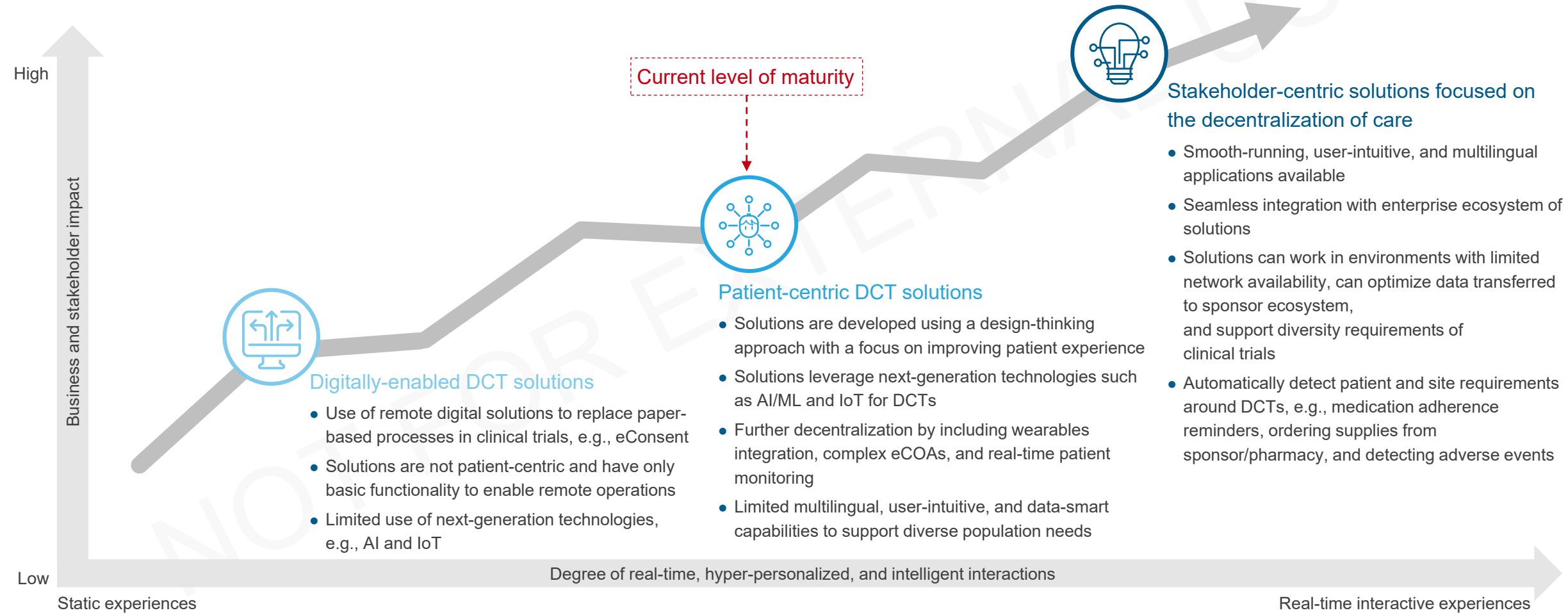
- Improved communication through telepharmacy
- Better consultation through medical therapy management, patient education, and multilingual services platforms
- Trial diversity by identifying and recruiting underrepresented populations, facilitating informed consent, and drug and device provisioning

Diversity and inclusion in clinical trials

- Access and education to the patient population
- Digitally-enabled clinical trial center of excellence
- Fair inclusion score, ESG, & social equity
- Startups using AI/ML, genomic data, and community outreach

Evolution of DCTs

Current suite of solutions needs to evolve from being patient-centric to becoming broader stakeholder-centric solutions



Source: Everest Group (2023)

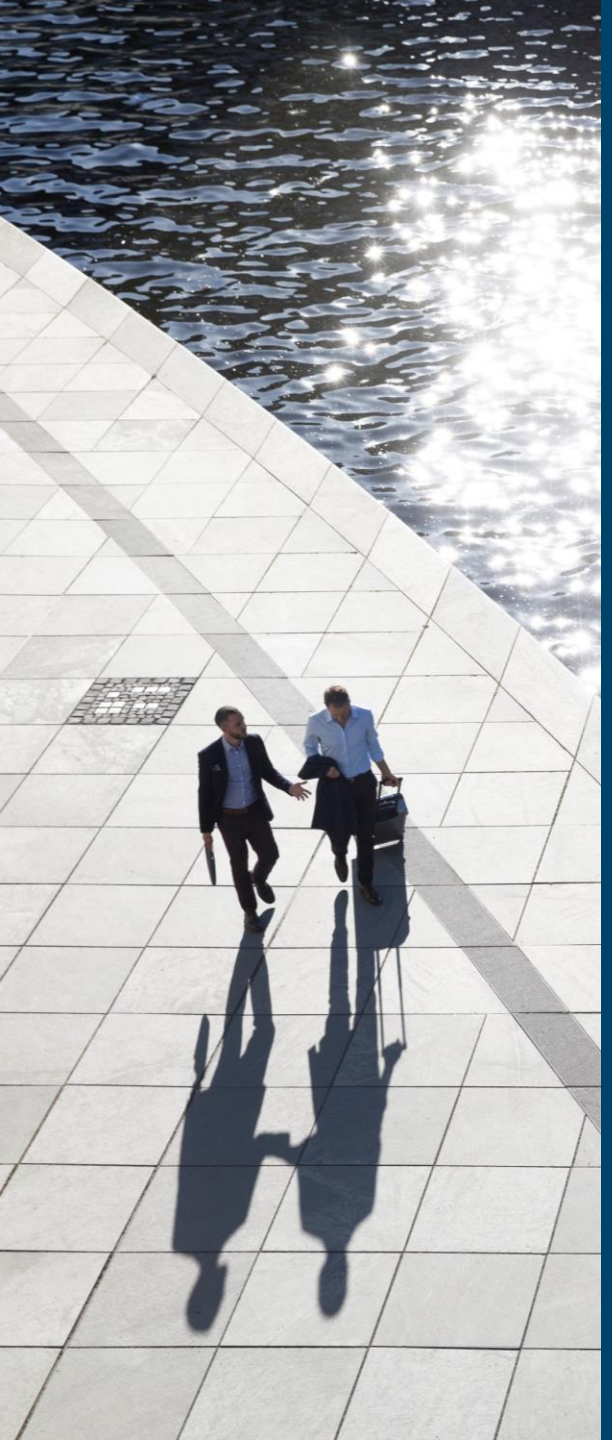
07

Appendix

- Glossary
- Research calendar

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
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
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
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
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 platform providers, 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 platform providers, 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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