Everest Group®

Decentralized Clinical Trial Platforms Provider Compendium 2023

December 2022

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Contents

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01

Introduction and overview

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

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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 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, providers, technology providers, and industry associations

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This report is based on four key sources of proprietary information

- Proprietary database of IT services contracts of major IT service and platform providers, with life science IT services in the scope of work (updated annually)
- The database tracks the following elements of each contract:
  - Buyer details including size and signing region
  - Contract details including provider, contract type, TCV & ACV, 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 providers and platform providers (updated annually)
- The database tracks the following for each service/platform providers:
  - 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/platform providers briefings
  - Vision and strategy
  - Annual performance and future outlook
- Buyer reference interviews, ongoing buyer surveys, and interactions
  - Drivers and challenges for adopting workplace services
  - Assessment of provider performance
  - Emerging priorities
  - Lessons learned and best practices
  - Key strengths and improvement areas
  - Emerging areas of investment

Providers assessed[1,2]

AliraHealth, aparito, BLOQCUBE Smart.Secure.Speedy, MEDIDATA, castor, CLARIO., CliniOps, Clinical ink, CLINPAL, Curebase, crucial DATA SOLUTIONS, DELVE, IQVIA, Jeeva INFORMATICS, labcorp, Medable, medrio, ObvioHealth, REDCAP CLOUD, Science 37, SIGNANT HEALTH, THREAD, viedoc, yprime

1 Assessments for IQVIA, Aparito, YPrime, and REDCap Cloud 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

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Introduction

Decentralized Clinical Trials (DCTs) include collecting data through sensors or remote monitoring devices carried by a patient 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.

The accelerated virtualization in both consumer and trial contexts caused numerous start-ups to come up with innovative and flexible offerings, changing the landscape. DCT platform providers are taking an ecosystem approach to address challenges in the DCT space through various partnerships and M&As. Through co-innovation, continuous product improvement, and market education, DCT platform providers are focusing on increasing trust, speeding up trial timelines, and delivering a smooth experience in running DCTs.

In this report, we assess the capabilities of 24 platform providers specific to the decentralized clinical trial platform. These platform providers are mapped on the Everest Group Decentralized Clinical Trial Platforms PEAK Matrix® Assessment 2023, which is a composite index of a range of distinct metrics related to a provider's capability and market impact.

We focus on:

- The landscape of platform providers for DCTs
- Assessment of the DCT platform providers on several capability and market success-related dimensions

Scope of this report

Geography
Global

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

Provider offerings
Decentralized clinical trial platforms

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Decentralized clinical trial platforms | scope of the research

In this report, Everest Group focuses on platforms that enable decentralized clinical trials

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

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02

Decentralized clinical trial platforms PEAK Matrix® characteristics

- Summary of key messages
- PEAK Matrix framework
- Everest Group PEAK Matrix for decentralized clinical trial platforms
- Platform provider capability summary dashboard
- Characteristics of Leaders, Major Contenders, and Aspirants

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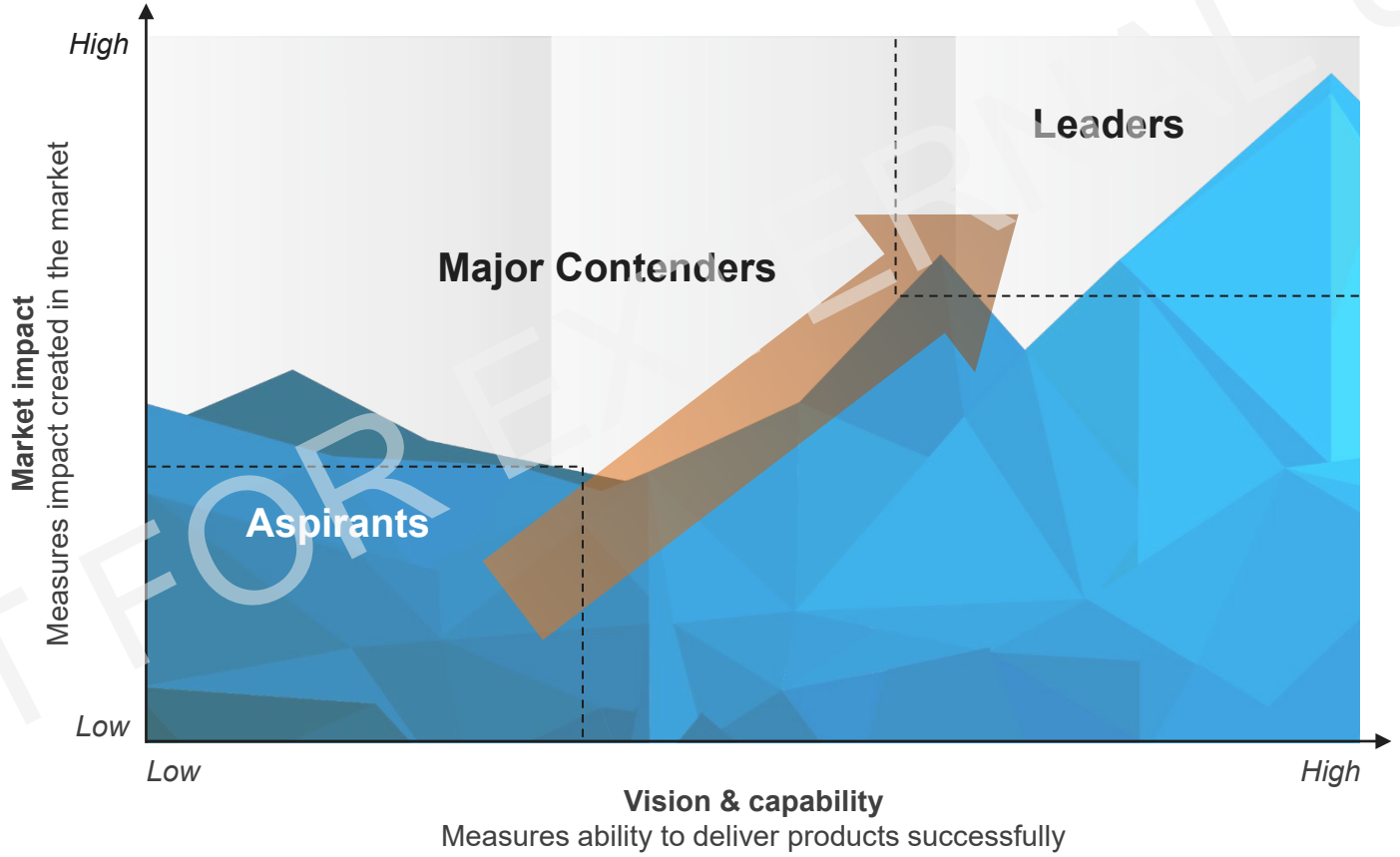
Everest Group PEAK Matrix® is a proprietary framework for assessment of market impact and vision & capability

Everest Group PEAK Matrix



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Products PEAK Matrix® evaluation dimensions

Measures impact created in the market – captured through three subdimensions

Market adoption

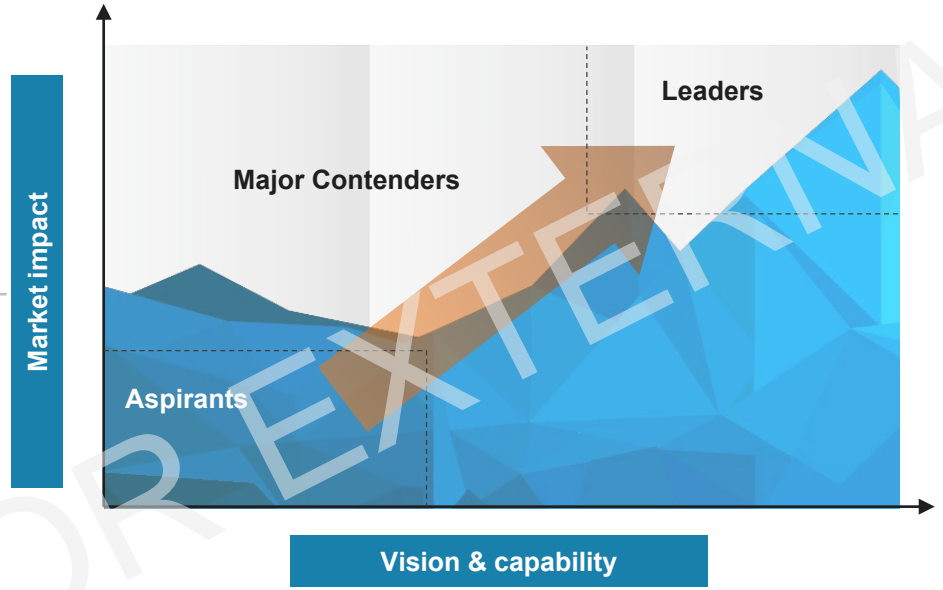
Number of clients, revenue base, and YoY growth

Portfolio mix

Diversity of client base across industries, geographies, environments, enterprise size class

Value delivered

Value delivered to the client based on customer feedback and other measures



Measures ability to deliver products successfully. This is captured through five subdimensions

Vision and strategy

Vision for the client and itself; future roadmap and strategy

Technology capability

Technical sophistication and breadth/depth across the technology suite

Flexibility and ease of deployment

Configurability/customize-ability, hosting and tenancy, integration, governance, and security and compliance

Engagement and commercial model

Progressiveness, effectiveness, and flexibility of engagement and commercial models

Support

Training, consulting, maintenance, and other support services

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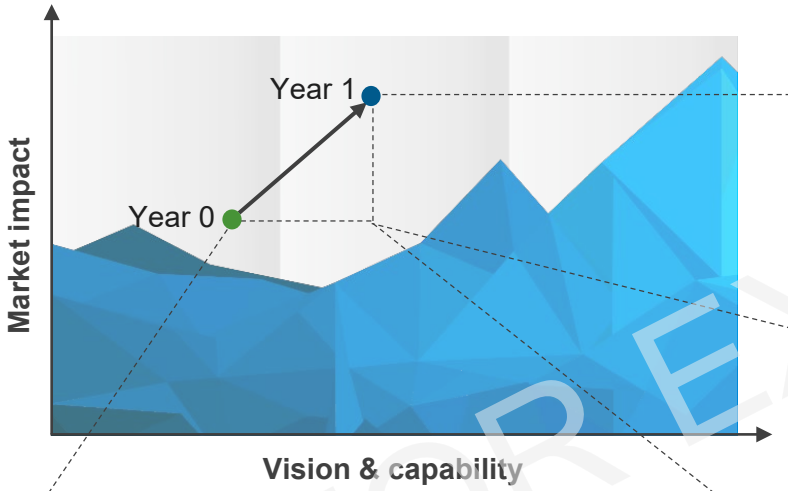
Everest Group confers the Star Performers title on providers that demonstrate the most improvement over time on the PEAK Matrix®

Methodology

Everest Group selects Star Performers based on the relative YoY improvement on the PEAK Matrix



In order to assess advances on **market impact**, we evaluate each vendor's performance across a number of parameters including:

- Yearly YoY revenue growth
- # of new licenses and extensions
- Value of license signings
- Improvement in portfolio mix
- Improvement in value delivered

In order to assess advances on **vision and capability**, we evaluate each vendor's performance across a number of parameters including:

- Innovation
- Increase in product scope and functionality
- Expansion of product associated consulting, training, support, and maintenance capabilities
- Technology/domain specific investments

We identify the vendors whose improvement ranks in the top quartile and award the Star Performer rating to those vendors with:

- The maximum number of top-quartile performance improvements across all of the above parameters AND
- At least one area of top-quartile improvement performance in both market success and capability advancement

The Star Performers title relates to YoY performance for a given vendor and does not reflect the overall market leadership position, which is identified as Leader, Major Contender, or Aspirant.

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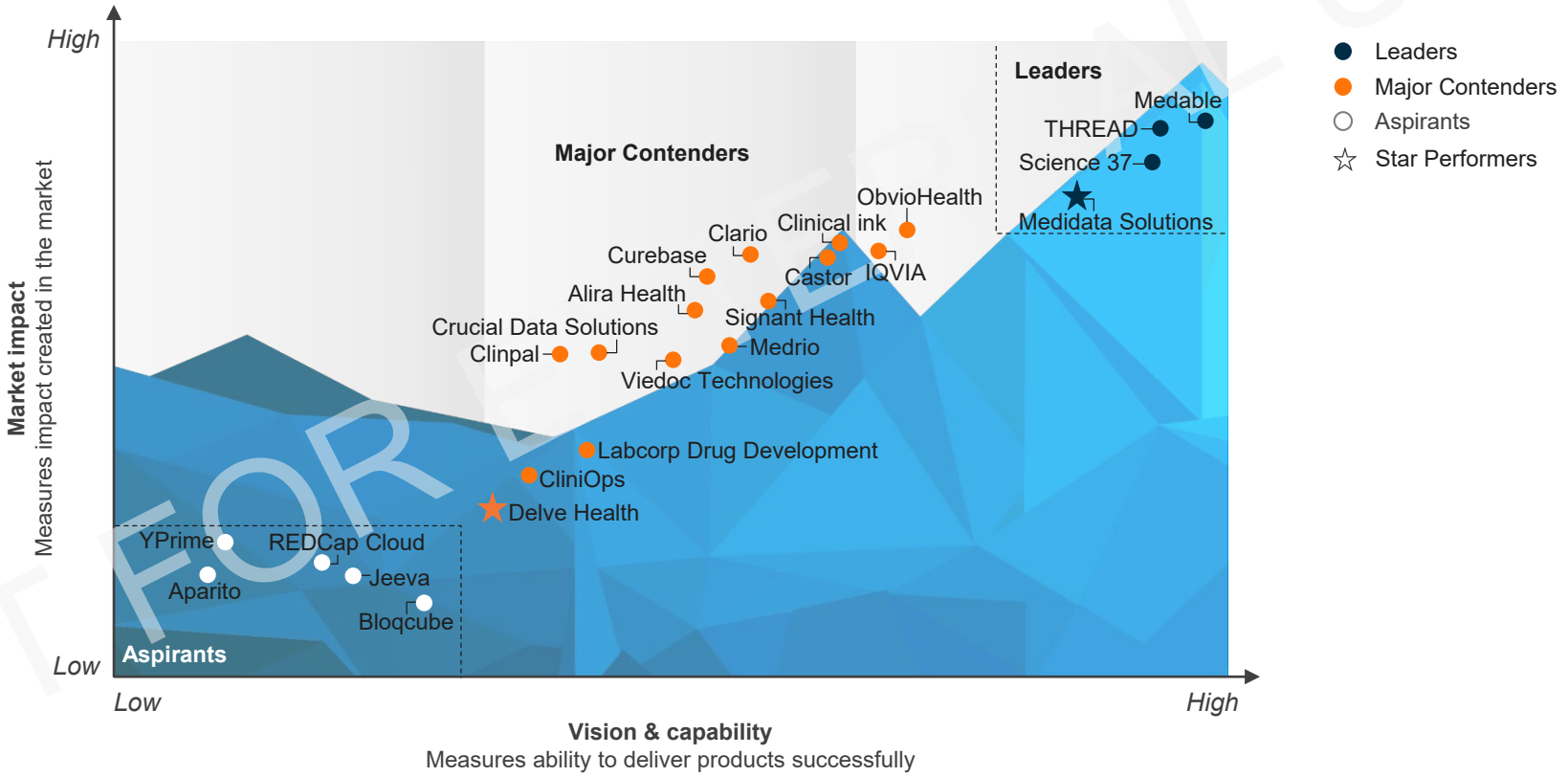
Everest Group PEAK Matrix®

Decentralized Clinical Trial Platforms PEAK Matrix® Assessment 2022

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

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Decentralized clinical trials platforms PEAK Matrix® characteristics

Leaders:

Medable, Medidata Solutions, Science 37, and THREAD

- Leaders offer clients an end-to-end modular platform with a unified data model that allows all patient data to be in a single repository, eliminating data silos
- Leaders offer not only the DCT platforms but also the auxiliary services required to run a DCT. Science 37 offers all the auxiliary services in-house whereas Medable and THREAD partner with home health nurse networks and other service providers to offer clients complete coverage where internal capabilities do not exist
- Leaders' DCT platforms are ranked high on user and patient experience, and they offer advanced use cases to clients (such as advanced analytics and patient recruitment campaigns) to enable them to run their DCTs
- Leaders work proactively toward building market awareness and stakeholder education via various forums and enjoy high mindshare and brand perception

Major Contenders:

Alira Health, Castor, Clario, Clinical ink, CliniOps, Clinpal, Crucial Data Solutions, Curebase, Delve Health, IQVIA, Labcorp Drug Development, Medrio, ObvioHealth, Signant Health, and Viedoc Technologies

- Some of the Major Contenders do not have an end-to-end platform for enabling DCTs as, clients cite, they lack a unified data layer. However, they offer all-point solution capabilities to run DCTs, and those who have been in the space for a long time, aspire to become Leaders (such as ObvioHealth)
- Most Major Contenders lack the complete spectrum of auxiliary support services, and even though they are trying to offer all the modules of DCTs, they struggle with desired patient experience
- Major Contenders have DCT coverage limited to certain therapeutic areas and focused majorly on the North American market with some presence in the UK and APAC region

Aspirants:

Aparito, Bloqcube®, Jeeva™, REDCap Cloud, and YPrime

- While Aspirants may have platform for running DCTs, the solutions are relatively new or undergoing pilots; very few therapeutic areas are covered and lack in desired UI/UX
- Aspirants do not offer clients the complete suite of DCT platforms and lack capabilities such as patient recruitment and medication adherence. Individual solutions also currently lack advanced features as offered by Major Contenders and Leaders. Some Aspirants are trying to give auxiliary services through partnerships such as remote nursing

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Everest Group has identified following platform provider as the Star Performers 2022

Decentralized Clinical Trials Platform Star Performer	Distinguishing features of market impact in 2022	Distinguishing features of capability advancements in 2022	Change in PEAK Matrix® positioning for DCT platforms
MEDIDATA	• Medidata's Circuit Clinical strategic partnership ($ 27Mn) and investment includes DCT sites standardized on Medidata technology, rating & reviewing the trial journey for stakeholders with 90 doctors, 30+site locations resulting in a better ecosystem • It is constantly building on sensor cloud technology solving challenges related to sensor integrations, standardization of sensor data, and the development of digital biomarkers and algorithms • It focused on eSource such as connecting EHR-EDC offering to decrease the data entry monitoring through RAVE • It is investing in the growth strategy for DCTs by – R&D Expenditure – Growth of Team – Roadmap & inorganic strategies around decentralization	• Enhanced RWD collection and analysis (Medidata AI) & DCT Professional services consulting and enablement • Creation of head of DCTs professional services role & EMR integration, and eSource • Significant growth of the patient insights program to develop patient-centric capabilities including patient insights workshops and focus on diversity • New programs in DCT certifications for sponsors and sites • Medidata eSource app: DCT/eSource Site data capture for bedside, home health nursing • myMedidata patient EHR integration: Allow patients to self-initiate EHR data into their profile	**Entered the Leaders category**
DELVE HEALTH	• Delve Health integrated with other platform vendors like Medidata RAVE, EHR/EMR sources for expanded DCT services • It increased the focus on improving the in-home patient experience by having the wearables, devices, etc. • Partnered with Afortiori Development to expand access to clinical studies through increased adoption of decentralized clinical trials • Number of hybrid and DCT trials conducted has increased over previous years	• Platform is focused on the integration of data and analytics and has implemented certain use cases • Randomization features for on-site logistics improved the experience for stakeholders • UI/UX has been improved in terms of browsing and processing	**Entered the Major Contenders category**

Source: Everest Group (2022)

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Summary dashboard | market impact and vision & capability assessment of providers for decentralized clinical trials platform 2022

Leaders

Measure of capability: Low High

	Market impact				Vision & capability					
Providers	Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
Medable										
Medidata Solutions										
Science 37										
THREAD										

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Summary dashboard | market impact and vision & capability assessment of providers for decentralized clinical trials platform 2022

Major Contenders (page 1 of 2)

Measure of capability: Low High

Providers	Market impact				Vision & capability					
	Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
Alira Health										
Castor										
Clario										
Clinical ink										
CliniOps										
Clinpal										
Crucial Data Solution										
Curebase										

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Summary dashboard | market impact and vision & capability assessment of providers for decentralized clinical trials platform 2022

Major Contenders (page 2 of 2)

Measure of capability: Low High

Providers	Market impact				Vision & capability					
	Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
Delve Health										
IQVIA										
Labcorp Drug Development										
Medrio										
ObvioHealth										
Signant Health										
Viedoc Technologies										

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Summary dashboard | market impact and vision & capability assessment of providers for decentralized clinical trials platform 2022

Aspirants

Measure of capability: Low High

Providers	Market impact				Vision & capability					
	Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
Aparito										
Bloqcube										
Jeeva										
REDCap Cloud										
YPrime										

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03

Enterprise sourcing considerations

- Leaders
  - Medable
  - Medidata Solutions
  - Science 37
  - THREAD

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Medable | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Leader

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
●	◔	●	●	●	●	●	◔	●	●

Strengths

- Medable offers an end-to-end DCT solution, combining technology products and auxiliary services in a unified manner. Clients have appreciated the modular nature of the platform
- Clients have rated Medable highly on the quality of its products and the user experience of the platforms from patients', sites', and sponsors' perspective
- It has an extensive partnership network collaborating with players for system integration, technology, data, direct-to-patient concierge, remote sites, and retail pharmacies
- Clients appreciate Medable for incorporating feedback and providing quick and responsive support services
- Its enterprise-level deals (such as with GSK) and expansion in European countries have increased clients' confidence in the scalability of its solutions
- Medable offers digital certifications (Medable Academy) empowering professionals to design and build DCT studies on the Medable platform, increasing DCT adoption at research sites

Limitations

- Medable is perceived as a premium-priced DCT platform provider
- Clients cite internal knowledge management as an area of improvement so that domain expertise does not remain limited to a handful of people in a certain project
- Testing and delivery of solutions can become more robust and error-free, especially in China and the APAC regions, as per clients' feedback
- Clients mention that sometimes they face challenges when it comes to integration with existing clinical systems and/or wearables and sensor devices

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Medable | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

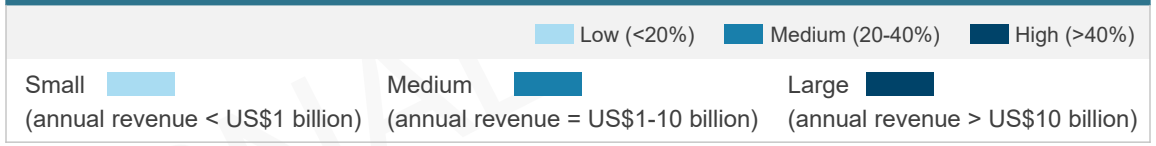
Medable is on a mission to get effective therapies to patients faster by transforming clinical drug development with disruptive technologies. Medable powers clinical trials so that more patients can participate from anywhere, scientists get more reliable and representative data, and safe and effective medicine reaches people faster. The company's vision is to open scientific research to the world, with a platform designed for humans, that accelerates cures and health outcomes for all.

Overview of the client base

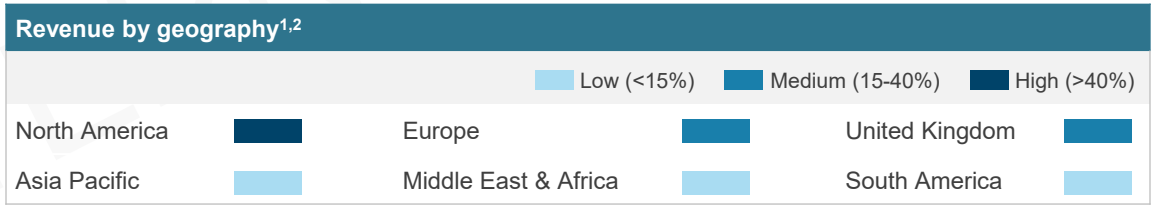
Medable's decentralized clinical trial SaaS products cater to all therapeutic areas, including neurology, infectious diseases, dermatology, oncology, endocrinology, gastroenterology, genetic or rare diseases, cardiovascular, ophthalmology, vaccine/virology, psychiatry, sleep, allergy, and reproductive medicine. Medable has created strategic partnerships with biopharma and CRO customers to develop processes intended to increase the adoption of DCT and Digital Technologies across all therapeutic areas.

Medable has a comprehensive global footprint of clients. Medable is trusted by 13 of the top 20 large pharmaceutical companies and 9 of 10 top CROs (Syneos, PAREXEL, ICON, etc.). In 2022 Medable has seen rapid growth with mid-market biopharma customers, which represent over 80% of new customers. Additionally, Medable is continuing to be selected as a priority partner by leading SIs (Accenture, Cognizant, PwC etc.), Academic Medical Centers (NYU) and retail pharmacies (CVS).

Revenue by buyer size[1,2]



Revenue by geography[1,2]



1 All the revenue components add up to a total of 100%
2 Based on analyst estimates

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Medable | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Top 10 Pharma looking to accelerate the delivery of new medicines with a decentralized clinical trials platform across their portfolio

Business challenge

A top 10 pharma company was looking for a patient-centered platform to embed into their IT infrastructure and development process; allowing them reduce cost to deploy and reduce the burden of adoption. Ultimately reducing the overall cost of development, improving the patient experience, and accelerating time to market across the entire portfolio.

Solution and impact

In order to achieve the goals, the solution is a cross functional capability bringing together Clinical IT and Clinical Operations. Together it is working to establish digital capabilities as the standard across all studies at the sponsor. The Medable Platform (eConsent, eCOA, Telehealth, etc.) is deployed as a core Patient Engagement solution and tightly integrated with the rest of the development ecosystem. The partnership with EDC, IRT, CTMS, and other clinical systems increases automation and lowers the risk of data quality issues.

Impact

Medable is on track to achieve the goal of greater than 50% adoption across priority therapy areas. As a result, a reduction in development cycle time, an improved & differentiated patient experience, and improved quality across digital data flow. Additionally, this framework for scaled digital capabilities is supporting an acceleration of future state priorities like sensors, home health, and real-world data.

Case study 2	A top 5 global pharma company focused on increasing patient safety in Oncology trials with remote monitoring

Business challenge

A top 5 global pharma company with a strong Oncology focus was seeking a partner to help improve clinician oversight of patients between site visits. They wanted clinicians to be able to monitor patients remotely for key signs and symptoms that could be an early indication of an adverse event that may require intervention and be able to prompt the necessary course of action.

Solution and impact

Medable provided a decentralized approach, including Daily SpO2 sensor measurements and PF related symptoms integrated into the platform for real-time participant tracking. The studies in the portfolio began going live in Q4 2020 and are currently enrolling patients. Feedback from sites and the sponsor has been extremely positive, with patients successfully performing remote sensor readings and patient diaries as needed. Most importantly, patient oversight has been greatly enhanced due to the increased frequency of lung function readings and the sponsor's ability to review patient-generated data in real-time.

Impact

Medable decentralized solutions dramatically enhanced clinician oversight and patient safety by performing daily lung function measures and ePROs remotely throughout the entire study. Site clinicians are then able to use this data to detect early signs of potentially life-threatening adverse events earlier than ever before. Through eCOA and sensor integration, there was a 7x frequency in measurement during dose escalation with daily monitoring and expansion vs. traditional approach (7 days), up to 90x frequency in measurement during follow-up with daily monitoring vs. traditional approach (30-90 days) with the aim of 10-20% of patients receiving a timelier intervention that ultimately improves their outcomes.

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Medable | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

Proprietary digital solutions (representative list)	
Offerings	**Details**
Medable Platform	Medable's core offering to the market is a SaaS platform designed to integrate with existing development ecosystems and enable DCT. Medable systems enable a seamless experience for patients and providers across capabilities such as remote screening, eConsent, eCOA, ePRO/diary, caregiver engagement, TeleVisits, wearables/remote monitoring, lab data, reminders and patient engagement. The platform is modular, and all capabilities are unified and work together in connected workflows to allow a seamless experience while adapting to the needs of each study protocol. The platform is built for patient-centered clinical trials on a stable, mature cloud architecture, enabling Medable to rapidly develop products that drive patient safety, data integrity, and quality.
Medable Total Consent	Medable Total Consent is a fully web-based offering, delivering a multimodal consent management tool that can be deployed easily to patients either on-site or in a remote capacity, supported by an on-platform TeleVisit. Total Consent can offer additional multimedia presentations, such as video or audio files combined with methods to check comprehension through knowledge reviews that can highlight where an investigator may need to focus the discussion. It also supports print-to-sign templates for wet-ink signatures with a document upload feature to support the remote monitoring and oversight of the complete consenting process across all patients, sites and countries. Total Consent also offers customers in-depth training to enable faster deployment of eConsent across their trials – including a new rapid onboarding option, with deployment in < 2 weeks.
Medable eCOA & ePRO	The Medable ePRO and eCOA platform enables, simplifies, and streamlines PRO/COA data collection for patients & sites. Providing sites with real-time and actionable data access to ensure both participant compliance and safety during the trial. It also offers a reusable library of validated instruments, transferable from a central repository to various study organizations to simplify build for sponsors. Every instrument package includes detailed information on the instrument, testing and build, with screenshots and step tables provided as part of the package. Instruments are built using new web-view steps that meet accessibility and eCOA design best practices.
Medable Remote Patient Monitoring	Medable's ability to collect data directly from the patient ensures a seamless, real-time data capture via connected devices and sensors, and offers a way to select the physiological parameters or devices used within the study. The app pulls data from HealthKit or Google Fit and/or pulls data from the integrated device API. As the field of sensors rapidly develops, Medable has established a partner certification processes that focus on many aspects required for a sensor to be successfully delivered on platform. This includes review of data flow, integration architecture and compliance requirements, assessment of proven durability, reliability and user experience, engineering maturity, and a robust supply chain, which is sustainable. As a result, our extensively vetted sensor library provides a seamless rightly integrated out-of-the-box platform experience. Lastly, Medable is actively developing patient engagement models to predict patients at lower or higher risk of trial compliance in near real-time.
Medable Televisits	Medable's Televisit feature enables patients to participate in clinical trials from their home by giving them access to video visits with the researcher. Televisits are available throughout the patient journey utilizing its unified platform. Medable's Televisit solution is a 21 CFR Part 11-compliant solution that can be fully integrated into clinical studies and can be utilized via web or app.
Vaccine Platform Packaged Offering	Medable has packaged a Vaccine - Therapeutic Area-specific platform offering that includes access to eScreening, eConsent, eDiaries, Televisit. Medable's pre-built and scalable vaccine offering enables faster trials, as well as better site and patient experiences and expedited data delivery, starting from 5 weeks. Medable's digital products and expertise advisory consultation are included for first time DCT adopters.
Oncology Platform Packaged Offering	Medable has packaged a Therapeutic Area-specific platform offering for oncology trials that simplifies data collection for sites and sponsors while keeping patients safe, comfortable, and engaged from any location.

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Medable | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns[1]	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition[2]	Sensor integration	Assistance with refills, health issues[3]

1 Enabled via Partner Network with integration into Medable eScreening Product
2 Facial recognition, has been deprioritized due to the poor results and burden for a patient. It has prioritized other avenues to support adherence for our solution such as predictive modeling for compliance and adherence behavior
3 Medable can support patients with reminders on refills and communication back to a site via Telehealth for health-related issues; however, at this time Medable relies on partnerships for the direct delivery of providing refill assistance from a supply chain perspective

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Medable | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
GSK	Partnership	In 2022, Partnered with GSK in a 4-year enterprise partnership agreement for DCT platform adoption
Tufts Impact Report	Initiative	Evidence based Research on DCT ROI, 5x eNPV in Phase II Trials - a 13x eNPV in Phase II Trials. KPI outlined on speed, cycle time, quality
Medable Partner Network	Initiative	Strategic partner ecosystem across system integrators, CROs, Data, Tech, Direct-to-Patient (DtP) and Retail Pharmacy
CVS	Partnership	In 2022, Strategic partnerships agreement between CVS and Medable for DCT to enter into retail pharmacy
CRO Partnerships	Partnership	Strategic partnership announcements across top CROs: Syneos, Parexel, ICON, LabCorp/Covance, eClinical, Advance Clinical, etc.
LEO pharma	Acquisition	Acquired mobile applications from LEO pharma to expand global engineering team and European presence
Series D	Funding	Medable raised $304 million in Series D funding to accelerate global adoption of digital and decentralized clinical trials, enabling ubiquitous access to the latest treatments for everybody and every biology
Tibbetts Award	Award	Medable wins the 2022 TIBBETTS Awards, Demonstrating Significant Economic and Social Impact from R&D Funding
Medable Academy	Initiative	In 2021, Strategic program launch to offer DCT certification
Dublin	Investment	Medable opens new office in Dublin to create 60 jobs as part of European expansion
Withings medical-grade sensors	Alliance	Alliance with Withings medical-grade sensors to integrate connected health devices
Datavant	Partnership	Partnership with Datavant to combine real-world health records, claims, diagnostic and other data sources with their clinical trial data. Tokenization of add on for consent offerings.
Labcorp/Covance	Alliance	Through an alliance with Medable for digital clinical trials, Covance is expanding its decentralized clinical trials technology ecosystem

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Medidata Solutions | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Leader and Star Performer

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Clients appreciate Medidata Solutions for the quality of its resources related to software, technology, and domain expertise around running DCTs
- Clients mention that Medidata Solutions has good project management capabilities and that project manager and the team stay with clients throughout the duration of the project
- Its partnership with Circuit Clinical will standardize site operations, increasing the ease-of-use for its platforms, expanding access to clinical trials, and enhancing its domain expertise across multiple therapy areas
- Medidata Solutions sensor cloud looks to integrate and standardize sensor data from disparate sensors and unify reporting from a single data platform
- Its solutions are rated highly on governance, security, and compliance – clients have reported no issues with security or any data breach

Limitations

- The EDC solution has high brand recall among enterprises as compared to the DCT solutions, reducing some enterprise mindshare in the DCT ecosystem
- Clients mention that the eCOA solution can be improved – better programming and testing to reduce system bugs, include all the standard reports, and shorten the patient guide. Overall clients desire the eCOA solution to be as mature as the EDC module
- Clients mention that sites face complications during data entry, and patients go through multiple logins to reach the screening page. Clients desire a simplified experience with single sign-on and a user-intuitive DCT solution
- Its price points have been deemed to be higher than other providers in this space
- Clients expect Medidata Solutions to reduce timelines on study build and migrations with quicker setups and smoother applications – making it easy to handle for patients

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Medidata Solutions | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

Medidata Solutions' vision is to power smarter treatments and healthier people. Medidata's strategy focuses on extending DCT technologies through the patient cloud and the myMedidata platform on top of clinical solutions, powered by Rave EDC. Medidata's approach to DCTs begins with a foundational layer of a unified platform of tools that connect to the Medidata Clinical Data Fabric, allowing customers and partners access to the broadest set of clinical trial data available in the industry.

Overview of the client base

Medidata has been involved in 1,509 decentralized clinical trials that capture some type of direct eSource data capture from patients outside of a site visit. This collective effort has touched over 1,095,272 patients, 72,074 sites, 501sponsors (including all the top 10 pharmaceutical companies and all the top 8 CROs) across dozens of disease TAs, countries, languages and clinical trial phases of research.

Revenue by buyer size[1,2]

Low (<20%) Medium (20-40%) High (>40%)

Small	Medium	Large
(annual revenue < US$1 billion)	(annual revenue = US$1-10 billion)	(annual revenue > US$10 billion)

Revenue by geography[1]

Low (<15%) Medium (15-40%) High (>40%)

North America	Europe	United Kingdom
Asia Pacific	Middle East & Africa	South America

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1 All the revenue components add up to a total of 100%
2 Based on analyst estimates

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Medidata Solutions | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Accelerate clinical development to bring a vaccine to the public in record time

Business challenge

The client wanted to accelerate clinical development to bring a vaccine to the public in record time. The client also wanted to collect data of 30,000 participant with remote data capture and data monitoring and analysis capabilities.

Solution

Leveraged eCOA for pre-built instruments, Rave EDC for capturing direct patient data including electronic patient-reported outcomes (ePRO), Safety Gateway to automate AE & SAE data collection, tracking, and transmission into the sponsor safety system and to eliminate multiple data entry and SAE reconciliation, reduce errors, improve patient safety, and save time, Trial Assurance to consolidated all collected data into an Analysis report. Insights from the report enable the sponsor to take preventative and corrective action for missed AE, data anomalies, procedural deviations, and other issues.

Impact

The engagement helped in 1200% faster delivery of vaccine to the public.

Case study 2	Rave RTSM's DtP capabilities and professional services to ensure trial continuity and integrity using an easy and flexible deployment of DtP IMP management

Business challenge

The client needed to give patients hypertriglyceridemia the choice between being dosed on site or at home for its investigational medical product.

Solution

As part of the engagement, Medidata Solutions integrated the DtP system across the entire supply chain. Its agility was used in decentralized, hybrid, or on-site trials and flexibility to offer a choice of dispensation scenarios, whether at the patient or visit level, ensured it met both the US and Canadian regulation requirements, and supported accelerated processes by automating workflows. Leveraged Rave RTSM to have a full overview of all shipments, including DtP shipments status updates for IP at each point.

Impact

This engagement helped the client to accelerate processes by automating workflows, and it helped to increase the flexibility, to offer a choice of dispensation scenarios. It enabled the study team to have a full overview of all shipments, including DtP shipments status updates for IP at each point.

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Medidata Solutions | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)	
Solution	**Details**
eCOA/ePRO	A platform which is enabled directly from an EDC through an easy-to-use configuration tool. The tools allows for complex decision trees, scales, and input control types in eCOA forms. eCOA data is automatically stored in the Medidata Rave EDC database, providing real-time oversight and eliminating the need for data reconciliation.
eConsent	A platform that is based on electronic informed consent, and patient enrollment system for clinical trials which can be used on-site with a native iOS application on provisioned devices, or remotely in a web-based BYOD model for patients that choose to consent remotely for decentralized or hybrid trials.
myMedidata LIVE	A HIPAA-compliant, secure two-way web-based live video conferencing capability connecting patients with their clinical trial study staff. The system is integrated in the myMedidata platform, allowing patients access without having to download additional software or go outside of the myMedidata web-based interface.
Remote patient monitoring and integration with wearable technology & BYOD	A sensor cloud which provides data ingestion capabilities to capture data from nearly any type of medical and consumer grade devices. Medidata has been executing its roadmap of sensors, which has completed the integration of devices from Actigraph, BioIntelliSense, Biobeat, Indie Health, and Oxitone, with more devices being integrated monthly.
Medication adherence	A solution which is based on Medidata which can track medication adherence via eDiaries and ePRO checks with automated reminders to complete a form or check-in. myMedidata LIVE can be used for live two-way interaction between site staff and trial participants, allowing visualization of medication application or 1:1 discussions on medication adherence.
RTSM	solution which supports Direct-to-Patient needs as part of Medidata's overall DCT offering. Medidata's RTSM solution enables API integration to global logistics and drug depots, which can be used to ship study drug and supplies directly to patients and participants in clinical research.
Detect	Medable has packaged a Therapeutic Area-specific platform offering for oncology trials that simplifies data collection for sites and sponsors while keeping patients safe, comfortable, and engaged from any location.
Remote Source Review	A solution which review provides site monitors remote access to physical sites so they can monitor source data and documents irrespective of location. This allows Clinical Research Associates (CRAs) to work remotely, even completing source document review or full site visits from home using the same types of technology that patients use for virtual visits.

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Medidata Solutions | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
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Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Medidata Solutions | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
Investment in Circuit Clinical	Investment	Invested in Circuit Clinical, as it has created a network representing over 90 doctors, across 40+ site locations, and a nationally accredited cancer center with a database of more than 2.5 million participants who may qualify for clinical trials.
MC10	Acquisition	Acquired MC10, a major life sciences company that is integrated in clinical research with its wearable body patch sensors and associated data science capabilities. The acquisition extends Medidata's offerings around the integration of sensor data from multiple sensors becoming more and more popular in clinical research settings. In addition, MC10 brings 40+ FDA-approved validated algorithms for biomarkers that build a foundation for Medidata's emerging business in new biomarker discovery.
Mytrus	Acquisition	Acquired Mytrus, an eClinical technology company specializing in patient-centered electronic informed consent (eConsent) and virtual trials. With this acquisition, Medidata expanded its patient cloud offering to provide patients with a simplified multimedia consent process, and a complete patient engagement platform for fully virtual trials as well as hybrid studies, improving patient experience.
SHYFT Analytics	Acquisition	Acquired SHYFT Analytics, a major platform for commercial and real-world data analytics, to transform clinical development and convert complex data into critical, cutting-edge insights. SHYFT Analytics formed the foundation for Acorn AI to provide a spectrum of data and analytics, including STRATA for commercial data management, QUANTUM for real-world evidence and health economics outcomes research, as well as additional commercial and medical analytics capabilities.
Intelemage	Acquisition	Acquired Intelemage, a leading imaging company that powers medical image file sharing in clinical trials as well as for hospitals, physicians, life sciences companies, research institutions, and core labs. Intelemage core technologies enable the 1:1 telemedicine platform of myMedidata LIVE as well as provide an image and file transfer capability that allows patients and clinicians to share information remotely.
Decentralized Trials & Research Alliance (DTRA)	Industry Alliance	Medidata joined an alliance of 50 life sciences and healthcare organizations to accelerate the broad adoption of patient-focused decentralized clinical trials and research. The DTRA is a consortium of stakeholders that aims to accelerate the adoption of patient-focused, decentralized clinical trials and research within life sciences and healthcare through education and research.
Chair of Association of Clinical Research Organizations (ACRO) Decentralized Clinical Trials Working Party	Partnership	Medidata is the Chair of the ACRO Decentralized Clinical Trials Working Party, which is currently working with the MHRA in the UK as well as other global competent authorities to provide a risk-based model for adoption of decentralized clinical trials.

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Science 37 | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Leader

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Science 37 provides an end-to-end SaaS platform with workflow automation, creating a unified experience for all users – patients, sites, and sponsors
- Clients appreciate the team for its expertise in DCT technology, enabling a smooth transition for enterprises new to this landscape
- It offers a user-friendly platform (website) with easy navigation and intuitive UI complemented with appreciable patient assistance for platform-related issues
- The provider is competitively priced and flexible during negotiations
- Science 37 has a wide partnership network including technology providers, CROs, and academic institutes
- Clients mention that it is challenging to find suitable patients for rare disease trials and appreciates Science 37's efforts in meeting the expected timelines for patient enrollment

Limitations

- It can look to improve its domain expertise in multiple therapy areas and develop consultative abilities to advice clients on how to decentralize trials
- Some clients mention that the platform took longer to get started and running as compared to the expected timelines set by the Science 37 team
- Clients mention that the mobile application needs improvement as it frequently crashes and has an inefficient notification system
- Clients quote that Science 37 can improve on its market education initiatives and bring in robust change management support for seamless adoption

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Science 37 | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

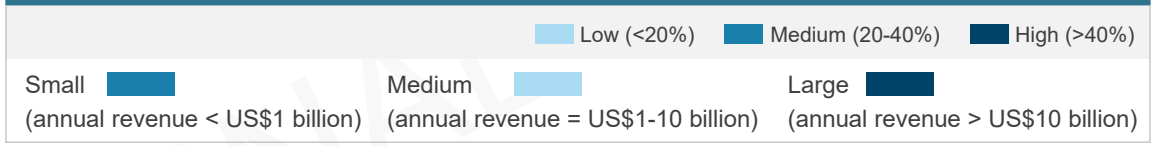
Company mission/vision statement for decentralized clinical trial platforms

Science 37 has the vision of enabling universal access to clinical research and making it easier for patients and providers to participate in and accelerate the development of new and innovative treatments that impact patient lives. Science 37's vision is to be the category-defining operating system that powers every clinical trial – centralized networks, standardized processes, and unified technology.

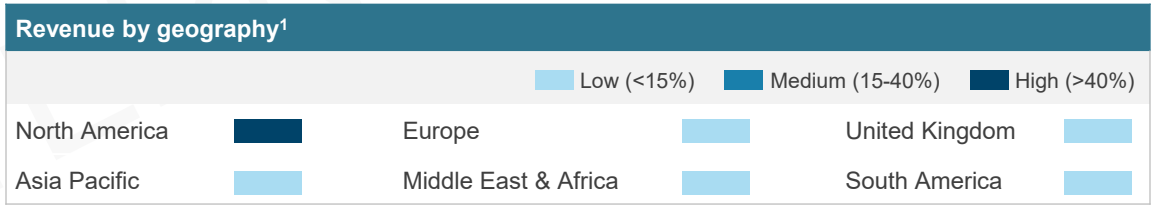
Overview of the client base

Science 37 is a strategic partner with several top 20 pharma companies, numerous biotech companies, leading vaccine providers, oncology diagnostic vendors, and industry-leading CROs. Some publicly cited partnerships/ customers include Novartis, Roche/Genentech, Boehringer Ingelheim, Sanofi, Janssen, Syneos, Thermo Fisher Scientific (PPD), and Amgen.

Revenue by buyer size[1]



Revenue by geography[1]



1 All the revenue components add up to a total of 100%

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Science 37 | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Science 37 technology platform was utilized for the end-to-end clinical trial

Business challenge

The client needed to recruit, enroll, and treat a targeted population of participants across the United States. The study was unique due to the challenge of carefully monitoring and tracking the COVID-19 virus and determining where hot spots would occur. Globally and across the US sites, the sponsor needed to leverage a single platform to capture data.

Solution

The Science 37 technology platform enabled a complete workflow orchestration, inclusive of recruitment with custom landing pages, eConsent, onboarding, a digitized schedule of assessments, data capture throughout the trial, Telemedicine visits, tracking of IMP shipments, and more. The Science 37 Platform enabled all data capture (for all global brick and mortar sites), with the execution of the trial via a Metasite (Virtual Site).

Impact

- Screened more than 200 patients per month
- Displacement of 14 sites reduced budget by an estimated US$2.1 million in study management costs for site set up, training, activation, and one year of monitoring costs

Case study 2	Decentralized clinical trial to improve novel data insight

Business challenge

The client wanted to improve novel data insight, enrollment speed, and patient retention, while also looking to improve real-world representation among study participants—as, historically lupus studies demonstrate underrepresentation from minority groups. Phase III randomized double-blind trial for an oral drug in combination with IV infusion.

Solution

Science 37 delivered a decentralized clinical trial, leveraging the Science 37 technology platform and the Metasite for end-to-end execution. The Science 37 technology platform enabled complete workflow orchestration, inclusive of eConsent, onboarding, a digitized schedule of assessments, data capture throughout the trial, Telemedicine visits, tracking of IMP shipments, and more – minimizing protocol deviation.
Multiple innovative wearables were leveraged in the trial design, including Actigraph (which the clinical research coordinator set up and trained over video), and Emerald (with setup and training at home with mobile nurses, and CRCs over video). Mobile nurses handled vitals and blood draws, while telemedicine investigators conducted physical exams for SLEDAI/ESSDAI.

Impact

Delivered three to four months in study startup time savings vs. similar studies with brick-and-mortar start-ups.

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Science 37 | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)

Solution	Details
Unified (End-to-End) Technology Platform	A fully configurable, end-to-end SaaS platform enables eConsent, Telemedicine, eSource, and eCOA, creating a unified experience for all users – participants, investigators, site staff, and community providers – effectively coordinating clinical research across all settings of care.
Metasite	A virtual site, which leverages Science 37's licensed telemedicine physicians, in-house mobile healthcare providers, and research coordinators, enabled with the Science 37 technology platform. Patients can enroll from anywhere and are seen in the comfort of their homes – providing access and convenience. Metasite leverages a single 1572 and one IRB submission across all 50 states in the US, simplifying the process and expanding reach.
Mobile Nursing	A network that delivers comprehensive and customizable capabilities in the comfort of home, leveraging the Science 37 unified platform. From home IV infusions and subcutaneous infusions, to investigational product administration, phlebotomy, PK/PD collection, specimen collection, 12-lead ECG, vital collection and more, its mobile HCPs support a wide range of protocol specific assessments across 60+ countries.
Patient Recruitment - patient relationship management	A patient relationship management platform that enables significant efficiency in media planning, placement, reporting and patient communications to yield faster, more qualified patient recruitment for clinical trials.
Community Provider Network	A Science 37's network of 36,000 providers enables access to more than 28 million patients. This provider network enables physicians/providers to present clinical research as a care option to their patients, without having to add expensive clinical research infrastructure. This network helps speed patient enrollment, which has been proven to enroll up to 21 times faster than the traditional model. It also dramatically extends Science 37's investigator capacity and enables it to take on more complex study designs across most therapeutic areas.

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Science 37 | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

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Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Science 37 | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
Partnered with Syapse	Partnership	In 2022, partnered with Syapse, to support patient access for Oncology clinical trials.
Partnered with Worldwide Clinical Trials	Partnership	In 2022, partnered with Worldwide Clinical Trials, to support full service end-to-end delivery and application of Science 37 Technology and Metasite within WWCT supported clinical trials.
Partnered with Linical Accelovance	Partnership	In 2022, partnered with Linical Accelovance, to support full service end-to-end delivery and application of Science 37 Technology and Metasite within Linical Accelovance supported clinical trials.
Partnered with PhysIQ	Partnership	In 2022, partnered with PhysIQ, to deliver global studies using biosensor technology.
Partnered with Syneos	Partnership	In 2021, partnered with Syneos, to support full service end-to-end delivery and application of Science 37 Technology and Metasite within Syneos supported clinical trials.
Partnered with CMIC	Partnership	In 2021, partnered with CMIC, to support full service end-to-end delivery and application of Science 37 Technology and Metasite within APAC.
Partnered with Thermo Fisher Scientific (PPD)	Partnership	In 2021, partnered with Thermo Fisher Scientific (PPD), to support full service end-to-end delivery and application of Science 37 Technology and Metasite within PPD supported clinical trials.
Partnered with 3-H Medi Solutions	Partnership	In 2021, partnered with 3-H Medi Solutions, to support APAC region with logistics, recruitment and mobile healthcare.
Partnered with Medgate	Partnership	In 2021, partnered with Medgate, to deliver global studies utilizing its telemedicine physician network throughout EU.
Partnered with Foundation Medicine	Partnership	In 2021, partnered with Foundation Medicine, to support patient access and recruitment for Oncology clinical trials.
Partnered with Clario	Partnership	In 2020, partnered with Clario, for end-to-end solution delivery in respiratory studies, utilizing Clario technology and training for at-home spirometry data capture.

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THREAD | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Leader

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- THREAD offers a unified platform with an integrated data layer. It also offers auxiliary services (such as recruitment, concierge, and home health services) through partnerships, creating an end-to-end DCT platform offering
- Clients share that the platform comes with multiple pre-included device integrations with wearables accelerating the study build timelines
- It is rated high for its technical and domain expertise, training and educational content, and project management abilities, resulting in superior customer interactions
- Clients appreciate the investments made toward the usage of next-generation technology, for example, the acquisition of InVibe for voice analytics and usage of AI/ML models to understand skin health
- Clients state that the enterprise-level deals increase the confidence in the scalability and maturity of the DCT platform

Limitations

- Clients mention that the user interface and navigation of the patient-facing application can improve. Patients are spending a lot of time understanding and coming to speed with the platform
- Sites are facing challenges with specific products such as eCOA/ePRO. They desire to have simplified operations – fewer clicks for report generation, easier navigation, and better guidance
- It should look to increase the strength of its client-facing people from both sales and delivery perspective
- Clients state that the solutions are priced higher than competitors

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THREAD | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

THREAD's near-term vision is to decentralize, automate and change how clinical research is conducted to make studies more efficient, comprehensive, and inclusive to bring products to market faster for everyone, everywhere. The mission is to provide a global, configurable, comprehensive platform with complementary services to our customers that enables decentralized studies to scale for all study stakeholders.

Overview of the client base

THREAD has supported 200+ DCTs and 1800+ projects with more than 250 customers, including 15 of the top 20 biopharma and 4 of the top 5 CROs.

Revenue by buyer size[1]

Low (<20%) Medium (20-40%) High (>40%)

Small	Medium	Large
(annual revenue < US$1 billion)	(annual revenue = US$1-10 billion)	(annual revenue > US$10 billion)

Revenue by geography[1,2]

Low (<15%) Medium (15-40%) High (>40%)

North America	Europe	United Kingdom
Asia Pacific	Middle East & Africa	South America

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2 Based on analyst estimates

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THREAD | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Worked with a CRO/Sponsor partnership to establish a hybrid design to support a Neurology Phase 3 study

Business challenge

The physical limitations caused by Multiple Sclerosis (MS) make travel to sites difficult for participants. To improve participant recruitment and engagement, the sponsor sought to enable the remote collection of data. Further, the client wanted a solution that would enable data to be collected from home health visits and communicated with sites through an integrated platform. Finally, the client required a flexible and scalable solution that could meet the global needs of 4 studies taking place in 40+ countries and Hong Kong, and in 30+ languages, some with specific regional dialects.

Solution

- Implemented DCT capabilities to ensure resiliency and reduced clinical trial disruption as participants were unable to travel
- Improved the participant and site experience leading to better compliance and engagement
- Enabled rapid detection of MS symptomatology changes, allowing for quicker decisions
- Employ experience with global scale studies, including managing multiple languages and dialects to ensure study performance
- Simplify workflow via one, fully configurable platform for all study stakeholders

Impact

- Successfully implemented technology that allowed active tracking and monitoring of data collected during Home Health visits
- Adoption by home health nurses globally
- Rapid startup of 4 studies in 12 weeks from contract to go-live
- Successful rollout in accordance with Sponsor start-up timelines

Case study 2	Safety follow-up for participants using the Free Style Libre 2 Glucose monitoring device

Business challenge

The client required a solution to enable remote safety monitoring and participant satisfaction reports for their diabetes management over the 6-month follow-up phase to a clinical investigation of a medical device.

Solution

THREAD designed a solution using the following functionality in support of the customer's need

- eICF configured for assent, parent consent, and adults
- eCOA and Survey implementation with configured notification to improve participants' compliance

Impact

The solution helped in improving efficiency and participant experience with the implementation of DCT model and real-time data review and monitoring by the study site.

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THREAD | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)

Solution	Details
THREAD eCOA	All eCOA solutions (ePRO, ClinRO, PerfRO, ObsRO, eDRO, eDiary) and assessments/measures, from simple to complex eCOA, are supported by THREAD's platform. THREAD's eCOA library contains nearly 500 licensed eCOAs to support a variety of therapeutic areas, languages, and participant assessments. Partnerships and contractual agreements with license aggregators (i.e., Mapi Research Trust), license holder entities (i.e.,. EuroQol), and direct license holders (i.e.,. Academic owned eCOA) experience. In addition to the library, THREAD's platform configurator can build additional eCOAs as required for individual studies. The newly built eCOAs will remain in the customer's instance and become part of their library for future use. THREAD also has the capabilities to work with the sponsor to create, design, verify, and linguistically validate additional eCOA and outcome assessments through the Modus outcome research team. Approximately 95% of THREAD studies include at least one (1) eCOA, with many in our library in use in Phase Ib – IV studies and registries. Continue to add global, multilingual eCOAs to our library in response to customer and study-specific needs.
THREAD eConsent	THREAD's Platform supports eConsent, including assent/consent, technology and processes. THREAD can also support hybrid scenarios where, for regulatory reasons, some sites/participants need to consent on paper and others can utilize full eConsent. In any scenario where paper is used, the documents can be uploaded into THREAD to facilitate remote review. THREAD can also support remote consenting in conjunction with Telehealth. The consent process (training, reconsent, etc.) and documents are easily managed fully within the platform. Access to the consent process and documents is controlled by roles and permissions. THREAD's eSignatures are compliant with global regulations such as 21 CFR Part 11, ERES, and others.
TeleVisits	THREAD's platform provides a native, robust telehealth feature that was designed specifically for clinical trials and can be configured in several ways to support different virtual visit approaches. These features enable participants and sites to hold telehealth sessions together, allowing for simultaneous data capture and an increase in low-friction engagement. Our telehealth feature supports simple scheduling and completion of virtual visits between the site portal and patient app for sites and patients to conduct telehealth visits. Virtual visits can be conducted as a scheduled visit or on-demand at any time using the platform by the site team (i.e., PI, SubI, study coordinator, home health, rater, etc.) and study participant. THREAD Telehealth allows for multiple attendees, session recording, screensharing and many other features that support participant engagement and compliance.
Trial Participant Recruitment (screening and enrollment)	THREAD has digital participant recruitment, screening, and enrollment solutions that help identify, guide, and determine eligibility of potential patients. This includes ambassadors, social media advertisement, other outreach and engagement solutions, and the ability to funnel participants automatically through the initial eligibility process.
Remote Patient Monitoring and Integration with Wearable Technology & BYOD	THREAD offers support for over 400 medical devices, sensors, and consumer wearables that are pre-integrated and pre-data mapped in our platform. This provides a more simplified and seamless experience for all involved in the DCT. THREAD also supports custom integrations where one does not currently exist. The platform offers both provisioned devices, BYOD, or a hybrid of the two approaches. It also provides mobile device provisioning services via in-house resources, including providing data plans, supporting phone setup and pairing, helpdesk support, and device exchange/return processes.
Medication Adherence	Medication adherence is supported via a series of features including, but not limited to, compliance surveys/eDiaries, notifications/alerts, device integrations, telehealth virtual visits, configured workflows and processes, etc. THREAD can support medication adherence through instructional activities, instructional videos, recording of videos by the participant of medication adherence activities, etc. THREAD also provides enhanced support for medication adherence through our many home health partnerships.

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THREAD | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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THREAD | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
UBC	Customer Announcement	UBC, a late-stage research and patient-support services organization selected THREAD to expand its global decentralized clinical research offering
Analytics solution for DCTs	Product Release	In 2020, THREAD launched a solution that provides descriptive key performance indicators, predictive measures and actionable insights to drive informed decision-making and optimized study performance
UPS Healthcare	Partnership	In 2021, partnered with UPS Healthcare to deliver the DCT platform
Modus Outcomes	Acquisition	In 2021, acquired Modus Outcomes, a research consultancy firm, to expand company offerings to support design, operation and scale of DCTs.
inVibe	Acquisition	In 2021, acquired inVibe, the leading voice-powered research and insights technology solution for the life sciences and health care industry, to expand company offerings to support design, operation and scale of DCTs.
CureClick	Acquisition	In 2021, CureClick, a community-powered platform that revolutionizes patient recruitment for clinical trials, to expand company offerings to support design, operation and scale of DCTs.
Eversana	Partnership	2022: THREAD and Eversana Announce Industry's first integrated, decentralized registry and RWD-driven evidence and commercialization solution
Global eCOA Library Expansion	Product Release	In 2022, THREAD achieves goal of nearly 500 researched, built and pre-validated eCOAs in a re-usable, configurable global library
Amazon Web Services (AWS)	Partnership	In 2022, THREAD and Amazon Web Services modernize clinical research with launch of cloud-based, AI-driven DCT technology

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03

Enterprise sourcing considerations

- Major Contenders
  - Alira Health
  - Castor
  - Clario
  - Clinical ink
  - CliniOps
  - Clinpal
  - Crucial Data Solution
  - Curebase
  - Delve Health
  - IQVIA
  - Labcorp Drug Development
  - Medrio
  - ObvioHealth
  - Signant Health
  - Viedoc Technologies

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Alira Health | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Alira Health offers a user-friendly and intuitive platform with easy navigation and flexible customizations. Clients mention that all stakeholders have a consistent experience with the platform
- Clients rate Alira Health high for its integration capabilities with external systems and devices - wearables, sensors, and chatbots
- It is part of multiple patient advocacy organizations across different therapy areas, enhancing its domain knowledge and insights into patients' challenges and expectations
- It is adaptive to client requirements and brings in good support services

Limitations

- While integration with external devices is smooth, clients have faced challenges in transferring data to the eCRFs from its platform
- It can look to partner with specialist providers to offer auxiliary support services (beyond home nursing) to enhance the end-to-end DCT play
- Clients desire more training and change management support from Alira Health (for patients and sites), increasing the ease of use for its solutions
- Its patient recruitment and televisit solutions have lower adoption compared to the other solutions

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Alira Health | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

Alira Health is a global tech-enabled and patient-centric service provider dedicated to healthcare and life sciences. It offers consulting and clinical services across the lifecycle of healthcare and life sciences organizations as well as their offerings. For its clinical development platform, Alira Health takes a patient-centric approach and demonstrates this by leveraging real-world data and patient-centered technology in its client work. Alira Health's proven expertise in clinical planning and development, biostatistics, RWE, regulatory, and market access enables the company to design and develop fit-for-purpose technology solutions with a patient engagement team at the core. These solutions cover interventional and non-interventional study types including Phases 1-3 trials, post-approval Real-World Evidence (RWE) studies and registries, and Direct to Patient (D2P) studies.

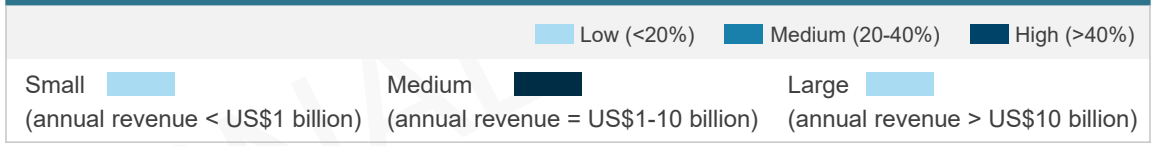
Alira Health's proprietary Decentralized Clinical Trial Platform (DCT) is an integrated solution that addresses the unmet needs of the entire clinical study process, complemented by patient-centric add-ons that provide a seamless user experience. Its work starts by harnessing subject matter expertise in clinical research and development and then leveraging technology as an enabler to run a clinical study in a virtual or decentralized manner, enabling cost savings and process efficiency improvements.

Alira Health brings systems thinking approach to the implementation of DCTs with the ability to advise on study design and execution based on business needs and then integrate DCT elements in a patient-centric approach. This is supported by a partner ecosystem that includes patient associations to co-advocate for patients as partners and specialized technology providers that extend technology capabilities into specific therapeutic areas.

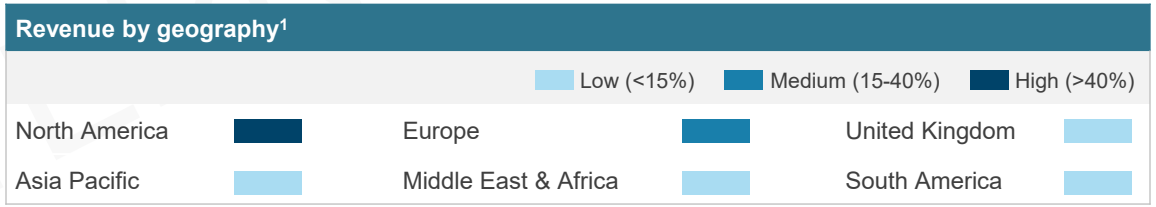
Overview of the client base

Alira Health key clients include key CRO's (e.g., IQVIA, Top 3 Global CRO, 2 Top French CROs) and key sponsors (e.g., Novartis, Roche, Janssen).

Revenue by buyer size[1]



Revenue by geography[1]



1 All the revenue components add up to a total of 100%

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Alira Health | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1 | **eCOA for phase IV non-interventional study**

Business challenge

The client was interested in collecting eCOA (ePRO+ClinRO) in phase IV non-interventional study to observe the use of Erenumab in order to assess real-world practice in treatment. The study focused on the quality of life and disability, as well as treatment satisfaction and persistence in a real-world migraine population in Italy.

Solution and impact

Alira Health's solution for hybrid/decentralized studies was enhanced with the MyReco™ virtual assistant feature built for long-term engagement of burdening and complex trial requirements. It keeps patients motivated via a dynamic and empathetic virtual assistant. The platform quantitatively measures patient engagement in real time so that compliance, retention, and efficiency of trial timelines are maximized. It also allows investigators and monitors (CRAs) to have access to a real-time indicator of patient engagement.

Impact

The client saw a protocol adherence of 95%, patient retention of 100%(for the patients enrolled in last six months) saving US$1 M and reduction in overall trial timeline by 8.3%.

Case study 2 | **Eyedrop usability study for FDA approval**

Business challenge

The client was interested in doing a usability study to confirm that patients were able to successfully self-administer eyedrops required to treat the rare disease Cystinosis, as a result of a change in bottle manufacturer. The additional data was required to support an IND application due by mid-February 2022.

Solution and impact

Alira health team contributed to the protocol design, development of all patient-facing materials, recruitment in partnership with the patient advocacy organization, configuration of the platform to collect data from patients (eConsent, usability questionnaire, Telehealth visit with a CRA to verify usability by direct observation of eyedrop administration), analysis, and reporting of the data.

Impact

The client saw a reduced overall trial timeline by 33% and 100% patient retention.

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Alira Health | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
EDC/eCRF EDC integrations	Provides in-house EDC solution to allow data management teams to design eCRFs, implement workflows/automated processes for edit checks, query management, reconciliation and codification, as well as reporting. Additionally, they can provide system integrations with other EDCs
eCOA (ePRO, eClinRO, eObsRO, ePerfO) & eDiary	Provides full spectrum of validated electronic clinical outcomes assessments, which can be implemented via the Alira Health DCT platform, migrated as per ISPOR guidelines. Ad hoc surveys and diaries can also be customized with various logics and data capture modules
eRecruitment	Facilitates participant recruitment and enrolment via online landing page with engagement metrics to improve targeting
eConsent	Provides participants with broader access to trials by offering informed consent remotely (via a variety of modules – eSignature, check-box, etc.)
Tele-visits	Allows users to connect with sites remotely to fulfil visits as per the assessment schedule
Medication tracker	Provides patients reminders, notifications, and motivational messages to boost their medication adherence
Virtual assistant feature/plug-in (MyReco™)	Keeps patients motivated via an empathetic virtual assistant while quantitatively measuring patient engagement in real time for long-term sustainable patient engagement, minimizing patient burden and maximizing compliance and retention in complex study designs
Payment modules	This module ensures seamless and secure transactions within DCT platforms, providing complete visibility across sponsors, sites, and patients
Circle of Support	Allows patients to connect with fellow participants, caregivers, and healthcare professionals and create an online network
Health Content library	Allows users to access useful study/health related information that can be updated through an integrated content management system
Creator/Admin platform	The admin dashboard allows the configuration of the different DCT capabilities as per study needs with different access levels depending on the user (e.g. sponsor, investigator, call centre, etc.)

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Alira Health | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Alira Health | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

Key events (representative list)

Event name	Type of event	Details
Bepatient	Acquisition	Acquired Bepatient in 2021, a PSP technology platform to boost the path of medical and digital technology development with medical care using patient data
PatchAI	Acquisition	Acquired PatchAI in 2021, an EIT Health-supported start-up, to empower patients through innovative conversation ePRO, gamification, chatbot, etc.,
Selfcare catalyst	Acquisition	Acquired selfcare catalyst in 2022, a digital health company to strengthen the growing global portfolio and patient-centric technologies. Health Storylines helps patients make sense of their patient journey through meaningful data that they own and control. Currently, it has 120,000 active patient users that use Health Storylines platform even after the clinical trial and RWE study is done
Cardinal Health	Partnership	Partnered with Cardinal Health for home nursing and 3PL home delivery services in the US
Legit Health	Partnership	Partnered with Legit Health for special image capturing software and algorithms for dermatology
Net Health	Partnership	Partnered with Net Health for special image capturing software and algorithms for wound care
Euromed	Partnership	Partnered with Euromed for home nursing and 3PL home delivery services in the EU

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Castor | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Clients appreciate the speed of eConsent build and integrating this with existing EDC solutions, resulting in a reduction in trial timelines
- Castor has partnered with providers for patient recruitment (Trialbee and 1nhealth) and home health testing (Let's Get Checked and ixLayer), strengthening its play in the delivery of auxiliary services, enhancing the value proposition for an end-to-end DCT solution
- It is responsive and offers quick resolutions to queries. Clients appreciate the training provided for patients and sites to increase usability and adoption
- Castor has strong expertise and previous experience to run Software-as-a-Medical Device (SaMD) trials on its suite of products
- Clients mention that Castor has a very competitive pricing model and is always flexible in incorporating the desired features and customizations

Limitations

- Clients cite that the solutions (eConsent and EDC) need some improvement on the UI/UX front – they desire a single login across solutions and better visualization (font size and color palette) to enhance the readability and usability of these solutions
- Clients mention that extracting and exporting data using API is limited to metadata while they desire to have project progress data as a standard feature with easy accessibility all the time
- Clients cite that there is room for improvement in the analytics and next-generation tech-related offerings. They also note that Castor has taken efforts in this direction, planning to add advanced analytics features in the future releases
- Its remote patient monitoring solution has lower adoption compared to similar solutions from competitors in this space

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Castor | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

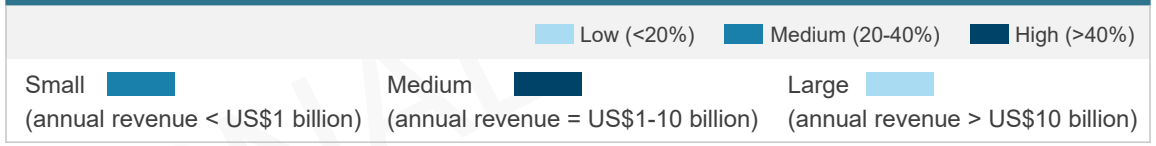
Castor is a leading provider of decentralized and hybrid clinical trial solutions to democratize research. Castor's vision is to make clinical research accessible to everyone, everywhere by maximizing the impact of data on patient health through technology. It is connecting clinical research by bringing human-centered design to the clinical trial process, from recruitment to analysis, and improving the quality, security, and reusability of data for researchers worldwide.

Overview of the client base

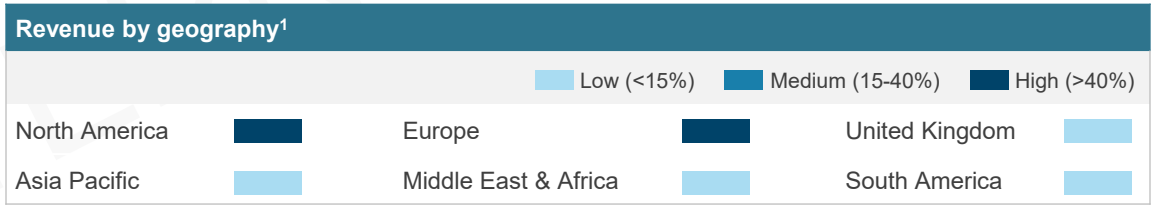
Life Sciences companies, digital health innovators, and researchers trust Castor to power their studies, evidenced by a 98% customer satisfaction rating and an increased customer base of 39% from 2020. Recently, Castor has worked with World Health Organization (WHO) and has landed over 30 top-tier digital therapeutics companies, and penned enterprise agreements with multiple top 10 pharmaceutical companies.

Key clients include Click Therapeutics, Essity, Akili, Stryker, Parexel, Johnson & Johnson, Takeda, Adelphi Group, and World Health Organization.

Revenue by buyer size[1]



Revenue by geography[1]



1 All the revenue components add up to a total of 100%

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Castor | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Boost data collection capabilities and workflow

Business challenge

A leading cardiopulmonary medical device company was looking for ways to optimize data workflow and scale data collection capabilities.

Solution and impact

Castor helped in connecting Electronic Health Records (EHR) and auscultation data directly to the EDC to create a streamlined experience for the site team. The platform's unique data collection capabilities helped in training its AI algorithms. Castor's open API helped its team to independently create the integrations needed for its product.

Impact

The medical device company has been using Castor's API to build a caregiver-facing app that would automate the collection of ACC sensor data from five university hospitals with additional diagnosis information from over 1,700 patients.

Case study 2	Affordable and timely in-house execution of trials

Business challenge

A leading global hygiene and health company needed to enable in-house execution of all clinical trials, which include trials of varying complexity, size, and duration, without negatively impacting budget or timelines.

Solution and impact

Castor offered a fully decentralized solution that consisted of remote enrollment, including remote eConsent, ePRO (online questionnaires) and EDC. Additionally, the company plans to reuse data for other studies in future using Castor's unique platform data collection capabilities.

Impact

The company witnessed a 30% trial cost reduction and increased recruitment rate by 30%-50%.

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Castor | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

Proprietary solutions (representative list)	
Solution name	**Details**
Modular Clinical Trial Platform	Castor plug-and-play platform offers rapid deployment at scale, enabling researchers to create quick trials with easy enrollment, eConsent, and real-world data capture. It helps study teams in optimizing the patient experience through streamlining workflows for data collection, patient enrollment, and engagement. User-friendly technology platform includes the following capabilities: patient enrollment portals, pre-screening, remote eConsent, EDC/CDMS, ePRO/eCOA, randomization, native patient apps, eSource, reporting and analytics, and an open API for interoperability. Castor also has an industry-leading support team and professional services organization that supports customers' needs throughout the life of their studies.
eConsent	Castor's eConsent is a web portal designed to facilitate remote recruitment, screening, and patient consent. The landing page can be customized to meet trial needs, including pre-screening surveys. The in-built video-call feature gives both study teams and patients confidence and assurance in the new remote trial space, increasing transparency and maximizing patient retention.
EDC /CDMS	Castor's cloud-based clinical data management system enables researchers to easily capture and integrate data from clinicians, patients, devices, wearables, and EHR systems. Add unlimited data, build complex forms, set up calculations, repeat measurements, and check validation and dependencies using the form-building functionality. The system's import/export tools allow study admins to then reuse those same configured elements to rapidly expand its programs. Currently, it supports over 85,000+ users across 7,000+ studies in 90+ countries with the core module.
ePRO / mobile apps (Castor Connect)	Castor's ePRO solution allows study subjects to complete surveys anytime, anywhere from their mobile or tablet. Configurable in-app notifications and a participant "to-do list" presentation showing pending and completed actions ensure compliance, and offline data storage means even participants with intermittent or otherwise unreliable internet connections can record and submit their data offline for submission later. Besides being able to offer a native app solution for both BYOD and provisioned devices, the app can be combined with Castor ePRO's web module for email-based ePRO surveys to maximize participant access. As a modular component of Castor's trial solution, the app can be made available rapidly for use on both new and existing studies.
Virtual Visits	Castor Virtual Visits simplifies hybrid and decentralized clinical trials by allowing sponsors to plan patient video interactions based on the study protocol, study subject type, and therapy. Castor helps sponsors combat recruitment, enrollment, and other scheduled activity challenges by reaching patients in the comfort of their own homes while breaking down asynchronous data collection silos. Additionally, virtual visit capabilities are built directly into Castor's data platform, allowing researchers to avoid manual or asynchronous data integration.
eSource (Interoperability & API)	Castor eSource assists in connecting clinical data across multiple domains, sites, and systems. Through our RESTful API, sponsors can integrate EHR data, information from wearables. sensors, as well as non-CRF data such as imaging and laboratory results directly into Castor EDC.

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Castor | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

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Castor | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

Key events (representative list)

Event name	Type of event	Details
Series B	Investment	Castor announced its US$45 million Series B financing round in July 2021, bringing the company's total funding to US$65 million. The round was led by Eight Roads Ventures and F-Prime Capital. with participation from existing investors Two Sigma Ventures and Inkef Capital. This will help Castor to modernize the clinical trials process and maximize the impact of research data on patient lives.
Patient enrollment and eConsent solution launch	Product	Castor announced a full patient onboarding experience to enhance patient enrollment, from recruitment to first study visit. Castor's comprehensive eConsent solution enables patients to experience a seamless transition on their journey from recruitment to screening, consent, and enrollment.
Lightship partnership	Partnership	Lightship and Castor announced a strategic partnership to run direct-to-patient (hybrid) clinical trials at scale.
Trialbee partnership	Partnership	Trialbee and Castor announced a strategic partnership to accelerate patient enrollment, optimize patient engagement, and reduce site burden for clinical trials globally.
CRO partnership program	Partnership	Castor's CRO Partnership program is designed to support clinical research organizations (CROs) by providing the technical capabilities, operational training and commercial resources required to successfully deliver traditional, hybrid, and decentralized clinical programs for trial sponsors.
COVID-19 support	Initiative	Castor continued rapid adoption of its decentralized clinical trial platform to power COVID-19 studies globally. Castor supports more than 250 COVID-19 studies in 40 countries across 1,750 hospitals. 62,000 participants are enrolled in these trials and more than 139 million data points have been captured.
US expansion	Initiative	Castor launched New York operations, doubled headcount to 172 employees across 18 countries. Derk Arts, the founder and CEO of Castor, relocated to New York City this year in order to continue the US market expansion.

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Clario | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Clario has good expertise in eCOA solutions and is capable of handling complex requirements across various therapeutic areas
- It enhances RWE by integrating RWD from multiple sources and leverages AI for predictive analytics, improving on its AI capabilities for imaging solutions with the recent acquisition of Saliency
- Clients rate Clario highly for its domain knowledge and support services, and appreciate it for meeting project timelines
- Clients mention that it has good APIs (develops custom ones as well) to manage integrations with existing or third-party systems
- Its solutions are competitively priced and result in cost savings

Limitations

- Clario can look to partner with niche providers to offer clients access to auxiliary support services in DCTs
- While clients desire a shortened device training schedule and better change management capabilities, they acknowledge that it is making efforts in the right direction
- Its virtual visit solution is comparatively new; clients expect it to improve (majorly UI/UX) and be at par with the leading solutions in this space
- Clients expect Clario to improve its dashboarding and reporting capabilities with more standardized and user-intuitive reports, KPIs, and queries

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Clario | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

Clario's vision is to stay ahead of the evolving clinical trials landscape by hitting talents who take pride and ownership in their work. Clario is relentless in pursuing the information, insights. and inspiration to continuously improve clinical trial site support services and technology solutions. It believes in customer first approach and delivering exceptional service to the patients.

Overview of the client base

Clario decentralized clinical trial products cater to therapy areas including cardiovascular & metabolic, dermatology, gastroenterology, hepatology, infectious diseases, musculoskeletal, neuroscience, oncology and respiratory.

The company services some of the top pharma companies in the world along with a handful of CROs and biotech companies globally.

Revenue by buyer size[1]

Low (<20%) Medium (20-40%) High (>40%)

Small	Medium	Large
(annual revenue < US$1 billion)	(annual revenue = US$1-10 billion)	(annual revenue > US$10 billion)

Revenue by geography[1]

Low (<15%) Medium (15-40%) High (>40%)

North America	Europe	United Kingdom
Asia Pacific	Middle East & Africa	South America

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1 All the revenue components add up to a total of 100%

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Clario | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1 — **High-quality compliant eCOA data captured across group of oncology studies**

Business challenge

A leading pharmaceutical company required an eCOA vendor to support a group of oncology studies in multiple oncology indications. The eCOA solution needed to be customized for each study to enable sites to easily enroll suitable patients, collect site-based Quality of Life (QoL) assessments on tablets, and deliver engaging training content. This study program involved 200 sites across 30 countries with approximately 2,500 patients across several indications

Solution and impact

Clario's eCOA solution provided efficient deployment of eCOA assessments across oncology studies in various indications. A range of QoL assessments was delivered on user-friendly tablets, along with integrated secure online enrollment of patients, animated and engaging patient training content. Clinicians collected assessments during site visits, deploying Clario eCOA on provisioned tablet devices. These devices provide a simple interface for patients, ensuring high-quality endpoint data collection.

Impact

Clario eCOA assessments across multiple sites enabled high quality data collection and was cost effective, which helped in faster decision making.

Case study 2 — **Phase 4 study achieves greater patient engagement using EDC**

Business challenge

The client was looking for a digital system to reduce the burden of participation on patients, simplify the data capture process and provide more consistent data to treat Hemophilia

Solution and impact

Clario's EDC solution enabled study participants to log daily activities and collect bleed and infusion data using an app-based electronic diary (eDiary). This allowed entries to be made using individuals' own smartphones, or a provisioned device if required. Furthermore, a Fitbit® wearable activity tracker was integrated into the app, allowing data to be easily logged in real-time. The patient experience was further enhanced by allowing individuals to view the past two weeks of data, including bleeds, infusions and daily activities.

Impact

Clario's EDC supported a post-approval study of 50 hemophilia patients, improved consistency of data and offered patients flexibility to use their own device.

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Clario | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

Proprietary digital solutions (representative list)	
Event name	**Details**
eConsent	Clario eConsent reduces patient burden by providing the appropriate information as required by the IRB in an easy to consume format. Patients have the ability to comment and ask questions during the consent process, as well as the ability to access the system at any time to review material, which includes downloading the consent forms
eCOA multimedia	eCOA multimedia provides a more holistic view of a patient's condition, tracks, and monitors patient's progress more accurately and achieves standardized, high-quality images and audio recordings
eCOA live	This decentralized clinical trial solution enables patients to complete ePROs, which were traditionally done at site, from the comfort and safety of their own home
eCOA suicidal ideation	Helps in monitoring Suicide Ideation and Behavior (SIB) in clinical trials effectively with Clario's suicide assessment tool. It provides electronic alerts based on patient and clinician responses in real-time
Televisit	Clario Virtual Visits reduces patient visit burden by providing them the means to join a video call with its site on its provisioned or BYOD device
FlexImaging	The solution gives the flexibility to expand the study's registered imaging center sites by adding alternate imaging locations known as FlexSites. FlexSites are medical imaging facilities that have partnered with Clario, meet GCP guidelines, and are located within 120 miles of targeted metropolitan areas to keep patient travel time under 30 minutes
Source Document Manger(SDM)	Clario Source Document Manager (SDM) allows to digitally transform, manage, and organize source documents for clinical trials. This web-based application can collect, de-identify, translate, and organize source documents in a centralized location that can be accessed from any part of the world

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Clario | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Clario | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Bioclinica	Acquisition	Acquired Bioclinica in the year 2021, combining its imaging, eClinical, and drug safety capabilities with ERT's eCOA, cardiac, respiratory, and wearables expertise, to create the most comprehensive and robust endpoint data collection portfolio in the industry
Saliency	Acquisition	Acquired Saliency in the year 2021, an AI powered software platform that speeds up analysis of medical images and is used to support trials of pharmaceuticals and medical devices
APDM	Acquisition	Acquired APDM in year 2020, a leading provider of wearables and digital biomarker solutions for clinical trials

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Clinical ink | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Clinical ink offers its platform as an eSource solution that facilitates Direct Data Capture (DDC) from patients supporting complex workflows and a unified data repository
- Clients appreciate its deep expertise in designing eCOA solutions and its ability to handle complex eCOA requirements
- It has been rated highly for the flexibility of its platform, responsiveness to queries, and agility in solution delivery
- Clients have rated Clinical ink highly on domain expertise across multiple therapy areas. It is well-versed in clinical operations and their complex nuances
- It is focusing its investment efforts on leadership hiring to improve product portfolio and improve patient experience

Limitations

- Clinical ink is perceived as a premium-priced provider
- It can look to refine the existing products – leveraging AI/ML capabilities to automate processes and increase efficiency (for example, capturing data through voice and incorporating voice analytics)
- It can look to bring in the right mix of business- and technology-focused people during deal solutioning. This would reduce gaps between client requirements and tech feasibilities, avoiding unnecessary confusion and delays
- Clients desire better support at the site level to increase adoption while the platform can look to improve on the reporting and visualization capabilities at the sponsor end
- While clients appreciate the helpdesk support for sponsors, they expect the support services to be more responsive and prompt for patients and sites

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Clinical ink | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

Clinical ink is a global life sciences company that brings data, technology, and patient science together. Its expertise in high complexity therapeutic areas, coupled with direct data capture, eCOA, eConsent, telehealth, neurocognitive testing, and digital biomarkers advancements, is driving a new industry standard for data precision and ushering in a new model of clinical trials focused on patient outcomes. The Clinical ink vision is to always be at the convergence of data, technology, and patient science in order to advance clinical discovery.

Overview of the client base

Clinical ink has worked in more than 65 countries, in over 80 languages, and has deployed over 500 unique scales and assessments. The company has participated in over 400 clinical studies, worked with over 150 pharmaceutical sponsors and CROs, and has been involved in over 50 regulatory submissions. The Clinical ink decentralized clinical trial platform capabilities are broadly suited to all therapeutic areas and it is particularly powerful in neurology, infectious diseases, immunology, dermatology, oncology, pulmonary and respiratory diseases, endocrinology, gastroenterology, medical device trials, genetic or rare diseases, cardiovascular, musculoskeletal, and vaccine and virology. Key clients include five of the top ten pharmaceutical sponsors, as well as Worldwide Clinical Trials, PPD, and Syneos.

Revenue by buyer size[1,2]

Low (<20%)	Medium (20-40%)	High (>40%)

Small	Medium	Large
(annual revenue < US$1 billion)	(annual revenue = US$1-10 billion)	(annual revenue > US$10 billion)

Revenue by geography[1,2]

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2 Based on analyst estimates

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Clinical ink | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1 **Fully remote voice data and ePRO sponsor study for novel endpoints**

Business challenge

A top 10 sponsor wished to obtain data to characterize the relationship between symptoms and voice features for participants with acute viral respiratory illness, including SARS-CoV-2. It needed a completely remote trial, but faced significant uncertainty knowing that patients would possess technology of differing qualities, and that remote sample collection, multiple vendor API integration, and greatly enhanced participant engagement tools would be needed to ensure success.

Solution

Clinical ink offered a technologically advanced, patient-centric, Bring Your Own Device (BYOD) approach. It designed, developed, and implemented a custom application in three months, including:

- Entire patient experience, conducted via application on Android or iOS phones
- A screening approach for over 20,000 participants, including web- and social-media-based recruitment
- Identify verification and eConsent, including patient and site signature
- Real-time adherence monitoring and reporting; CDC infection and vaccine surveillance reporting
- Lab ordering and kit protocol support
- Local notifications, embedded multimedia training, and a weekly payment system for adherence
- Automated QA and processing for daily reporting, automated audio QA, and calibration

Impact

- Over 20,000 downloads, with 1 million voice samples collected over 1,000 phone models/CPUs
- Data will be used to build voice and symptom algorithm(s) for detection and monitoring of respiratory illness, benefitting vaccine development across key areas (SARS-CoV-2, influenza virus, RSV)
- Significant data study ongoing to demonstrate disease can be detected based on audio recordings

Case study 2 **Advanced ePRO tools enabled a global CRO to expand its service offerings.**

Business challenge

A global, full-service Clinical Research Organization (CRO) operating in more than 50 countries observed increasing demand for electronic Patient Reported Outcome (ePRO) assessments vs. paper equivalents. While this CRO supported studies using paper-based PRO services, it lost revenue to ePRO provider partners when clients elected to use a digital solution that provided several benefits in timeliness, compliance, and data integrity. The company wanted a partner that would add ePRO to its offering and provided a simplified, single point-of-contact interface for its valued sponsor clients.

Solution

Clinical ink deployed its technology enablement model by following a structured, step-by-step transfer of ePRO technology and service ownership. A technology enablement solution allows CROs to evolve its role in implementing and deploying an ePRO solution over time.

Impact

- Enabled adding an ePRO service offering to ePRO delivery model
- Provided a unified service approach to sponsor while enabling an innovative technology
- Studies achieved a total 12,330 completed ePRO scales, during up to eight at-home patient visits per study schedule
- Patients were able to engage with study-specific content, educational materials, and on-device training

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Clinical ink | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)	
Solution	**Details**
Direct Data Capture (DDC)	The Clinical ink DDC solution is a unified platform developed to be a fully-enabled clinical data management system. DDC essentially replaces an EDC system by moving the point of data capture to the patient visit. Source and CRF data are combined in a single application, with edit checks and data validations occurring in real-time, and documents for remote monitoring available in real-time, including audio. Risk-based monitoring goes beyond standard queries and reports to include targeted data reviews and rater evaluation workflows.
eCOA/ePRO	Clinical ink eCOA technology combines audio, video, photography, and pixel-perfect rendering of copyrighted instruments to capture data and support even the most complex assessments. It allows for workflow-driven design – only presenting assessments needed based on triggers. Highly configurable, detailed drawings, images, and videos can be embedded. Allows instantaneous rendering of translation updates. Flexible deployment options support BYOD and web-backup capabilities.
eConsent	Clinical ink eConsent technology optimizes the informed consent process by combining electronic form workflows and interactive question-and-answer sections. It offers a dynamic, easily understandable user experience. The patient activates the account and reviews the eConsent content on any device, marks questions, and electronically signs using advanced electronic signatures. The module can be standalone or deployed within the Clinical ink platform.
Televisit	Clinical ink Televisit or DCT technology seamlessly manages remote interactions for sites and patients. Televisit functionality is an optional visit type and requires zero additional setup. Sites also have the option to use their own solution. The patient interface is as straightforward as straight-to-consumer technology.
Medication Adherence	The Clinical ink Medication Adherence solution, part of its patient engagement technology, enables patients to demonstrate and track their compliance. Reminders and alerts can be configured to remind patients to demonstrate adherence and to alert site personnel to patient non-adherence.
Sensors & Wearables	Clinical ink Sensors & Wearables technology powers remote, mobile tasks aligned with traditional in-clinic assessments as well as the continuous, passive, high-frequency, in-context collection of data. Expertise in movement, cognition, sleep, voice, audio, and other functional activity developed in collaboration with leading academic institutions and the US military.
Digital Biomarkers	Clinical ink has developed comprehensive AI/ML capabilities to support the development and evaluation of digital biomarkers in clinical trials. Its solution allows large volumes of data to be assessed and compared to traditional outcomes data in order to develop new insights, early predictive triggers, and greater disease specificity.

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Clinical ink | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Clinical ink | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
Digital Artefacts	Acquisition	In 2021, Clinical ink acquired Digital Artefacts, a digital endpoint-based technology company with an unrivaled modular platform for complex cognitive, behavioral, and physiological data capture.

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CliniOps | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Clients cited that CliniOps's platform is seamless for data movement and operates smoothly
- Pre-configured settings of the platform allow clients to run a trial without building the platform from scratch, saving time
- Clients believe that CliniOps is a flexible platform and accommodates changes on the go and has good responsiveness in terms of conveying the updates
- UI/UX of the platform is rated good and has a separate platform for patients (Connect) and site (Edge)

Limitations

- The majority of the client base is based out of North America and has a little presence in the European and APAC markets, which can be expanded
- It can improve the ability to have support relationships in every time zone as clients faced some challenges in terms of time zone difference and on-time support
- CliniOps currently lacks the medication adherence capabilities and can look at developing a solution around this

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CliniOps | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

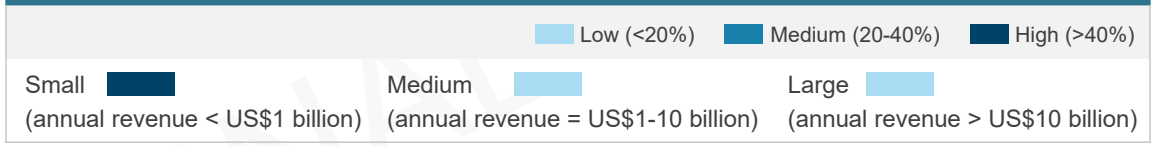
Company mission/vision statement for decentralized clinical trial platforms

CliniOps provides an enterprise platform for the life science industry, enabling hybrid and Decentralized Clinical Trials (DCT), Real World Evidence (RWE), Patient Quality of Life (QoL), and patient engagement powered by integrated telemedicine, with a vision to make drug trials accessible, inclusive, faster, and efficient. It wants to provide comprehensive and global solutions for eSourcing, monitoring, and patient engagement, and improve the monitoring function through efficient and timely information exchange via mobile and collaboration technology. It also wants to improve patient engagement through better communication and collaboration and provide eSourcing of data through a multi-channel integration of several electronic sources (EMR, medical device, lab data, ICF, etc.) into a central data hub.

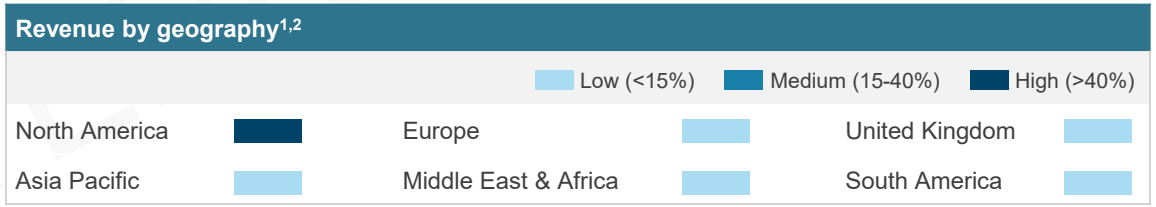
Overview of the client base

The company services some of the top pharma companies in the world along with a handful of CROs and biotech companies globally.

Revenue by buyer size[1,2]



Revenue by geography[1,2]



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CliniOps | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Configurable platform for ground-breaking clinical study

Business challenge

The client was looking for economical solution that could efficiently flex and customize its database to seamlessly handle the level of complex workflow for the vMap clinical study.

Solution

The client wanted to randomize and assign the non-invasive cardiac arrhythmia mapping tool (vMap) data process to its own site. Separate sites were used for capturing data and were blinded from ground truth and needed to be reconciled at single source. CliniOps was able to make the changes to the database without writing new code at short time.

Impact

vMap received US FDA 510(k) clearance in November 2021 and is the first and only non-invasive mapping tool that uses 12-lead ECG data to help physicians rapidly locate potential cardiac arrhythmia sources.

Case study 2	A multicenter, open-label, cluster-randomized study

Business challenge

The aim of the study was to assess the safety of ivermectin with diethylcarbamazine and albendazole (IDA) and diethylcarbamazine plus albendazole (DA) in a variety of endemic settings.

Solution

CliniOps assisted in conducting the study in five. Two studies were performed in areas with no prior mass drug administration (MDA) for filariasis (Papua New Guinea and Indonesia), and three studies were performed in areas with persistent LF despite extensive prior MDA (India, Haiti, and Fiji).

Impact

Results of this study suggest that IDA should be as safe as DA for use as a MDA regimen for LF elimination in areas that currently receive DA.

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CliniOps | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

Proprietary digital solutions (representative list)	
Event name	**Details**
CliniOps Connect	CliniOps Connect puts patients at the center of the clinical trials, and enables seamless participation via telemedicine, from the comfort of their homes or at their regular care facility. It increases patient engagement, retention, and protocol adherence, with regular reminders, notifications, alerts, and educational materials
CliniOps Edge	CliniOps Edge is a purpose-built platform for high quality & real-time electronic data collection. The application runs on standard mobile devices in offline mode, with all checks and balances, ensuring clean and high-quality data, collected digitally at the point of care
CliniOps Conduct	CliniOps Conduct is a unified platform to streamline clinical data management, clinical operations, and accelerated regulatory submission processes. It enables sponsors and CROs to view the data along with dashboards, reports, and study KPIs, to support decentralized (DCT), virtual, or hybrid trials.

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CliniOps | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
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CliniOps | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

Key events (representative list)

Event name	Type of event	Details
Microsoft	Industry collaboration	In 2020, it partnered with Microsoft to launch Open Data Campaign, to address the data divide and help organizations of all sizes to realize the benefits of data and the new technologies it powers.
Stefanini	Industry partnership	In 2020, it partnered with Stefanini to launch TRUST platform to transform clinical trials. The platform helps digitize and automate trials from the study-building phase to support decentralized, virtual, and hybrid trial capabilities.
Exostar	Partnership	In 2022, CliniOps partnered with Exostar for providing better access across digital data systems concurrently as part of research studies, including electronic data capture (EDC), electronic health records (EHR), lab systems, wearables, and connected devices for single sign-on.
My Total Health	Partnerships	In 2022, CliniOps announced the strategic partnership with My Total Health Inc., in partnership with Commonwealth Diagnostics International, Inc. (CDI), in which the companies will collaborate to provide an end-to-end clinical trial solution for the Gastroenterology (GI) community.

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Clinpal (by Cambridge Cognition) | decentralized clinical trial platforms provider profile

(page 1 of 7)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Clinpal has good experience in conducting DCTs (Clinpal platform) across therapy areas in a wide range of geographies
- It is responsive to client feedback, requests, and suggestions – co-developing with the clients, designing and implementing tailor-made solutions
- It has partnered with providers, such as Patient RM, MRN, and Cambridge Cognition, to augment the delivery of auxiliary services (patient concierge, home nursing, and logistics)
- Clients appreciate the face time with senior leadership and commend Clinpal for its expertise on clinical regulations and proactive problem-solving abilities

Limitations

- Clients desire improvements on the UI/UX of the Clinpal platform, expecting it to become more user-intuitive and sophisticated
- Clients cite difficulties when it comes to integration with existing systems or other third-party platforms
- While clients acknowledge its efforts around query resolution, they expect it to increase the team size for smoother, faster, and uninterrupted support services
- Clients desire more out-of-the-box solutions from Clinpal, requiring minimal customizations, so that they can reduce study timelines

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Clinpal (by Cambridge Cognition) | decentralized clinical trial platforms provider profile

(page 2 of 7)

Overview

Company mission/vision statement for decentralized clinical trial platforms

Clinpal's mission is to improve the participant journey, from study recruitment to close out, with a decentralized research platform that unifies data collection for all parties and devices. Orchestrating these parties with workflow tasks and messages and communication capabilities allows for effective and efficient, seamless and error free conduct of the study. A point-and-click studio for study configuration allows a rapid, collaborative study design, either self-build or as a service for all its clients.

Overview of the client base

Clinpal decentralized clinical trial platform caters to therapy areas including neurology, immunology, oncology, pulmonary and respiratory diseases, cardiovascular, diabetes, ophthalmology, obesity, nutrition, and women's health. One focus area will be the CNS therapeutic area, one of the fastest growing DCT areas.

Clinpal's major end clients include a top 10 pharma companies, midsized pharma and Biotech companies, research institutes, medical device companies, and digital therapeutics companies. Having served over 40 companies, there are several in each of these categories.

Revenue by buyer size[1]

Low (<20%)	Medium (20-40%)	High (>40%)

Small	Medium	Large
(annual revenue < US$1 billion)	(annual revenue = US$1-10 billion)	(annual revenue > US$10 billion)

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Clinpal (by Cambridge Cognition) | decentralized clinical trial platforms provider profile

(page 3 of 7)

Case studies

Case study 1	METNA RA – a cross-sectional electronic survey to validate a new methotrexate treatment adherence tool in rheumatoid arthritis, in collaboration with F. Hoffmann-La Roche global medical affairs.

Business challenge

For the validation of the tool patients had to be identified meeting inclusion/exclusion criteria, invited via their primary care practices to join the study, fill in four questionnaires and once completed have the primary care physician do a chart review and fill in ClinROs. The number of patients recruited needed to meet stratification criteria in terms of adherence. At the end of the study patient entered data, clinician provided data, and EHR prescription data were merged.

Solution and impact

The end-to-end process – from identifying high density practices and eligible patients, to recruiting, inviting, and engaging participants through questionnaire completion – was facilitated by the Clinpal DCT platform. Patients signed up online by accessing a landing page that provided an explainer video, they then could activate their account using an activation code. Onboarding included a stringent Consent process built into the system as well as the option for patients to choose between two different rewards. Upon giving consent, participants completed the online questionnaires, which, in turn, triggered the practices to complete their own patient-related charts and questionnaires. Clinpal's workflow automation minimized the burden on practices,

Impact

- 1,043 Patients invited across 51 primary care practices
- 325 Patients enrolled, 320 completed questionnaires
- 31% Enrollment and completion rate

Case study 2	Recruiting 3 studies in parallel in the US and Canada

Business challenge

Referring patients to sites based on a sophisticated algorithm, selecting the sites with best performance or capacity to absorb these referrals within a geographic range, and distributing them across the three trials in order to meet the recruitment targets.

Solution and impact

Clinpal was integrated with the sponsor's micro-site hosting a pre-screener for pre-recruitment, web-recruitment, and call center-based recruitment. Clinpal provided online and call-center based site selection based on a load balancing algorithm.

Clinpal provided

- Scripts and communication support for call agents to reach patients (e-mail, SMS)
- Referral management and site oversight (sites get referrals assigned in the system)
- Analytical reports to track sources of patients, site performance, and reaction time, and delivering information to adjust load balancing algorithm

Impact

Only Clinpal could offer such a solution with a tight integration with the sponsors microsite, the different channels of patients (pre-recruit, call-center, web-screening) as well as the load balancing and analytical capabilities in the required timeframe in order to meet recruitment targets ahead of plan.

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Clinpal (by Cambridge Cognition) | decentralized clinical trial platforms provider profile

(page 4 of 7)

Offerings

Proprietary solutions (representative list)	
Clinpal Solutions	**Details**
Multichannel Recruitment	Clinpal multi-channel recruitment solution allows recruitment of participants using digital and traditional media, following the entire patient journey and assessing participants suitability with pre-screening, optional secondary pre-screening with a call centre, warm-handover to the research site, following patient disposition up to randomisation and allowing for full attribution reports from the advert to randomised patients.
Informed Consent	Clinpal informed consent solution allows for electronically assisted as well as full electronic informed consent. One of its most salient feature is the full support of qualified electronic signatures that uses AI based participant identification full integrated into the Clinpal system besides user-id/pw. Many modes such as fully remote at home, print-to-sign, and tablet-based at the site deploying are engaging multi-media supported user interface for patients can be deployed.
Advanced eCOA	Clinpal enhances and extends what can be achieved when capturing data from patients either directly (electronic patient reported outcomes) or through clinician interviews (electronic clinical outcome assessments) with Clinpal Capture. Whether a sponsor is looking to apply standard instruments questionnaires such as EQ5D or BPI, or, bespoke instruments, Clinpal has the configurable power supported by advanced workflow and reminding capabilities.
Consult	Clinpal Consult allows for integration with bespoke and off-the shelf videoconferencing solutions bringing telemedicine for clinical trials to a new era. Scheduling consultation, initiating, and conducting them is seamlessly integrated within the Clinpal experience and user-interface via any browser or the Clinpal app.
EDC+	Clinpal EDC+ provides a cloud-based and patient-centric environment for capturing clinical trial data. EDC+ brings in together most of the capabilities often seen across different eClinical products. Suitable for simple single-site or virtual trials through to mega-trials, Clinpal EDC+ provides advanced and dynamic configured forms that deliver structured datasets.

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Clinpal (by Cambridge Cognition) | decentralized clinical trial platforms provider profile

(page 5 of 7)

Offerings

Proprietary solutions (representative list)	
Clinpal Solutions	**Details**
Clinpal Build	Clinpal Build provides a point-and-click studio for study configuration. It enables CROs and self-built clients to quickly and easily design studies with all the features of Clinpal.
Clinpal Presence	Clinpal Presence provides the clinical study with a professional and secure web portal to help engage patients, clinicians, and sites. It also provides interactive, geographical site maps for patients to easily locate a convenient site for their participation in a study.
Clinpal Recruit	Clinpal Recruit provides the functionality for study sites to issue invitations to pre-qualified patients and for patients to self-register their interest to join the study. It also assists with recruitment dashboard, which helps in identifying bottlenecks and supports optimizing the recruitment process for maximum effectiveness.
Clinpal Educate	The framework provides a solution for delivering patients with eConsent. The eLearning mechanism can be used to either completely replace face-to-face training in investigator meetings, or to enhance the training by providing tools for completing self-paced training, remotely enabling the in-person training sessions to be shorter and more focused on engaging discussion rather than one-directional training.
Clinpal Capture	Clinpal Capture provides an end-to-end solution for study conduct that proactively guides different stakeholders through the life cycle of data acquisition. With the provision of data capture tools and the ability for patients to enter outcomes directly as ePRO, data collection is standardized for both sites and patients, resulting in an efficient process.

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Clinpal (by Cambridge Cognition) | decentralized clinical trial platforms provider profile

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Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Clinpal (by Cambridge Cognition) | decentralized clinical trial platforms provider profile

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Recent developments

Key events (representative list)

Event name	Type of event	Details
Investis Digital	Partnership	Partnered with Investis Digital, a global digital communications company. The alliance combines Investis Digital's propriety framework Connect.ID Health, known for targeting and engaging hard-to-reach patient populations, and Clinpal's cloud-based platform, which connects patients, study teams, and sites for providing solutions for recruiting, learning management, and engagement (see also Clinpal Solution: Multi-channel Recruitment).
Trials@Home	Investment in Research in DCT	The Trials@Home consortium explores the opportunities of moving clinical trials from the traditional clinic setting to the participant's immediate surroundings. These Remote Decentralized Clinical Trials (RDCTs) make use of digital innovations and enable participants to visit a clinical trial center less frequently. These trials are expected to be conducted faster, more efficiently, and provide results that are more representative, because the data is collected in the daily context of the participant. The research to be conducted includes an inventory and evaluation of existing and new techniques for use in RDCTs as well as a pan-European pilot trial
	Client for the RADIAL study	Clinpal has been selected to provide the core platform for the Trials@Home proof-of-concept RADIAL study, having been a valued consortium member working alongside 30 EFPIA and Academic and SME partners since 2019. The solution covers recruitment, electronic informed consent, engagement, telemedicine, data collection from patients and sites, integration with Glucometers and with smart injector pins and advanced reporting across 3 arms in 6 European countries.
LTI	Partnership	Partnered with LTI in 2021 to accelerate innovation in decentralized clinical trials resulting in better and faster outcomes. With the Larsen & Toubro / Mindtree partnership, it will gain an entry into the Asian market.
Cambridge Cognition	Acquisition	Cambridge Cognition is already an active player in the Central Nervous System (CNS) market, supplying world-leading digital solutions to assess brain health. With the acquisition and integration of the patient-centric Clinpal platform, Cambridge Cognition will be able to offer clients a fully integrated solution covering all trial modules – from recruitment to clinical reporting in CNS and across therapeutic areas. Many CNS disorders, such as Depression and Alzheimer's disease, are particularly suited to DCT's at home daily measurements that can offer richer information on the progress of the condition. Consequently, over the last two years, there have been more virtual DCT for CNS disorders than any other therapeutic area. The acquisition will allow Clinpal to continue provide solutions on a global basis from it's European HQ and US offices. The company has employees world-wide. While many clients are US-based and Clinpal meets all regulatory requirements, it also has unique features for the EU with regulatory compliance and multilingual abilities

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Crucial Data Solutions | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Crucial Data Solutions offers an end-to-end platform (TrialKit) capability for conducting both hybrid and fully-decentralized trials
- Clients mention that it leverages emerging tech solutions in its platform, for example, AI to unearth insights from unstructured data, blockchain for security and compliance, and OCR for reading data from pdfs
- It is adaptive to client requirements, provides quick resolutions of support issues, and ensures that clients have enough face time with senior leadership
- Clients appreciate the speed of study build with the TrialKit platform; accelerated by the pre-built templates and existing libraries
- Its mobile-native (not a rendered version of the website on mobile) application is easy to customize and is rated high on ease of use for patients and site users

Limitations

- It can look to visually enhance the platform. Clients desire an attractive and intuitive user interface for the platform
- Clients mention that it can augment platform capabilities by enabling data extraction and integration from additional sources
- While clients acknowledge that it does a good job with change management, sometimes it becomes difficult to roll out a change on all the platforms (iOS and android)
- It can look to improve the content of the help topics and explanations on the patient app. Clients mention that sometimes patients find them to be ambiguous and generic

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Crucial Data Solutions | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

Founded in 2010, Crucial Data Solutions (CDS) delivers innovative “low-code/no-code” software to clinical research professionals that make it easier and more affordable to bring advance treatments to patients. Unlike other technology providers, its do-it-yourself commitment empowers research professionals with the freedom to design, build, and manage clinical trials and registries faster without a huge price tag.

Overview of the client base

TrialKit, its cloud-based web and mobile-native platform, enables a unified and end-to-end clinical trial management technology infrastructure for medical device, diagnostics, digital therapeutics, and biopharma companies of all sizes. Thousands of global companies have leveraged the flexibility of TrialKit to deploy over 8,000 studies across all phases of development, including Verily (a subsidiary of Alphabet), ICON, Catalyst Clinical Research, SISCAPA Assay Technologies, CDx Diagnostics, and Optinose, and many more.

Revenue by buyer size[1]

	Low (<20%)	Medium (20-40%)	High (>40%)
Small (annual revenue < US$1 billion)			■
Medium (annual revenue = US$1-10 billion)			■
Large (annual revenue > US$10 billion)	■		

Revenue by geography[1]

	Low (<15%)	Medium (15-40%)	High (>40%)
North America			■
Europe	■		
United Kingdom	■		
Asia Pacific	■		
Middle East & Africa	■		
South America	■		

1 All the revenue components add up to a total of 100%

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Crucial Data Solutions | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Mobile app and wearable integration

Business challenge

Mobile app and wearable integration to collect longitudinal data for SISCAPA Assay Technologies

Solution

SISCAPA's daily blood sampling solution, TrialKit's mobile app (i.e., ePRO), and wearable sensors (i.e., Apple Watch), all data from the study would be submitted remotely by participants and made accessible to SISCAPA in real-time through TrialKit's secure cloud database. SISCAPA team was trained on how to design, configure and manage its study database in the TrialKit platform. It had created a prototype study.

Impact

The trial timeline was reduced from 6 months to less than 2 weeks.

Case study 2	From paper to digital study management in large patient registries

Business challenge

From paper to digital study management in large patient registries for CDx Diagnostics. CDx required a robust platform that gave it the needed feature and functionality set, combined with specific capabilities for payment tracking and reporting. It wanted a system that could be managed by CDx's own research coordinator and have all its studies built in-house. It required an intuitive user interface that it would improve adoption, ease-of-use, and limit training time and work effort.

Solution

TrialKit's mobile app was used by 100 doctors to enter the data on behalf of site. TrialKit's role-based permissions feature was used in providing configurable access to TrialKit for CDx representatives who were working with the doctors in the field. CDx was able to share the study design with its team and make necessary changes quickly and easily.

Impact

With the study moving forward, CDx was able to have consistent reporting, and data cleanliness was no longer an issue.

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Crucial Data Solutions | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)	
Solution	**Details**
TrialKit eCOA/ePRO	TrialKit eCOA/ePRO solution is running on the TrialKit platform OR stand-alone tool for studies conducted outside of the TrialKit platform. The data is available as soon as it is saved by the patient and notifications can be sent in real-time to alert specific users that new data has been uploaded remotely into TrialKit through the ePRO/eCOA module.
TrialKit eConsent	Trialkit eConsent platform configures and implements various workflows and methods of data collection to allow sponsors to manage the patient consent process electronically and store all eConsent data within TrialKit.
TrialKit Engage (TeleVisit)	Trialkit Televisit solution provides sites with the flexibility of having embedded visit scheduling and videoconferencing for remote visits via TrialKit engaged within the same platform in which patient data are collected. All data are validated, and an audit trail is provided to track all such activities to ensure compliance.
Trial participant recruitment (screening and enrollment)	TrialKit AI allows for the ingestion of unstructured EHR data to be sent in PDF format to TrialKit AI, middleware that uses AI and ML to parse data, transform it into structured data and populate it in any eCRF or ePRO form for review and analysis by a site and study team. TrialKit AI can parse data from EHR records such as inclusion/exclusion criteria to determine if a patient is eligible for a particular study.
Remote patient monitoring and integration with wearable technology & BYOD	TrialKit' Admin module allows any TrialKit Administrator to design any type of form for remote data collection and review (eCRFs, ePRO/eCOA, eConsent) through a web-based patient portal or the native TrialKit mobile app that can be downloaded on any iOS or Android device. TrialKit can also be configured out-of-the-box with point-and-click ease to integrate directly with any device that stores device data on Google Fit or Apple Health.

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Crucial Data Solutions | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
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Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Crucial Data Solutions | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
OM1	Partnership	Crucial data solution partnered with OM1 to develop large electronically-connected networks of clinicians and health data in rheumatology, dermatology, gastroenterology, cardiometabolic, respiratory, mental health, central nervous system, and other specialty areas. Crucial data solution leverages its extensive clinical networks and unparalleled technology and artificial intelligence (AI) platform.
Triall	Partnership	Crucial Data Solution partnered with Triall to bring Web3 to medical research by creating a digital ecosystem of blockchain-integrated software solutions that secure and streamline clinical trials. Triall's solutions make clinical trials tamper-resistant and enable secure and efficient integrations between the many isolated systems and parties involved in clinical trial processes. Triall's software is co-created with clinical trial professionals to ensure optimal user experience, solving actual industry pain points.
Google	Initiative	Google uses TrialKit exclusively on all regulated studies conducted by it.
Verily Life Sciences	Partnership	In 2015, Crucial Data Solution partnered with Verily, a subsidiary of Alphabet focused on life sciences and healthcare, to make the world's health data useful so that people have healthier lives. Verily develops tools and devices to collect, organize, and activate health data, and creates interventions to prevent and manage the disease.

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Curebase | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Curebase tries to adopt an end-to-end approach by offering its own technology products while partnering for some of the auxiliary services (mobile nursing and patient recruitment)
- Clients mention that it has a better understanding of the digital health and therapeutics (DTx) space as compared to some of the large CROs
- It has been rated highly for its support services, project management abilities, and competitive pricing models that have resulted in cost savings for clients
- Clients mention that they saw a very low patient drop-out rate compared to traditional trials after adopting Curebase solutions

Limitations

- Clients mention that they faced challenges while implementing the solutions, especially while integrating wearables and sensors with the Curebase platform
- While patients had a good experience with the platform, sites and sponsors experienced performance lags and difficulties in extracting large data sets, and expect Curebase to improve the reporting capabilities
- Clients mention that Curebase lacks domain expertise but also appreciate the fact that it is putting efforts into building that expertise
- It can look to increase partnerships to offer the complete array of auxiliary support services, strengthening the value proposition of an end-to-end DCT solution

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Curebase | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

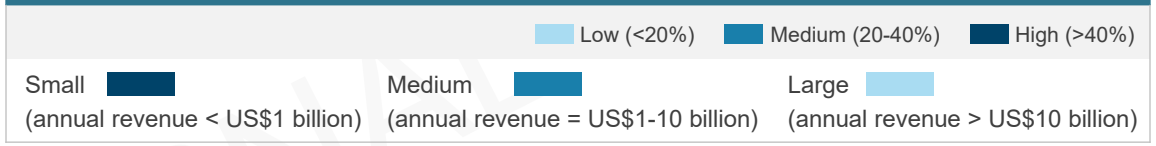
Company mission/vision statement for decentralized clinical trial platforms

At Curebase, the mission is to bring quality medical innovations to patients faster and improve human well-being through efficient clinical studies. It offers the full package of robust services and tools built in-house to run clinical studies end-to-end that reach more patients through in-home, community-based, and site-based care, leading to faster, cost-effective, and diverse studies.

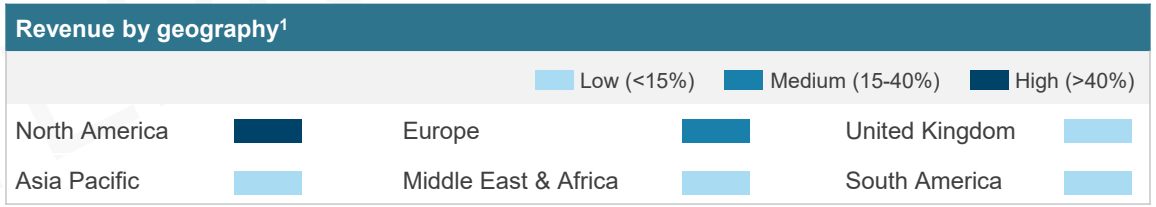
Overview of the client base

Curebase runs decentralized studies that reach any patient, anywhere to enable trials that were not possible before. The key clients are Gilead, Walgreens, Genentech, Sumitomo/Sunovion, Mitsubishi, Vicore, J&J, and Adaptive.

Revenue by buyer size[1]



Revenue by geography[1]



1 All the revenue components add up to a total of 100%

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Curebase | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Setting up virtual site to run a virtual Randomized Controlled Trial (RCT)

Business challenge

The client wanted to run a virtual Randomized Controlled Trial (RCT) tracking sleep patterns with Fitbits to understand the impact on veterans with Post-traumatic Stress Disorder (PTSD). It needed to engage a challenging population.

Solution

Curebase set up the virtual site and used dedicated virtual research coordinators to engage one-on-one with veterans to help them via telemedicine. Fitbits were integrated with the Curebase platform to track participants' sleep and regularly collect data points on Curebase EDC.

Impact

Cost savings increased by 60% by using telemedicine to conduct the study remotely

Case study 2	Established a user-friendly patient engagement platform to track patient long-term health

Business challenge

The client wanted its Phase I HIV prophylaxis to track patients long-term without putting the burden on patients after a single site visit.

Solution

Curebase provided a user-friendly patient engagement platform with built-in notifications and reminders for patient adherence to study activities for over 18 months, including telemedicine visits and ePROs. The integrated telemedicine application enabled monthly check-ins.

Impact

- The client became a strategic investor after experiencing the value of Curebase digital tools and platform
- Patients were provided flexibility in scheduling that led to retention and efficiency

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Curebase | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)	
Solution	**Details**
Curebase ePRO/eCOA	The Curebase eCOA/ePRO solution is the platform for decentralized research. The solution works in synchronous integration with other software solutions allowing for one seamless experience.
Curebase eConsent	Curebase eConsent platform allows videos and images to be included in the document. The eConsent is configurable to a multitude of scenarios such as one-party, two-party, multi-party, LAR, and pediatric assent plus support for remote and on-site consent in addition to site-specific consents.
Curebase Medication adherence	Curebase Medical Adherence includes a dashboard provided to the sponsor to monitor adherence in real-time and make necessary determinations for withdrawal, as applicable per protocol along with custom alerts and notification about missed doses.
Curebase Remote patient monitoring and integration with wearable technology & BYOD	The Curebase platform allows participants to connect wearable devices of their own or study-provisioned devices directly within their patient portal. Wearables, such as Fitbits, can be connected directly to the system by providing the participant's wearable app login information and providing permissions for Curebase to capture certain data points from their device. These devices can be connected and monitored in real time through dashboards configured along with custom notifications for adherence thresholds.
Televisit Curebase	Curebase Televisit platform allows participants and site staff to schedule and conduct telemedicine visits through any device. The telemedicine feature can be utilized during eConsent, which allows the participant to see both the site staff and the consent form within the same window on their computer or mobile device. Telemedicine features can save sponsors time and money by augmenting or replacing physical sites, as well as creating more options for participation leading to greater diversity.
Trial participant recruitment (screening and enrollment)	Trial participant recruitment helps to recruit participants in different ways. Its in-house marketing team builds custom landing pages and digital ads to recruit the correct population of participants for studies on behalf of the sponsor and funnel patents into the prescreening/enrollment workflow in the platform directly.

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Curebase | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
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Curebase | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
Companion	Initiative	In 2022, Curebase announced the initiation of the pilot phase of COMPANION, the first clinical investigation of a new Digital Therapeutic (DTx) for patients with IPF, a rare lung disease. The DTx is owned by Vicore Pharma, a clinical-stage pharmaceutical company. The COMPANION study is a randomized, controlled, parallel-group clinical investigation evaluating the impact of Vicore's digital cognitive behavioral therapy on psychological symptom burden, specifically anxiety and depressive symptoms, in adults diagnosed with Idiopathic Pulmonary Fibrosis (dCBT IPF).
Digital Therapeutics Alliance	Partnership	In 2021, Curebase partnered with Digital Therapeutics Alliance (DTA), a global non-profit trade association with the mission of broadening the understanding, adoption, and integration of digital therapeutics into healthcare. Curebase is co-leading with the DTA, an industry first guidance on how to conduct DTx clinical trials for regulatory and reimbursement purposes expected to release at the end of 2022.
PCM, MRN, Axle Health	Partnership	Curebase partnered with external mobile nursing partners to deliver home health to patients when a physical site is not involved.
Universal App Experience	New Product Feature	Curebase launched a Universal App feature that allows patients on any of its studies to simultaneously use web-based experiences and app-based experiences on any device and pick up where they left off. This gives patients dramatic flexibility on any study to choose how they would like to participate in a study and change mid-stream if they would like.

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Delve Health | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender and Star Performer

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Delve Health has partnerships for in-home nursing and patient screening to provide auxiliary support services to clients
- It has a good solution for integrating the wearables and pulling data from multiple providers
- It provides more detailed eCOA outcomes by providing capabilities to measure ePerfO, eClinRO, and eObsRO
- It has good domain expertise when it comes to serving medical device clients

Limitations

- It does not have adequate capabilities for patient recruitment and medication adherence, some of which has been launched recently
- Clients cited a few challenges in terms of on-time support due to less bench strength of the people on the project
- Delve Health can look at incorporating multilingual capabilities to cater to diverse clients as well as a different section of the population across the globe
- Currently it lacks the expertise specific to life sciences clients in broader therapeutic areas such as Oncology and respiratory diseases, and focuses more on the medical devices space

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Delve Health | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

Delve Health understands the need to spearhead clinical trial advances. It uses science, technology, and human science to make informed decisions about the present and the future.

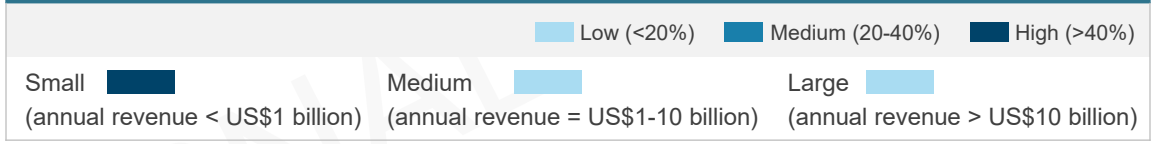
The possibilities for major decentralized clinical trial advances in healthcare happen only if data is gathered from many patients. Hence, remote data gathering is at the forefront of Delve Health's clinical trials advances. It enables a smooth and timely approach to the data processor. It also enables teams to reach patients where traditional methods cannot.

Overview of the client base

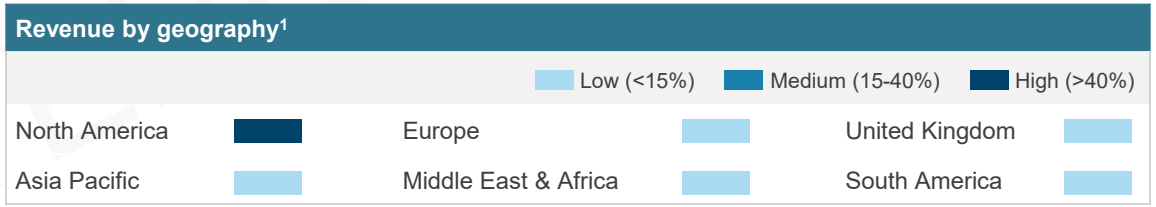
Delve Health has managed, designed, and executed numerous studies across multiple disease states. The company joined xCures and Cancer Commons to support the Beat19 data initiative to conquer COVID-19.

Some of the key partners include Recor, Mednet, Sightglass Vision, Inari Medical, and Orthofix.

Revenue by buyer size[1]



Revenue by geography[1]



1 All the revenue components add up to a total of 100%

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Delve Health | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Oncology clinical trial for a pharma company

Business challenge

The client was interested in a simplified solution to quickly randomize, get consent, and collect patient-reported outcomes from patients remotely.

Solution and impact

Delve Health configured its IWRS solution and uploaded all patient consent multi-media information, as well as set up ePRO for patients internationally. Investigators randomized patients into Clinical StudyPal, and upon randomization, patients received an SMS to download the app and consent into the study. Patients had the option to login to Clinical StudyPal or download the mobile app to consent and respond to their diaries.

Impact

Patients were notified of their diaries via SMS. The client utilized Clinical StudyPal to monitor patient progress and manage compliance.

Case study 2	Provide a solution to monitor hypertension for a medical device company

Business challenge

The client was interested in developing a way to monitor patients with hypertension at home.

Solution and impact

Delve Health integrated with multiple blood pressure monitors and managed the activation of blood pressure monitors across the US and EU and utilized ePRO to collect patient-reported outcomes via mobile phones. Patients received SMS or WhatsApp for ePRO notification based on their geographical regions. Delve Health collected data from the blood pressure monitor, created analytics, and helped manage the shipment process of the wearable device.

Impact

The client utilized Delve Health big data platform to collect and analyze patient outcomes.

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Delve Health | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

Proprietary solutions (representative list)	
Event name	**Details**
ePRO/eCOA	Electronic Patient-Reported Outcomes (ePRO) in a clinical trial allows patients to answer questions and report on their health through an electronic device, such as a smartphone, and tablet while Electronic Clinical Outcome Assessments (eCOA) involves questions that are presented to a patient using an electronic device
Patient concierge services	The patient concierge acts as a central point of contact, helping in pre-screening patients, and actively guiding patients through the complexities of clinical trials while offering assistance with comprehension, logistics, and technology. It enhances the patient experience in a clinical trial by improving clinical effectiveness, streamlining patient flow, and patient satisfaction.
Wearables	Connect to over 100 wearables providers to provide remote patient monitoring, surveillance, screening, and providing assistance at various stages of treatment. Allowing customers to design their own analytics and algorithms against raw data collected from wearable and IoT devices.
Patient eConsent	Patient eConsent feature enables patients to provide consent via video or digital hand signature. It automates the patient enrollment process and on-boards patients directly into platform.
Nurse & Caregiver CRM	Allows study team to assign nurses to specific patients, and specific visits, where a nurse can also collect data directly from patients in home or remotely.
TeleVisit	The televist platform enables performance of remote visits via video calls and helps in keeping studies moving ahead. It helps to reduce patient burden and improve compliance.
Patient Engagement	Study owners can setup automated ways of engaging patients via remote messages, whether it wants to provide an automated welcome message, a message of empowerment, or even a reminder to complete a specific task, improving compliance and providing a guided protocol at their fingertips.

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Delve Health | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Delve Health | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

Key events (representative list)

Event name	Type of event	Details
Afortiori Development	Partnership	Delve Health partnered with Afortiori Development, a Clinical Research Organization (CRO) to expand patient access to support the delivery of clinical trials worldwide. Delve Health provides a fully-customizable mobile and web-based platform that enables remote patient monitoring and interaction to provide a foundation for the delivery of decentralized clinical research for trial sponsors.
xCures and Cancer Commons	Partnership	Partnered to support Beat19 – a crowd-sourcing initiative to jump-start COVID-19 data collection from around the world. Role of Delve Health is to leverage its expertise in technology and combine it with its knowledge of cancer care, in order to create a user-friendly and secure mobile app for the Beat19 project, which will allow volunteers to share their data

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IQVIA | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- IQVIA orchestrates decentralized trials through its Orchestrated Clinical Trials (OCT) suite, which is a wide combination of technology products and auxiliary service offerings
- It leverages its CRO heritage to gain enterprise mindshare and can support clients in conducting DCTs globally across multiple therapy areas
- It has made good investments around data analytics, BI, AI, ML, and emerging tech capabilities through the Clinical Data Analytics Suite (CDAS) offering
- Clients have appreciated the responsiveness of IQVIA's 4-tier support model
- It has good domain expertise and engages in consultative activities, helping clients with trial designs

Limitations

- IQVIA's CRO heritage sometimes creates skepticism in enterprise minds about its abilities as a DCT platform provider
- Clients mention that the user experience of the product suite can improve. While it is well-designed, it keeps crashing, is slow, and clunky
- Clients cite challenges with the software updates – often come with glitches and are time-consuming to correct and implement

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IQVIA | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

IQVIA Decentralized Trials provide purpose-built clinical services and industry-leading technologies to encounter the appropriate patients wherever they are. For each therapeutic area, the onsite and community-based solutions provide adaptable patient and site strategies. With over 300 Decentralized Clinical Trials (DCT) currently underway in over 50 countries and 30 indications, IQVIA has the experience, resources, and reach to satisfy the demands of any sponsor.

Overview of the client base

IQVIA has over 350 customer adoptions from companies ranging form top 10 pharma and biotech, specialty drug, consumer health, and MedTech.

Revenue by buyer size[1,2]

Low (<20%)	Medium (20-40%)	High (>40%)

Small	Medium	Large
(annual revenue < US$1 billion)	(annual revenue = US$1-10 billion)	(annual revenue > US$10 billion)

Revenue by geography[1,2]

Low (<15%)	Medium (15-40%)	High (>40%)

North America	Europe	United Kingdom
Asia Pacific	Middle East & Africa	South America

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1 All the revenue components add up to a total of 100%
2 Based on analyst estimates

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IQVIA | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	IQVIA expertise ensures the success of a critical next generation neurovascular device Research

Business challenge

The client wanted to adopt neurovascular as it was growing over the market. It was difficult for smaller companies to progress when they were financially and scientifically concentrated on a constrained number of potential therapies.

Solution

IQVIA MedTech team helped the client to conduct 10 neurovascular pre- and post-market studies collectively spanning 50 sites and including more than 1,700 patients. This experience helped it to foresee and overcome difficulties.

Impact

- Decreased clot fragmentation rate
- Helped to improved the services for comparable safety metrics

Case study 2	IQVIA Biotech sets the stage for successful oncology trial execution

Business challenge

The client faced difficulties in timelines to finalize the protocol, have sent it to the FDA, and coordinate the versions of regulatory documents. Secondly, it faced challenges while the sponsor established the deadline to accomplish a business goal connected to a funding event. It was a rushed 10-week First Patient In (FPI) target to open sites, enroll patients, and launch a database.

Solution

The team from IQVIA Biotech was using its knowledge of important personnel, regulatory, contracts, and budget processes at the selected sites to speed up FPI. The sponsor gave the site contracts team permission to negotiate a deal on its behalf and stipulated reasonable terms that cut down on the number of review cycles.

Impact

- Met the 10-week FPI goal along with a live database
- Patient enrollment was completed in four months as opposed to the one-year timeline originally projected

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IQVIA | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)	
Solution	**Details**
Orchestrated Clinical Trials (OCT)	OCT suites are designed to involve patients while enhancing the speed and adaptability of clinical research. The majority of OCT products are interoperable with legacy systems and are cloud-based solutions created to enhance the clinical trial process. This includes a digital site suite, patient engagement suite, trial management suite, and clinical data analytics suite.
Enterprise Information Management (EIM)	With EIM set of products from IQVIA, a customer could build a solid basis for developing data-driven, agile, and strategic thinking.
Performance Management and Insights (PM&I)	The functionality provided by IQVIA PM&I solutions could be tailored to the needs of a particular position. Additionally, the systems' scalability, flexibility, and responsiveness to changing information and analytics requirements are all a result of its cloud-based construction.

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IQVIA | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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IQVIA | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
Redslim	Partnership	It has incorporated the data sources using a flexible and tailored strategy. Its outputs satisfy the demands of various user types and include data ingestion for IT departments and web dashboards for the benefit of analytical teams. It was flexible in meeting the globally changing demands for data democratization.
Orchestrated Customer Engagement Platform	Investment	The addition of Grants and Funding Management, a new module within the Orchestrated Customer Engagement (OCE) solutions portfolio, will provide health sciences organizations with a tool to administer and supervise their global strategic giving initiatives.
Patient-centric Laboratory Solutions	Initiatives	Q2 Solutions, IQVIA's global clinical trial laboratory organization, has several programs and initiatives around decentralized trial solutions including near patient collection, nurse supplies, self-collection, direct to patient specimen collection kits, Point of Care Testing (POCT) at home, and lab network solutions.
Cenduit IRT	Partnership	IQVIA offers an end-to-end IP Management Centre of Excellence within partnership with Cenduit IRT (An IQVIA company) and IQVIA Clinical Supply Chain. This full service CoE focuses on the IP Management critical activities throughout the study lifecycle.
Berlinger	Partnership	Cenduit (An IQVIA company) offers a fully-automated temperature management solution together with Berlinger. Data from temperature loggers from shipments and from site storage can be uploaded to the Cenduit system.
Salesforce	Partnership	Leveraging Salesforce innovation, together combined with IQVIA's deep life sciences expertise, includes both SaaS and technology-enabled services that will automate study processes, drive R&D insights from artificial intelligence and machine learning, and strengthen connections between patients and clinicians.

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Labcorp Drug Development | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Labcorp takes an end-to-end approach by offering tech products through the snapClinical® DCT Platform and auxiliary services through its CRO heritage
- Its partnership with Circuit Clinical provides access to a wide network of physicians and clinical research professionals, accelerating the adoption for DCT solutions
- It brings in gamification with the DCT platform to increase patient engagement in clinical trials
- Clients appreciate the support services for patients and sites – both for technical requirements and clinical protocol-related issues

Limitations

- The CRO heritage and a heavy focus on services might eclipse its capabilities as a DCT platform provider
- It has limited thought leadership content or consultative capabilities to help clients design and deploy decentralized trials
- It can look to focus on leadership hiring to improve product portfolio and patient experience

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Labcorp Drug Development | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

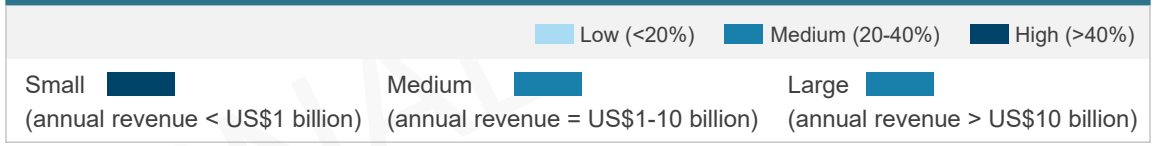
Company mission/vision statement for decentralized clinical trial platforms

Labcorp is a global life science and healthcare company harnessing science for the human good. The mission is to improve health and improve lives. It uses diagnostics to improve patient care and accelerate drug development.

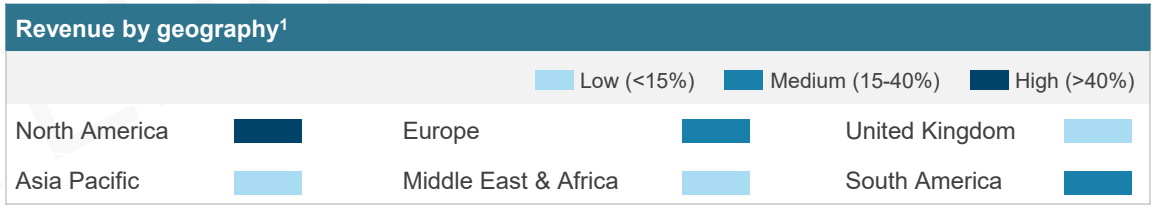
Overview of the client base

Labcorp offers digital solutions within the DCT space for over a decade. It has more than 70,000 employees and serves clients in more than 100 countries. The key areas include managed care organizations, biopharmaceutical companies, governmental agencies, physicians and other healthcare providers, hospitals and health systems, employers, patients and consumers, contract research organizations, and independent clinical laboratories.

Revenue by buyer size[1]



Revenue by geography[1]



1 All the revenue components add up to a total of 100%

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Labcorp Drug Development | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Enabled in-home evaluation

Business challenge

The client required a fully-integrated platform and implementation of mobile clinical for non-diabetic chronic kidney diseases with in-home visit.

Solution

The Labcorp solution enabled it to do in-home evaluations of patient vital signs, body weight, biological sample collection, sample processing and transport to a central laboratory, and document seen and/or spontaneously reported indications and symptoms. It also assisted in the performance of study intervention checks to examine the bottles at the patient's home for IMP accountability. This system also has integration possibilities with EDC, CTMS, IRT, and eCOA.

Impact

Supports real-time data availability in a single location for the entirety of electronically collected patient data. Querying for home health improves data quality, reducing average of 3-4% error rate resulting from manual data entry. Increases safety and oversight as potential AEs can be proactively identified.

Case study 2	Minimized patient burden

Business challenge

The client wanted to minimize patient burden and travel alternatives by assisting them with televisit-based trial design using snapClinical and assisted AI analysis of lesion images.

Solution

The solution benefited the support of trial capabilities with a variety of companies. The submission of images of skin lesions obtained at home for examination utilizing AI technology was a critical component.

Impact

Removes the need for onsite visits to support measurement and review of potential reactions. Removes travel burden for patients and allows more accurate measurement and storage of images illustrating lesions.

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Labcorp Drug Development | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)	
Solution	**Details**
ePRO/eCOA	Labcorp Electronic Patient-Reported Outcomes (ePRO) platform for clinical trials improves the capacity to monitor patients remotely, with the ability to understand compliance and retention proactively. It reduces manual steps to collect data and increases the convenience of capturing electronic data to enable increased connectivity with trials.
eConsent	Labcorp eConsent platform reduces the manual scanning process, uploading executed consent forms and ensures that all signatures get captured along with date and times for entry to electronic records. It provides the ability to drive protocol amendments and new ICF versions with reduced risk of unapproved ICFs.
TeleVisit	Labcorp TeleVisit platform allows patients to schedule ad hoc visits in addition to visits per the Service Oriented Architecture (SOA) and increases the connectivity of patients and sites.
snapClinical® DCT Platform	Labcorp snapClinical platform is a highly configurable no-code technology suite designed to accelerate study setup and execution while providing an integrative approach supporting all elements of a clinical trial.

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Labcorp Drug Development | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
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Labcorp Drug Development | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
Medidata	Partnership	In 2022, Labcorp partnered with Medidata, a Dassault Systèmes company, to co-develop digital biomarkers and expand the use and functionality of decentralized clinical trials to accelerate patient care while providing valuable information to study sponsors.
HealthVerity	Partnership	In 2022, Labcorp partnered with HealthVerity to expand existing end-to-end solutions for drug and diagnostics development, commercialization, and clinical trial efforts to include large-scale access to real-world data for research applications.
Circuit Clinical	Partnership	In 2021, Labcorp partnered with Circuit Clinical to bring clinical trials directly to patients and increase access to underrepresented populations, network of physicians, and clinical research professionals. The collaboration will further accelerate patient engagement and recruitment through the development of a Decentralized Clinical Trial (DCT) Investigator Network. This network aims to cultivate a broad nexus of physicians who can support decentralized clinical trials, accelerate patient recruitment, increase clinical trial access to more diverse patients, and reduce the burden of participation by supporting remote patient engagement.
Toxikon Corporation	Acquisition	In 2021, Labcorp acquired Toxikon Corporation, a contract research organization delivering nonclinical testing services to expand its nonclinical development portfolio and create a strategic footprint for the company to partner with pharmaceutical and biotechnology clients in Boston.
SnapIoT	Acquisition	In 2020, Labcorp acquired snapIoT, a global medical technology company that provided a digitized clinical platform (snapClinical®) that supports remote participation in clinical trials. It provided Labcorp full control of its DCT platform development and allows for the acceleration of trial design and implementation while de-risking the execution process by providing complete, integrated solutions from a single partner.
Infirmary Health	Partnership	In 2020, Labcorp partnered with Infirmary Health, the largest non-governmental health care system, to provide laboratory services to patients and providers throughout the eastern Gulf Coast region.

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Medrio | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Medrio has an intuitive, easy to set up, and easy-to-use platform. Clients mention that sponsors and sites could use the solutions with little product or tech knowhow
- Clients appreciate Medrio for its responsive support services and the practice of continuously upgrading its products based on end-user feedback
- Its price points are competitive and transparent, and clients have realized cost savings in the engagements
- It has an online customer community where end users can connect, share feedback, and gain access to product knowledge and educational materials

Limitations

- Clients mention that the platform is not DCT-native (rather designed for on-site data collection and has been tweaked to accommodate decentralized trials); hence, patients' experience is not smooth and seamless, causing a delay in patient recruitment
- It can look to improve the UI/UX on the ePRO platform. Patients often find the instructions ambiguous and mention interface inconsistencies between sections
- Clients desire more flexibility on the ePRO platform (easily customizable forms) and lesser time for the overall database build
- Clients expect Medrio to improve its dashboarding and reporting capabilities with more standardized and user-intuitive reports, KPIs, and queries

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Medrio | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

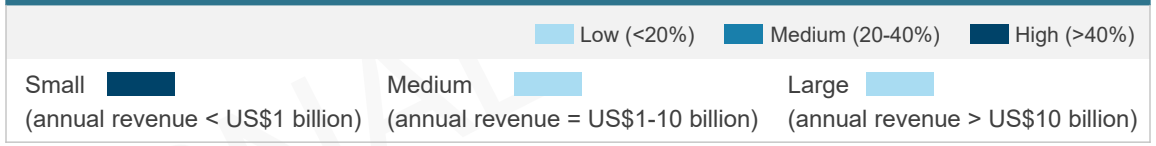
Company mission/vision statement for decentralized clinical trial platforms

Medrio provides hybrid and decentralized trials eClinical solutions, with more than 2,000 decentralized studies of experience to date. Medrio to establish customer trust and streamline clinical trial workflows for decentralized trails by offering technology designed for accuracy, ease-of-use, predictability, and flexibility. Medrio's view of decentralized trials is that a hybrid model will dominate trial designs since not all trials can be fully virtual or site-less.

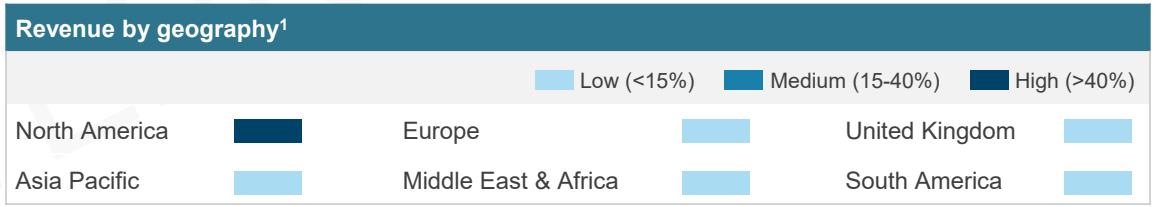
Overview of the client base

Medrio maintains a depth and breadth of customers in all industry segments including pharma, MedTech, diagnostics, consumer health, and animal health. Key customers include major pharma clients, seven of the top diagnostic companies, an employee-owned company that develops, manufactures, and markets healthcare products and services, a world-leading procurement and supply chain consultancy, a company that provides digital therapeutics for people with chronic conditions, a rare disease biopharmaceutical company, and pioneering biotechnology companies.

Revenue by buyer size[1]



Revenue by geography[1]



1 All the revenue components add up to a total of 100%

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Medrio | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1 | **Successfully engaged and empowered rare cancer patients**

Business challenge

The client wanted to expand patient access without physical or geographical constraints and enhance patient understanding of the molecular drivers of their rare cancer. Client was facing difficulties in real-time visibility into the consent process.

Solution

Implemented Medrio's remote eConsent function in its TCF-001 TRACK study, which has an objective to determine if rare tumors can benefit from matched molecular therapy and remotely enrolled a total of 400 patients in the United States using electronic informed consent. Medrio's eClinical solution provided significant benefits to the client including reduction of unnecessary delays, improved access to dispersed patients, privacy of review within the patient's home environment, and increased patient and caregiver understanding.

Impact

- Ability to make changes immediately and leverage on-demand support when needed
- Always informed with real-time patient consent status
- Patients and caregivers are empowered to initiate the consent process themselves, and from the comfort and privacy of their home
- Geographic and physical barriers that often plague rare cancer patients are removed from the consenting process

Case study 2 | **Leveraged Medrio ePRO in a proof-of-concept DCT hybrid study**

Business challenge

The client was looking to see if a remote trial would be feasible for patients and sites. The client faced challenges such as feasibility of conducting a largely virtual trial, patient compliance in a remote setting, and site preparedness and training.

Solution

Medrio conducted follow-up visits either through video conference or by phone, and sites reported that it preferred telehealth visits over in-person visits due to the ease of scheduling and convenience for patients. Leveraged Medrio ePRO in a proof-of-concept for a decentralized hybrid study. Electronic Patient-Reported Outcomes (ePRO) technology was used to assess the results of varying digital therapies and the feasibility of conducting a largely virtual clinical study in a fibromyalgia population.

Impact

The engagement helped the client to achieve 97% patient compliance, increased site productivity, and increased patient engagement. It also reduced administrative burden on the site, which allowed for timely data collection and analysis and an overall positive experience for the site.

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Medrio | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)	
Solution	**Details**
eCOA/ePro	A solution that handles the complexities of patient-reported data, from the flexibility to switch between in-clinic and remote data collection, to the ability to support popular validated survey instruments. It allows patients to respond to surveys anywhere at any time on any deceive they choose. Democratizes the ePRO+ space through drag & drop tools, intuitive interfaces and integrated platform with EDC for real-time tracking and addressing to accelerate timelines
eConsent	A solution that empowers organizations to accelerate all aspects of the consent process, from setting up and modifying forms to ensuring patient comprehension, while remaining in full regulatory compliance. This solution supports both electronic and paper-based processes, allowing customers to prioritize the patient experience and the sites' needs. Supports regulatory requirements and increases efficiency, quality, and tracking by eliminating paper.
Direct Data Capture	A solution that enables eSource data collection through its web-enabled Electronic Data Capture (EDC) and via tablet app using its direct data capture product. With this app, data is available for data management review within minutes of the device going online. With either approach, data edit checks can be easily configured to help ensure only quality data are submitted for review. Provides offline capabilities for home health professions or anyone in the field collecting data that wants extra security in internet unstable areas.
Electronic Data Capture (EDC)	A powerful solution that centralizes all source data for an entire clinical trial. Studies that capture data in Medrio EDC experience greater efficiencies, reduced costs, and nearly 90% fewer errors compared to solutions that require data transcription. Medrio EDC also improves visibility among research, operational, and other teams by giving users the ability to access data any time, from anywhere, on any device. Market leader in streamlining the study creation and close out processes to speed time to market.
Participant Portal	A solution that allows sponsors, CROs and sites to share study or site-specific information with a participant on the participant portal. It provides the ability for a potential participant to access the participant portal to create a profile and receive consent documents or surveys for completion. Integrated with Medrio's eConsent, ePRO and EDC solutions. Increases participant engagement, adherence to protocols, and compliance.
Medrio API Connect	An integration solutions product line that includes API and SSO technology solutions for building integrations with third-party applications and datasets based on standards such as OData and Open API Specification (OAS).
Medrio Recruitment	A solution that allows for social media and targeted recruitment by providing a link where prospects can access the participant portal to create a profile and receive additional information about a study to determine interest and match

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Medrio | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Medrio | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
Partnered with Red Nucleus	Partnership	In 2022, partnered with Red Nucleus, an award-wining advisory, scientific services, medical communications, and L&D for the life sciences industry, for video research visits.
Acquired HMD Clinical	Acquisition	In 2021, acquired HMD Clinical, a leading provider of Randomization and Trial Supply Management (RTSM), to expand its portfolio of proven eClinical technology solutions to global sponsors, CROs, and sites. The acquisition integrated HMD's expertise in RTSM with Medrio's expertise in electronic data capture including ePRO, eConsent, and eSource providing a full service unified eClinical suite.
Acquired DFS Pharma	Acquisition	In 2021, acquired DFS Pharma, a contract research organization.
Partnered with Thoughtsphere	Partnership	In 2021, partnered with Thoughtsphere, an IT consulting & software development, to offer additional Risk-Based Quality Management (RBQM) and E2B (R3) Compliance solutions.
Partnered with Pharmaseal	Partnership	In 2021, partnered with Pharmaseal, a SaaS-based B2B clinical trial governance platform, to offer integrated Clinical Trial Management System (CTMS) and Electronic Trial Master File (eTMF) solutions
Partnered with AG Mednet	Partnership	In 2021, partnered with AG Mednet, a managed care service provider, to offer additional imaging workflow management and adjudication workflow management solutions to its customers.

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ObvioHealth | decentralized clinical trial platforms provider profile (page 1 of 7)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- ObvioHealth has good knowledge and expertise in the consumer health industry. Clients mention that they do not adopt a tech-first approach but bring in business-oriented focus during deal solutioning
- Clients appreciate the speed of study built and the time taken to start patient recruitment. This has resulted in a significant reduction in trial timelines
- It is appreciated for its responsiveness to queries, project management abilities, and CRO services such as regulatory support
- While it focused on the APAC market during the initial days, clients now acknowledge its efforts in conducting global studies
- It has been rated high on the user experience of its products and solutions along with its training modules and services

Limitations

- While it is responsive to queries, clients mention that implementing new changes can become faster and more streamlined
- Some clients cite difficulties while exporting data from ObvioHealth's system to their existing clinical development platforms
- It can improve on its speed of delivery as clients expect that the speed of operations should match the client governance expectations and that the results are communicated on time
- The patient screening process can become more robust and secure, preventing pretentious participants from taking part in trials. Clients acknowledge that ObvioHealth is already working on this

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ObvioHealth | decentralized clinical trial platforms provider profile (page 2 of 7)

Overview

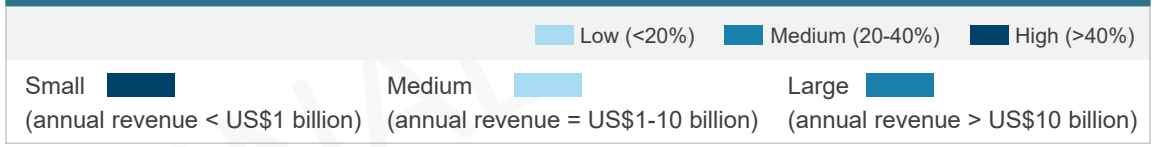
Company mission/vision statement for decentralized clinical trial platforms

ObvioHealth's vision is to drive the industry forward with a DCT platform and clinical science that will deliver stronger evidence of therapeutic efficacy and safety to sponsors. The company's vision is to transform health research to help bring more life-improving innovations to the market.

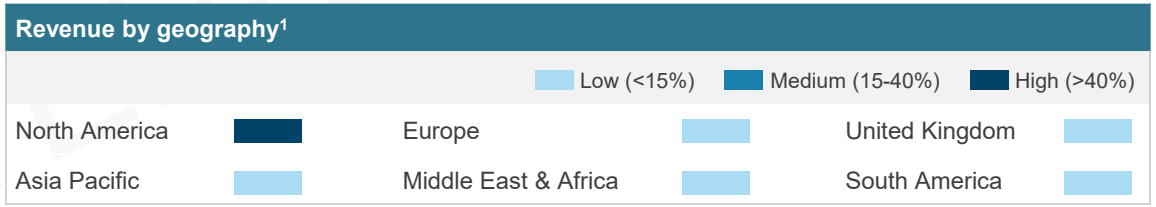
Overview of the client base

ObvioHealth serves a diverse customer base of pharmaceutical, biotech, medical device, and consumer health clients including Johnson & Johnson, Pfizer, GSK, Bayer, Evolve BioSystems, Entrinsic Health, Janssen, Renovia, Lycored, RedHill Biopharma, Mithra, General Mills, Danone and others.

Revenue by buyer size[1]



Revenue by geography[1]



1 All the revenue components add up to a total of 100%

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ObvioHealth | decentralized clinical trial platforms provider profile (page 3 of 7)

Case studies

Case study 1	Enhancing end-to-end engagement from study design and consulting through database lock

Business challenge

The client wanted to validate efficacy of its Pelvic Health System on Women's incontinence which is a health concern in 62% of US adult women over 50

Solution

- Deployed a digital recruitment strategy using targeted advertising on social media
- Designed creative assets to appeal to women in specific age groups, decreasing cost per click
- Patients were trained on how to use the device using three different methods: a video, a pamphlet, and three phone calls

Impact

- Provided closed integration with the device for capturing participant usage data for incorporation into the study data
- The study was recruited via social media in just under 14 weeks at a cost per patient more than 10 times lower than traditional studies

Case study 2	Designed decentralized study to examine safety and efficacy of a novel and orally administered serine inhibitor

Business challenge

The client wanted to examine the safety and efficacy of RHB-107 (upamostat), a novel and orally administered serine inhibitor with antiviral and potential tissue-protective effects which targeted human cells rather than the virus itself

Solution

- Designed the decentralized study to be conducted where most patients recovered from illness—in their homes
- Introduced wearable devices, patient vitals that can monitor from home, ensuring patient safety at all times

Impact

Achieved 100% reduction in hospitalizations due to COVID-19 and an 87.8% reduction in reported new severe COVID-19 symptoms

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ObvioHealth | decentralized clinical trial platforms provider profile (page 4 of 7)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)	
Solution	**Details**
Study Design	Optimize study build and accelerate amendment time: • Configures and customizes eConsent, screening, eCOA, and ePRO components according to each protocol. • Tests, previews, and publishes study screens to the ObvioGo mobile app so sponsors can approve or provide feedback without a hitch. • Easily pivots to address mid-study change orders with flexibility, empowered by real-time learning. • Captures insights gathered during daily use across studies to enable our in-house design team to perform iterative optimizations.
Outcomes Capture & Assessment	Capture more accurate data: • ePRO, eClinRO, eObsRO, and ePerfO capabilities are paired with FDA- and CE-validated medical devices, as well as a range of wearables and other digital instruments, which can capture vitals and other signals remotely and accurately. • Participants can report changes in their health statuses or medications at any time. • Innovative data collection options like Augmented ePRO enable easy reporting of symptoms through image, audio, and video capture. This data can then flow to a centralized portal to be clinically rated by experts. • The outcomes capture capabilities are also built to integrate EHR, labs and imaging, and other clinical data from sites and hospitals.
Mobile Application	Frictionless patient interfaces: • Multi-media training ensures participants have clear and simple explanations of all they need to do to complete their tasks. • Easy eConsent includes informational screens and comprehension checks to ensure full understanding. • Patient engagement features like gamification, motivational nudges, and compensation milestone markers keep participants engaged and compliant. • Automated notifications remind participants when tasks are due. • Participants can track their study supply shipments as well as their milestone payments through the app. • On-demand video and chat support through the app ensures participants get near real-time answers to their questions.

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ObvioHealth | decentralized clinical trial platforms provider profile (page 5 of 7)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)

Solution	Details
Study Management	Increase compliance and retention: • Dynamic recruitment and screening dashboards provide real-time data, enabling study recruitment up to 4x faster than traditional sites. • Intuitive dashboards notify study teams of any compliance, data entry, technical, or safety issues, helping to facilitate monitoring. • Live text and video chat enable real-time communication and personalized support between ObvioHealth's COACH (Clinical Oversight and Coordination Hub) team and participants.
COACH Team & Live Communication	A live text and video chat solution which enables real-time communication and personalized support between ObvioHealth's COACH (Clinical Oversight and Coordination Hub) team and participants. These virtual coaches are available throughout the course of the study to answer questions and resolve concerns as well as facilitate enrollment and eliminate drop-off during those portions of the funnel.
Data Management	Make data oversight more efficient: • Secure gating prevents unvalidated data from being accepted into the vault. • Permissions-based functionalities enable sites, labs, and other stakeholders to enter data directly into the platform. • Study data is efficiently managed and cleaned by the study team, empowered with automated branching, sub-scoring, total scoring, and automatic edit checks. • Real-time data processing with automatic data cleaning, auto-edit checks, and advanced query resolutions empower study teams to get more quickly to database lock. • Seamless integration with EDC, CTMS, RTSM, and eTMF. Robust documentation capabilities support audits. • A full in-house EDC that stores and processes all data in one place.

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ObvioHealth | decentralized clinical trial platforms provider profile (page 6 of 7)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
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Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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ObvioHealth | decentralized clinical trial platforms provider profile (page 7 of 7)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
Dedalus Integration	Partnership	Partnered with Dedalus, the largest EHR vendor in Europe, to unite ObvioHealth's proprietary decentralized clinical trial tools with Dedalus' software solutions, connecting the dots between clinical research and EHR data from over 330 million patients, while supporting healthcare providers from 6,000+ hospitals and clinics across the world.
Novotech	Partnership	Partnered with Novotech, a leading biotech specialist CRO in the Asia-Pacific region, to increase growth in the biotech space.
IQVIA	Partnership	Partnered with IQVIA, an American multinational company serving the combined industries of health information technology and clinical research, to deliver clinical trials together on a global scale. They have completed several key studies through this partnership and have many more in the study design phase, with a robust pipeline of opportunities on the horizon.
Oracle Integration	Partnership	Partnered with Oracle, to primarily focus on the APAC region, where both the companies can resell the other platforms for Hybrid and full DCTs. As this partnership expands, both companies will be enabling commercial, Go-to-Market strategies expanding to a global scale.
Hyfe	Investment	Invested in Hyfe's Series A round and announced a partnership to integrate Hyfe's AI technology for tracking and analyzing coughs to expand ObvioHealth data tools for DCTs, providing clients of ObvioHealth with higher quality clinical data.

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Signant Health | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Signant offers a unified DCT experience through the SmartSignals platform suite (eConsent, eCOA, telemedicine, RTSM, analytics, and consulting services)
- The eCOA solution comes with an easy, drag-and-drop feature to build the workflows, requiring no/minimal programming, and supports multiple languages
- Clients rate Signant highly on the user experience, security, and privacy of the platform
- It offers a patient-friendly, intuitive, and easy-to-use eCOA solution complemented with quality educational content
- It is rated high on security and privacy. Clients mention that the platform meets all regulatory and compliance standards

Limitations

- Clients mention that sites often face difficulties with the platform as it requires separate logins for the individual modules, missing on single sign-on feature
- Clients desire that Signant expand its domain expertise to a broad range of therapy areas and mention that they are moving in the right direction with the centers of excellence and industry memberships (like DTRA)
- It can improve its change management capabilities, communicating the right timelines, and enhancing its training modules to enable a smooth transition for clients
- It has a CRO partner program but can expand its partnerships with service providers for providing auxiliary services

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Signant Health | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

Signant Health leverage its scientific expertise along with its technology suite to enable the right data to be collected, at the right time, with the right solution, in the right setting, to ensure an empathetic experience for the patient, and reduced burden for sites. Signant Health are driven by the need to provide high quality clinical evidence, and it applies its scientific and clinical expertise, alongside its technology capabilities, to ensure valid and accurate measurements when migrating assessments from clinic to remote settings.

Overview of the client base

Signant Health is serving for more than 20 years, it has a client base of sponsors and CROs of all sizes. Nineteen of the top-20 life science companies have trusted Signant Health's eCOA, eConsent, and telemedicine solutions. It continues to work with hundreds of sponsors including 19 of the top-20.

Revenue by buyer size[1,2]

Low (<20%)	Medium (20-40%)	High (>40%)

Small	Medium	Large
(annual revenue < US$1 billion)	(annual revenue = US$1-10 billion)	(annual revenue > US$10 billion)

Revenue by geography[1,2]

Low (<15%)	Medium (15-40%)	High (>40%)

North America	Europe	United Kingdom
Asia Pacific	Middle East & Africa	South America

1 All the revenue components add up to a total of 100%
2 Based on analyst estimates

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Signant Health | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Enabled accurate remote assessment for Alzheimer's patients

Business challenge

The client wanted rapid migration to video-assessments to enable continuation during pandemic for Alzheimer's trial.

Solution

Signant Health provided in-depth electronic clinician ratings in 1,800 Alzheimer's patients and enabled the migration of these from in-clinic to remote due to the pandemic. Its scientists worked on adapting the existing ClinRO assessments for administration by video, collected data and worked with scale authors to evidence measurement equivalence, provided training to home nurses to enable technology set up and oversight to ensure clinician video assessments could be conducted, and provided further rater training to ensure standardized rating administration in the remote setting. It implemented telemedicine alongside eCOA to enable remote assessment.

Impact

This solution was executed quickly and enabled the continuation of the trial during the pandemic. The clinical and data science experts provided analytics to support the equivalence of complex clinician assessments, including cognitive function, made remotely to those conducted in the normal setting.

Case study 2	Trials@Home consortium selects Signant Health for European clinical trial to develop recommendations that will drive the implementation of decentralized clinical trials in Europe

Business challenge

Trials@Home is an EU and pharma funded research program to derive best practices in decentralized trials. Signant SmartSignals RTSM and telemedicine solutions were chosen as leading solutions containing the expertise and capabilities needed, and because of their ability to integrate with the other solutions selected.

Solution

As part of a five-year research program, Signant Health provided integrated RTSM and telemedicine solutions for a clinical trial in 800 diabetes patients, that aims to reshape clinical trials in the European Union (EU) by developing and piloting standards, tools, and best practices for remote, decentralized clinical trials (RDCTs). From this, the industry will learn best practices and approaches for leveraging decentralized study methodologies in clinical trials. Signant Health was selected to provide RTSM and Telemedicine components, which underlines solutions, services, and credibility in applying these to traditional and remote studies alike.

Impact

The company's solutions will play an instrumental role in supporting decentralized and hybrid modes of clinical trial design and conduct. The recommendations and best practices that it will establish in collaboration with Trials@Home consortium partners will allow medical researchers in Europe to increasingly take advantage of decentralized methods to accelerate and streamline clinical development processes.

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Signant Health | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)

Solution	Details
eCOA	A solution that meets the needs of simple and complex studies alike, with rich configurable functionality built from 20+ years of experience. Its consumer-grade patient interfaces operate in web and app, using BYOD or provisioned devices, all from a single study configuration. The solution contains extensive multilingual instrument library capabilities, and comprehensive real-time reporting and data visualization. The patient interface (web/app) includes patient engagement, visit schedules, study reminders, video visits, and wearable device connectivity to provide an uncomplicated single DCT application for patients. The solution accommodates complex clinician ratings (ClinROs) and associated rater training and qualification services, and blinded data analytics (to identify changes in data consistency and reliability, as well as ensure timely corrective actions limit data quality impact). The comprehensive technology is provided alongside scientific expert consulting to ensure high quality data for regulatory submission, global scale, and mature service offerings including device procurement and logistics, scale license management, and patient-facing helpdesk.
eConsent	A solution that provides a highly flexible solution to meet the needs of any study. From simple signature management solutions based on pre-produced pdf-versions of the ICF (e.g., for simple late phase studies), to a fully interactive, multi-media web-based solution, it can meet the needs of all studies. The solution is web-based, which facilitates simple provision of access to patients away from site – e.g., ahead of a site visit, or during remote consenting, as well as at site via a provisioned tablet.
Telemedicine	A telemedicine platform that enables secure and compliant video connectivity between sites and patients worldwide, which is designed specifically for clinical trials, its virtual waiting room enables patients to complete pre-consultation questionnaires to help guide discussions with the site staff, and instant messaging to waiting patients as needed. Visit-specific checklists guide the investigator to ensure all elements of each visit are covered as required by the protocol. Using proprietary video glasses, the solution also facilitates the oversight of home nurse assessments by the site investigator to ensure correct and standardised remote procedures and measurements in DCTs.
RTSM	A solution that enables rapid setup for simple and complex studies. Its solution contains leading functionality to manage direct to patient medication provision in a way that unburdens the site while ensuring its oversight and control. The solution securely stores patient address and contact details in an encrypted manner and provides these to logistics vendor ordering systems – e.g., its integration with Marken. This solution fully manages last mile delivery and means that this is not left to the investigational site to arrange locally.
Data aggregation and Intelligence	A platform that enables ingestion, standardization, and aggregation of real-time data from multiple sources in one convenient location. Using its analytics modules (medical monitoring, statistical monitoring, RBQM) enables sponsors/CROs to comprehensively monitor and manage data, and generate actionable insights in a timely manner.

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Signant Health | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
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Signant Health | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
Oncology Complete	Investment	In 2022, launched Oncology Complete, an integrated solution tailored to the needs of oncology trials, including eCOA, RTSM, Telemedicine, and eConsent.
Masimo	Partnership	In 2022, partnered to build an integrated solution with Masimo Pulse Ox Bluetooth device for Android/IOS.
eCOA designer enhancement	Investment	In 2022, invested in eCOA designer enhancement to speed rapid trial builds and enable self-service by sponsors and CROs.
Telemedicine platform enhancement	Investment	In 2022, invested for improvements in telemedicine platform to enable video recording, background blurring, and face pixelation.
ThoughtSphere	Investment	In 2021, invested in ThoughtSphere, to enable embedding of data aggregation and analytics capabilities within Signant Health solution suite, and enable direction of future product development activity.
Marken	Partnership	In 2021, partnered with Marken, an industry leader for Direct-to-Patient (DTP) and Direct-from-Patient Services (DFP), to automate and simplify direct-to-patient medication provision.
Data integrations	Investment	In 2021, invested in data integrations across the product suite to enable sponsors and sites to benefit from integrated best in class solutions.
Santok	Partnership	In 2021, partnered with Santok, a UK based group of companies that designs and develops brands in the consumer electronic, telecoms and medical sectors, to provide custom smartphone devices for eCOA requiring provisioned devices (e.g., fully provisioned, or partial provisioning in BYOD studies).
VirTrial	Acquisition	In 2020, acquired VirTrial, to enhance its digital enablement of clinical research sites and evidence generation capabilities for remote video-enabled assessments.
Greenphire	Partnership	In 2020, partnered with Greenphire, a leading global provider of clinical trial financial solutions, for patient reimbursement solution integration. Used, for example, to address several challenges within a high-profile, multinational vaccine study.
Aural Analytics	Partnership	In 2020, partnered with Aural Analytics, for the collection of voice data for voice acoustical analysis.

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Viedoc Technologies | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Major Contender

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Viedoc Technologies has a user-friendly system and good UI/UX design as cited by clients
- It is competitively priced as the license fee is acceptable as per their clients
- The setup time of the platform for decentralized clinical trials is less
- Good at change management by providing all the necessary guidance for the execution
- Platform supports 35 different languages for connecting the diverse patient population

Limitations

- It can develop a good technology solution for eSignature that is accepted by authorities
- It only provides tech solutions and not services and can look at partnering with service providers to provide auxiliary services
- It can improve on building the social media presence, and patient and sponsors education via frequent webinars, podcasts, conferences, blogs, etc.
- It can look at increasing the mindshare for pharma enterprises beyond med tech and consumer health

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Viedoc Technologies | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

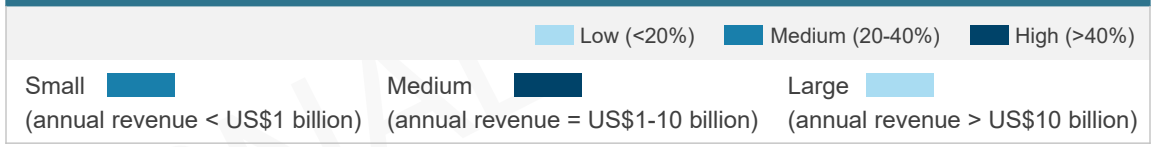
Company mission/vision statement for decentralized clinical trial platforms

Viedoc's vision is to design solutions that empower greater discoveries in order to accelerate innovation within life science in traditional, hybrid, or virtual mode. It adapts across studies in various therapeutic areas, scales to each trial phase, and makes it easy to collect data directly from the source. Viedoc seamlessly reflects the fluid transition between physical and digital spaces, making clinical trials smooth and engaging regardless of who you are, and where you sign in from.

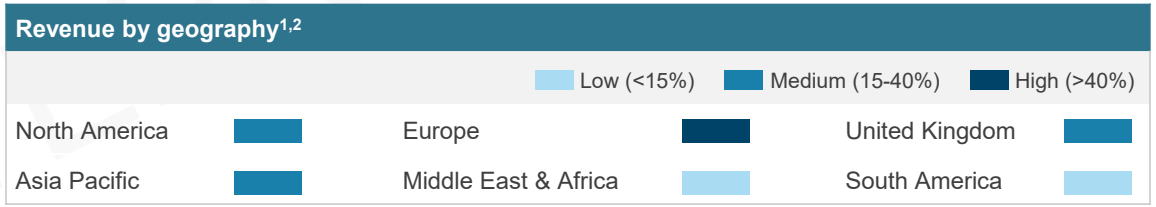
Overview of the client base

The company is trusted by 9 of the top 10 largest pharmaceutical companies; of the customer base, 9% make up the key clients in the A category and 30% make up the clients in the B category.

Revenue by buyer size[1,2]



Revenue by geography[1,2]



1 All the revenue components add up to a total of 100%
2 Based on analyst estimates

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Viedoc Technologies | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Secure, innovative, economical and patient centric

Business challenge

The client was interested in an EDC system that was easy to use, economical, and highly secure, which could also support decentralized trials with equal ease.

Solution

The client team was trained by Viedoc product specialist team to use the Viedoc platform and also placed a support team in place to help client team with handling platform queries after training was completed. Viedoc has a well-designed and user-friendly eCRF that fulfills most of the client's needs as a CRO. It is easy to configure the data checks to limit data entry errors and it is very helpful in configuring visibility of forms and visits, so that not everything is visible at once. The Viedoc Me application is a great addition to the eCRF Clinic allowing the subject to fill in electronic questionnaires. In an ongoing trial for a novel treatment for neuropathic pain, the client is using Viedoc's DCT solution. Viedoc's eConsent process includes videos explaining the study details, which are shared with the patients, along with the informed consent form (ICF).

Impact

Viedoc's hybrid capabilities, down to the level of individual study sites and patients, proved to be handy. Patients appreciated that they have plenty of time to watch the video and read the ICF document in advance. If patients had issues filling out the forms, the study site offered help using the televisit solution integrated within the Viedoc EDC platform.

Case study 2	Comprehensive and intuitive EDC system

Business challenge

The client was interested in a comprehensive EDC solution that was future proof.

Solution

Viedoc was found to be a comprehensive solution including features such as randomization, supply management, data review, source data verification, reference range management, medical coding, and reporting. With fast and efficient user training and certification, team was trained in no time.

Impact

The client has used Viedoc since 2018 for more than 60 studies. Viedoc releases new (backward compatible) versions regularly. For each release a highlights video is published and documentation containing all the information needed to fulfill regulatory expectations is updated.

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Viedoc Technologies | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

Proprietary digital solutions (representative list)	
Event name	**Details**
Viedoc Clinic	Viedoc clinic allows you to efficiently access, manage, review, and share clinical trial data—from any device, at any time through one modern, streamlined interface
Viedoc Admin	Viedoc admin provides you the full control by setting up clinical studies, managing sites and user roles, and close everything once you're done without having to go through a helpdesk or tech manager.
Viedoc Connect	Viedoc connect is a fully integrated telemedicine solution enabling flexible investigator and patient interaction with the help of secure video calls. It facilitates the eConsent process, run pre-screening and recruitment activities, and conduct follow-up visits.
Viedoc Me	Smarter, faster, and more personal, Viedoc Me is the future of data collection. Fully integrated with Viedoc, this ePRO/eCOA module lets the subjects report their own data via their smartphones, tablets, or computer for maximum flexibility.
Viedoc Logistics	Viedoc Logistics is a fully integrated supply management system, designed to optimize and secure your trial inventory. Easily configured and with a wide range of features, it more than lives up to what you'd expect from a modern RTSM system.
Viedoc Designer	Viedoc Designer is the customization endpoint where certified Viedoc designers configure their studies. It includes ready-to-use templates and drag-and-drop technology to create professional input fields and questionnaires tailored to particular study.
Viedoc TMF	Viedoc TMF is a digital repository for capturing, monitoring, sharing and storing essential documents for clinical trials. The TMF reference model categorizes documents in zones, sections, and artifacts in a hierarchical structure and includes documents in all different phases of a clinical trial.
Viedoc Reports	Viedoc Reports is a fully integrated application for viewing and analyzing study progress and performance. It allows you to browse your data and illustrate it in reports and graphs. The data is collected from your Viedoc study according to the design, and the information is updated every 24 hours.

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Viedoc Technologies | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Viedoc Technologies | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Viedoc Consent	POC	Viedoc Consent was launched in Jan 2021 to offer flexible eConsent process inclusive of information sharing, quizzes, Q&A, and signatures.
Viedoc Recruit	POC	Viedoc Recruit pilot project was launched in May 2021 to facilitate recruitment and pre-screening activities
Viedoc Connect	Product release	Viedoc Connect was launched in November 2021, it is a fully-integrated telemedicine solution enabling flexible investigator and patient interaction with the help of secure peer-to-peer video calls
Viedoc Move	POC	Viedoc Move pilot project was launched in March 2022 to integrate the iHealthapp with Viedoc Me.
Viedoc Me (ePRO/eCOA)	Product release	Viedoc Me was launched in June 2022, a completely new ePRO/eCOA application with a new UI and offering an enhanced user experience and improved functionality compared to the previous ePRO application (that was launched in 2015).

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03

Enterprise sourcing considerations

- Aspirants
  - Aparito
  - Bloqcube®
  - Jeeva™
  - REDCap Cloud
  - YPrime

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Aparito | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Aspirant

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Atom5™ is the clinical trial platform that offers video assessments, PROs, telemedicine, EDC, and eConsent, all via one smartphone app
- Aparito covers clients from biotech, pharmaceutical, CROs, and academic groups
- It incorporates computer vision, image & signal processing, and time-series analyses combined with machine learning to generate clinical data analysis

Limitations

- Aparito does not provide the capabilities for patient recruitment and medication adherence
- It can partner for auxiliary services, such as home nursing, and patient concierge, as it currently provides only tech capabilities
- It needs to improve market awareness through webinars, conferences, summits, blogs, etc.
- Thought leadership can be improved as other major players in the space are building a brand image via various forums and expertise on board

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Aparito | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

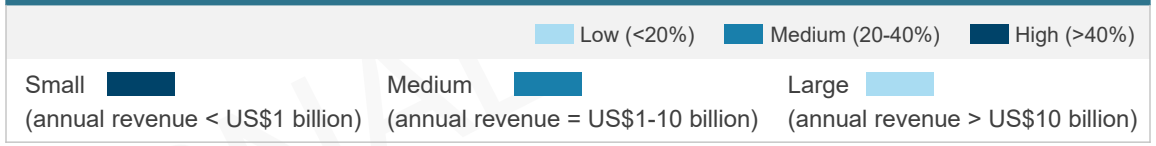
Company mission/vision statement for decentralized clinical trial platforms

The company offers patient-centric operations that integrate required clinical and regulatory expertise to capture patient data and develop digital endpoints for hybrid and decentralized clinical trials through an iOS and Android-compatible web and mobile application.

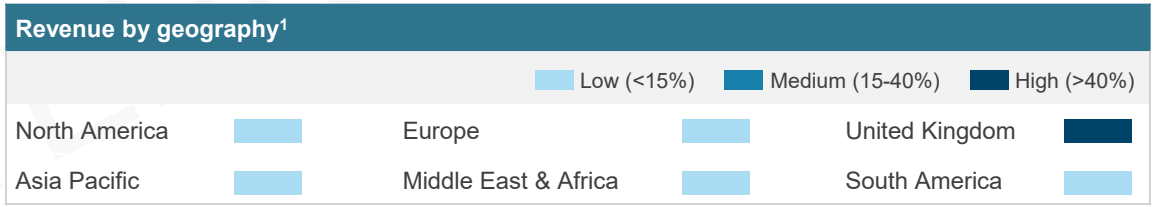
Overview of the client base

Aparito serves biotech, and pharma enterprises, CROs, and academic institution.

Revenue by buyer size[1]



Revenue by geography[1]



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1 All the revenue components add up to a total of 100%

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Aparito | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1 | **ePROs and eConsent for Long COVID-19 (TLC)**

Business challenge

The client encountered difficulties in developing a new ePRO measure. The Symptom Burden Questionnaire (SBQ) for Long COVID was designed to capture the disease's distinctive symptoms. As a result, it was a time-consuming procedure to create a team that asks patients to document their responses to a set of questions aimed to determine symptom burden in adults with Long COVID.

Solution

Aparito provided the SBQ through the ePRO module of the Atom5™ app to provide vital support and information to enable patients in self-managing extended COVID-19 and reporting their symptoms. It implemented its eConsent module to provide a regulatory-compliant solution for maintaining continuous patient consent.

Impact

- Discovered more regarding the development and implementation of the symptom burden questionnaire for chronic conditions (SBQ-LC)
- Aparito's Atom5™ technology enabled patients to report their health condition in near real-time

Case study 2 | **Remote patient monitoring for oncology patients**

Business challenge

The client encountered a dilemma because the lockdown eliminated the ability to monitor oncology patients through inpatient clinics, and it required a method of remote monitoring of patients to continue collecting patient data.

Solution

Aparito helped to achieved high data capture via Atom5™, and additionally, allowed good data quality for sophisticated analysis informing on near real-time patient health.
Remote monitoring and decentralization enabled efficient deployment, patient enrollment, and study

Impact

- 89% increase in median engagement with the wearable
- 80% increased in recruitment rate of patients just two weeks
- More than 2,800 patient were collected via the Aparito Atom5™ app with a median engagement of 73%

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Aparito | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)	
Solution	**Details**
Decentralized Clinical Trials (DCT)	DCTs examine the capabilities and expectations of all stakeholders, which is expected to increase recruitment and study adherence, improve study outcomes, and shortening the time to market for sponsors. It reduces the burden of in-person visits amongst critical patients and increase the scope of clinical trials with the Atom5™ Telemedicine module.
Hybrid Clinical Trials	Hybrid clinical trials integrate site-based trial methods with the addition of Real-World Evidence (RWE) and digital biomarkers, as well as access to a larger patient population. This allows for data collection to speed up the trial process and to enroll more diverse patient populations regardless of their proximity to trial sites.
Remote Patient Monitoring (RPM)	It harvests patient-generated data at regular intervals using digital biomarkers and digital Patient-Reported Outcomes (PRO) (ePROs). Aparito, by integrating these data points with an electronic Clinical Outcome Assessment (eCOA), gives a comprehensive picture of patients for medical trials and trials via Atom5™ without raising patient burden.

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Aparito | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
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Aparito | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
Fondation Maladies Rares	Partnership	The Digital Tools for Rare Diseases (DT4RD) project was established as a result of the rare disease research call issued by the European Joint Program on Rare Diseases in collaboration with Fondation Maladies Rares and sponsored by Chiesi and CSL Behring. The goal of the research is to create non-invasive instruments for monitoring mobility in patients with uncommon diseases using cutting-edge wearable sensors coupled with Aparito's Atom5™ clinical trial platform to gather physiological and psychological characteristics.

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Bloqcube® | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Aspirant

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Bloqcube® offers remote trial participation, data collection, monitoring (via BYOD), and the proprietary C2TA™ module for tracking resource consumption and financial spends
- Clients appreciate Bloqcube® for its investment in technology – using audio for consent process, blockchain to enhance data integrity and security, enabling recommendation systems based on machine learning, etc.
- It is rated high for the user experience of the platform – smooth UI, easy navigation, and seamless integrations – with existing software and third-party applications
- Clients appreciate Bloqcube® for its responsiveness in query resolutions

Limitations

- Bloqcube® can look to develop in-house solutions for patient screening and enrollment, medication adherence, and telehealth
- Presently, it does not offer all the auxiliary support services, such as home nursing, patient concierge, and medical review services, which are valuable to run DCTs
- It can look to partner with CROs and SIs for geographic expansion beyond the North American region
- It should augment efforts around market education (for patients, sites, and sponsors) beyond the regular training sessions (certifications, webinars, and podcasts)

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Bloqcube® | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

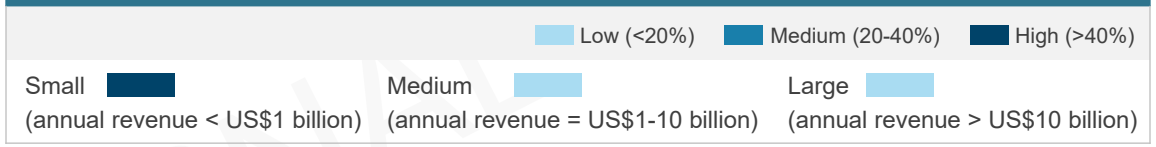
Company mission/vision statement for decentralized clinical trial platforms

Bloqcube® is an integrated Clinical Trial Management & Financial System (CTMFS) platform for the acceleration of Decentralized Clinical Trials (DCT) with an integrated financial module for speedy payments, reconciliation, and accounting. The company's mission is to accelerate decentralized and hybrid clinical trials using blockchain-based platforms. Its vision is to enable a fully decentralized clinical study solution with self-sovereign ID and Federated learning to support larger participation of study subjects – a Web 3.0 for Clinical trials solutions. It aims to build future-ready solutions for clinical trials.

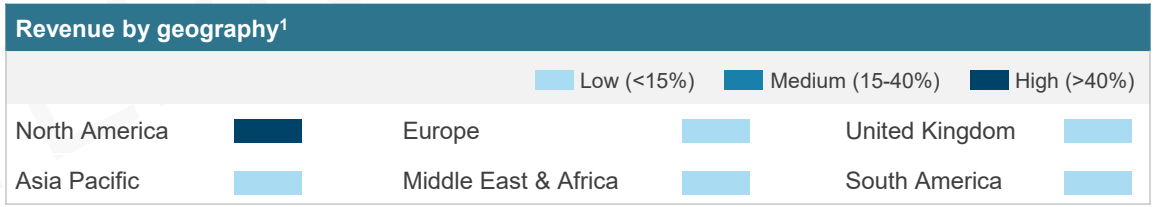
Overview of the client base

Clients include Indira Gandhi Medical College and Research Institute, Grace Cancer Foundation, India, and a CRO from Houston, Texas.

Revenue by buyer size[1]



Revenue by geography[1]



1 All the revenue components add up to a total of 100%

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Bloqcube® | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study	Observational Diabetes study with 150 patients

Business challenge

Client faced difficulties while running an observational diabetes study with inefficiencies, paper forms, multiple input errors, and repeated visits to study subjects.

Solution

The client has leveraged eConsent/CTMS/Audit module, and remotely monitored in real time. Also, solutions leveraged in remote patient monitoring and speedy data processing with data integrity.

Impact

150 patients were processed in 50% less time than planned in the protocol.

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Bloqcube® | decentralized clinical trial platforms provider profile (page 3 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)

Solution	Details
Bloqcube® Clinical Trials Management and Financial software	Bloqcube's user-friendly offering addresses critical challenges faced today by clinical trials around access assurance. It allows patients to engage remotely, thus enabling better enrollment of the diverse, underrepresented, and geographically dispersed populations. The distributed ledger system allows data to be time-stamped and stored at various nodes, reducing vulnerability to ransomware attacks while providing data in real time. The Financial Module C2TA(™) runs on a smart contract and combines control checks, payments, accounting, and budgeting. C2TA has a patent pending filing. The blockchain solution makes us amongst the pioneers in applying this solution in software offerings.
eConsent	Bloqcube® eConsent solution allows audio, written, e signatures, geotagged, date and time stamped, and study subject's native language; integrity maintained.
TeleVisit	Bloqcube® Televisit platform can be accessed via smartphone for call set up by site PI/CRC.

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Bloqcube® | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
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Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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Bloqcube® | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
NTT DATA	Partnership	In 2019, Bloqcube® partnered with NTT DATA, a recognized leader in global technology services, to benefit the healthcare and life sciences industry. NTT DATA will provide its expertise in enterprise-scale domain consulting, application implementation, and integration services through the company's healthcare and life sciences business consulting and blockchain technology competencies. In 2020, Bloqcube® signed a CREDA with National Institute of Standards and technology (NIST) for joint development activities. It has been chosen by NVIDIA to join its cohort of entrepreneurs. CEO also completed an entrepreneurship course at Draper University ("Heroes program"); Nominated for Prix Galien's Best Startup in Digital Health category- 2022 and UCSF Digital Health Rising Star nomination.

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JEEVA™ | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Aspirant

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- Jeeva™ offers eClinical Cloud – an integrated and modular platform for conducting decentralized trials
- Clients rate Jeeva™ highly on domain knowledge, especially in the field of rare diseases and genetic disorders
- It has partnered with CROs (Metflux, Farmacon, and Actu-Real) for expanding its geographic reach into the APAC and LATAM regions
- It offers an easy-to-use platform and clients mention that patients with mid/low levels of digital literacy can use the solutions seamlessly
- Clients appreciate its competitive pricing models and responsive customer service

Limitations

- Jeeva™ can enhance the user experience by improving the UI/UX of the solutions and allowing clients to easily customize the ICFs without going through the lengthy process of programming and enabling the function
- It can look to bring in open APIs to enable smooth integrations with wearables and sensors
- While clients appreciate its expertise on rare diseases, they desire Jeeva™ to build domain knowledge on therapy areas beyond rare diseases
- The patient enrollment, televisit, and adherence solutions are new compared to its other solutions and has limited maturity and brand recall

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JEEVA™ | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

Company mission/vision statement for decentralized clinical trial platforms

Jeeva™ eClinical Cloud helps clinical researchers, CROs, public health organizations, health, and human services, and biopharmaceutical sponsors accelerate clinical study execution including remote patient screening, enrollment, engagement, and retention. Jeeva's modular software design allows flexible pricing for a rapid study configuration with the features and workflows that fit the specific trial protocol whether short-term or long-term, cross-sectional or longitudinal, interventional or observational. Jeeva's device-agnostic Bring Your Own Device (BYOD) SaaS solution works on any browser-enabled mobile device and saves time/logistical burden on study teams and patients. The platform enables DEI in decentralized trials and integration with a growing number of third-party tools.

Overview of the client base

Jeeva's suite of products is currently being used by the leading academic research organizations, patient advocacy organizations, and clinical trial site networks. Use cases include longitudinal cohort study, patient registry, home-based sample collection study, and observational real world data collection study. The key clients include George Mason University, Frantz Viral Therapeutics, ImmunoACT, Children's National Hospital, Koncord Clinical Research Services, and COMBINEDBrain.

Revenue by buyer size[1]

Low (<20%)	Medium (20-40%)	High (>40%)

Small	Medium	Large
(annual revenue < US$1 billion)	(annual revenue = US$1-10 billion)	(annual revenue > US$10 billion)

Revenue by geography[1]

Low (<15%)	Medium (15-40%)	High (>40%)

North America	Europe	United Kingdom
Asia Pacific	Middle East & Africa	South America

1 All the revenue components add up to a total of 100%

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JEEVA™ | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Implemented DCT+EDC solution for a Phase II clinical trial for cell/gene therapy

Business challenge

The client wanted to execute a Phase II cell/gene therapy clinical trial for patients with leukemias and lymphomas. It had limited budget and a mandate to make the treatment affordable to patients in emerging markets. It was seeking to execute the clinical trial faster, cheaper, and better.

Solution

Jeeva™ eClinical Cloud provided the complete solution with its DCT + EDC features to configure and execute the multi-center clinical trial.

Impact

The clinical trial configuration matched the exact expectations of the Director of Clinical Operations, with study starting within four weeks of receiving the protocol. Client is receiving CEO led customer support and is delighted by the customer experience in executing the clinical trial faster, cheaper, and better.

Case study 2	Implemented a rare disease patient concierge and registry

Business challenge

A global non-profit 501c(3) organization, focused on providing care navigation service to patients with multiple rare & undiagnosed diseases, needed a flexible & affordable light weight solution to manage patient referral and multi-channel communications, without compromising data quality, patient privacy, or data security.

Solution

Jeeva™ eClinical Cloud implemented the patient registry & concierge solution to enable automated workflows for patient self-identification, communication, engagement, retention, and capture of health data from patients globally with an optional patient portal for continuous engagement.

Impact

Within 12 months, over 50 patients with rare or undiagnosed medical conditions, mostly of Asian-Indian origin, were able to contact the organization via the patient concierge platform online and receive care navigation including clinical trial matching, second opinion tele-video-consultation, and support, all on the Jeeva™ platform.

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JEEVA™ | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary solutions (representative list)	
Solution	**Details**
Jeeva™ eClinical Cloud SaaS	Jeeva™ eClinical cloud SaaS is a comprehensive set of modules and features supported by Jeeva. The customers can pick all or a subset of modules and features on a study protocol fit basis. Customers pay only for the selected modules and users will only see the menu options based on the features selected. The modules include eConsent, ePRO, eCOA, eVisits/tele/vide/visits, electronic data capture (EDC), concomitant medication tracking with MEDdra coding, appointments scheduling, communications package, and automated patient engagement workflows with patient portal.
Jeeva™ TRIALMAGNET™	Jeeva™ TRIALMAGNET is a package of modules to enable rapid patient enrollment from numerous channels. The features include remote tele screening, form builder, eConsent, reconsent, bi-directional communication, recorded video, reminders, and multi-site studies with centralized monitoring dashboards.
Jeeva™ Televisit / Videovisit	Jeeva Televist platform allows patients to receive a direct phone call at a scheduled time from site users from the browser and access recordings at any time.
Jeeva™ eConsent as a Service (eCaaS)	Jeeva™ eConsent-as-a-service (eCaaS) has features such as pre-screening, remote eConsent, patient-reported outcomes, drag-and-drop workflow builder, Bring Your Device (BYOD), and multimedia content management that empowers clinical researchers and coordinators with a compliant way of ensuring the same goal remotely without the associated repetitive tasks or burden.
Jeeva™ Remote patient monitoring and integration with wearable technology& BYOD	Jeeva™ remote patient monitoring and integration with wearable technology and BYOD is a dashboard that allows patients to log in to its portal from any browser-enabled device and monitor their progress.
Modules and Add-Ons	• ePRO/eCOA • Communications package: email, SMS, audio calling, and video calling • Adverse event capture with MedDRA data coding • Visits / Appointments scheduling • Schedule of visits configuration • CRA query capability • Patient workflows (site specific or for central referral coordination) • Long-term follow-up study • Form templates

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JEEVA™ | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

NOT EXHAUSTIVE

eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
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JEEVA™ | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event name	Type of event	Details
KiwiTech	Partnership	In 2020, Jeeva™ eclinical cloud partnered with KiwiTech LLC, an innovation platform that helps start-ups build viable products, drive traction, and raise capital for product development, access its start-up ecosystem, and fast-track accelerating clinical research..
AWS	Partnership	Jeeva™ eClinical cloud partnered with AWS for infrastructure, microservices, technology stack, and elastic cloud services.
Metflux Research	Partnership	Partnership combines MetFlux Investigative Physiology™ platform with Jeeva's eClinical trials platform. The partnership enables end-to-end pre-clinical and clinical trial solutions to pharma companies seamlessly linking deep physiology research, advanced research analytics with the scalable digital clinical trial execution, and outstanding customer support.
Perficient Inc	Partnership	Jeeva™ partnered with Perficient, Inc, a global digital consultancy for global clinical trial delivery.
Farmacon Global	Partnership	Jeeva™ partnered with Farmacon, a strategic CRO and consulting company that works with pharmas, biotechs and other CROs with a focus in rare disease and Latin America for clinical trial services. Access to a network of investigator sites across Latin America.
Koncord Clinical Research Services	Partnership	KCRS needed a mobile-friendly software platform for engaging diverse patients in the Texas-Mexico border region. With Jeeva™ eClinical Cloud, the team is gathering accurate and faster eConsent, followed by biospecimen collection from elderly Hispanic persons with liver and gastrointestinal disorders.
Frantz Viral Therapeutics	Customer	FVT selected the Jeeva™ eClinical platform to effectively execute a multi-site Phase 2 clinical trial focused on the treatment of anal squamous intraepithelial lesions (anal HSIL)
ImmunoACT	Customer	ImmunoACT is pioneering the first cell and gene therapy in India for patients' long-term cures, both for common and rare diseases. It chose Jeeva™ to accelerate clinical development timelines without tapping into a large, full-service Contract Research Organization (CRO) or creating an in-house IT infrastructure. ImmunoACT selected Jeeva™ as a strategic technology partner to optimize its clinical trial operations from the very early stage through study closeout and long-term follow-up.

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REDCap Cloud | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Aspirant

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- REDCap Cloud uses Redcap's technology suite, which is good in maturity for clinical data aggregation, reporting, and dashboarding
- It has a unified data management cloud-based platform integrating eConsent, EDC, eCOA, and ePRO modules in a single place
- It works with a diverse set of clients such as academic research centers, non-profit organizations, and government agencies

Limitations

- It can look to expand its relationship with core pharmaceutical enterprises or CROs along with the existing client base
- REDCap Cloud does not have adequate capabilities for medication adherence and wearable integration
- It can build partnerships to provide patient concierge services and other auxiliary services along with DCT tech capabilities

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REDCap Cloud | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

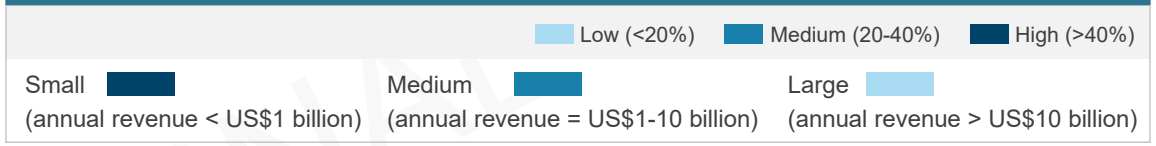
Company mission/vision statement for decentralized clinical trial platforms

REDCap Cloud's platform helps clinical research and care to enhance medical discoveries and establish new standards of care based on real-time use cases. The platform offers an integrated set of applications built on a state-of-the-art cloud-based platform that supports the entire data management process.

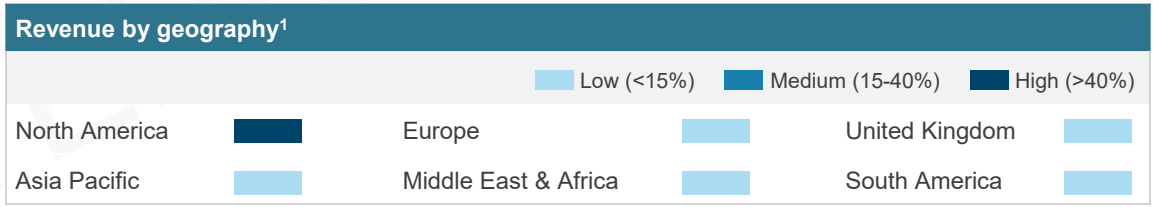
Overview of the client base

REDCap Cloud allows patients, life science companies, and healthcare organizations to collect, manage, analyze and share health data to support a collaborative, patient-centric approach to create healthcare solutions. REDCap Cloud serves clients and partners worldwide such as life science companies, CROs, academic research centers, integrated health systems, government agencies, and foundations.

Revenue by buyer size[1]



Revenue by geography[1]



1 All the revenue components add up to a total of 100%

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REDCap Cloud | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	Telemedicine in addictions feasibility RCT

Business challenge

Wanted to understand the effect of telemedicine on travel and improvement at appointments

Solution

Keyworker-led drug testing and telemedicine provided by addiction prescribers located remotely at the hub was compared to face-to-face meetings with patients in a clinical trial. Patients saw keyworker for drug testing first and were offered treatment via keyworker's laptop. Post-trial research interview conducted assessing patient and staff experience of Telemedicine versus Face-To-Face.

Impact

Both patients and staff were satisfied with telemedicine as compared to face-to-face consultations.

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REDCap Cloud | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

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Proprietary solutions (representative list)	
Solution	**Details**
eConsent	REDCap Cloud's flexible eConsent solution offers interactive and engaging informed consent workflows suitable for trial. It enables patients to make informed decisions in a simplified and consistent way at their own pace, learning style, language, and location, whether at a clinic site or virtually.
Business Intelligence Studio	REDCap Cloud business intelligence studio is a data analytics and warehousing solution that enables to visualize data and share insights across your organization. It allows teams to make fast, informed decisions.
REDCap Cloud iPaaS	REDCap Cloud iPaaS (Integration-platform-as-a-service) platform electronic health record (EHR) systems analyze health data from patients, ask new scientific questions and detect patterns to inform the development of new drugs or better care. The REDCap Cloud's EHR Integration Hub seamlessly exchanges HL7 standards-based data between EHR systems and REDCap Cloud.
Televisit	REDCap Cloud Virtual Visits platform enables two or more individuals to engage over a web-based video conference, reducing the need for in-person visits. Virtual visits include appointment scheduling capabilities, that empower patients to schedule a time that works for them.
Advanced Reporting & Dashboards solution	REDCap Cloud's Advanced Reporting and Dashboards solution is custom reporting on steroids. It empowers users to define contents, look, and output format of a report in a way they would like. It empowers users to define reports using code, mostly HTML and JavaScript templating engines.
Clinical data warehousing	REDCap Cloud's Clinical Data Warehousing solution enables the aggregation of heterogeneous data sources (EDC, imaging, labs, ePRO, EHR, and wearable) to a common standard for clinical analysis. The solution allows the user to collect clinical data and write SQL queries that can used as regulatory and management reports and dashboards for others to see.

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REDCap Cloud | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

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eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
eConsent	Multi-lingual eConsent	Interactive content (images, videos, etc.) for guidance and comprehension	Reconsent capabilities	Multimedia support (-audio, video, etc.)	Dedicated dashboards and visualization tools
TeleVisit	EHR/EMR-agnostic	Text, e-mail, and appointment scheduling features	Screening tools	Available to download on patient phone, Android/iOS support	Usage analytics
Trial participant recruitment	Social media campaigns	AI/ML or intelligent automation for patient screening	Progress of potential study participants	Access to patient data (RWD or EHR)	Diversity of patient population
Remote patient monitoring and integration with wearable technology & BYOD	Overview dashboards and analytics capabilities	Data authentication and accuracy features	Data management capabilities	Integration with multiple wearables, including phones, glucometers, etc.	Alert mechanism for preventive control
Medication adherence	Available to download on patient phone (BYOD format), Android/iOS support	Daily/Weekly reminders	Facial recognition	Sensor integration	Assistance with refills, health issues

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REDCap Cloud | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

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Key events (representative list)

Event name	Type of event	Details
HER integration HUB	Launch	A software as a service solution that connects to any electronic health record system supporting FHIR HL7 messaging into REDCap Cloud EDC
REDCap Cloud eConsent	Update	An updated release of REDCap Cloud eConsent, the agile electronic informed consent solution on the market
Cloud Business Intelligence Studio	Launch	Business Intelligence Studio is a data analytics solution that enables companies to visualize data and share insights across an organization.

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YPrime | decentralized clinical trial platforms provider profile (page 1 of 6)

Everest Group assessment – Aspirant

Measure of capability: Low High

Market impact				Vision & capability					
Market Adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
									

Strengths

- YPrime provides eClinical consulting and statistical consulting to their life sciences customers for clinical trial design and analysis
- It provides a summary view of data for better-summarized insights and its data science team works on building such insightful dashboards
- It provides strong eCOA capabilities in addition to advanced analytics

Limitations

- It lacks the adequate capabilities for managing televisits and telemedicine along with patient recruitment
- Advanced analytics use cases are applicable only in the case of eCOA that can be expanded to other DCT capabilities
- It does not have partnerships with CROs or auxiliary service providers such as home nursing

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YPrime | decentralized clinical trial platforms provider profile (page 2 of 6)

Overview

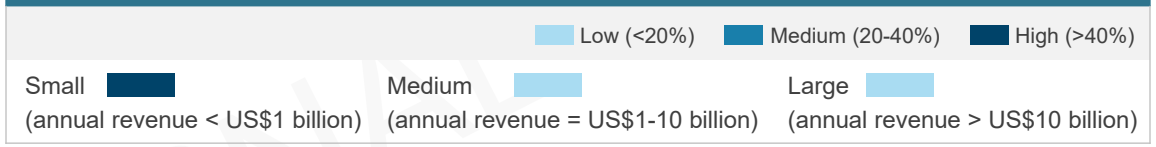
Company mission/vision statement for decentralized clinical trial platforms

YPrime has eClinical systems to accelerate and improve the quality of patient management, clinical supplies, drug accountability, and clinical data. YPrime has a clear vision for the future; it might develop a revolutionary solution that addresses the most pressing difficulties related to acquiring, engaging, and retaining patients.

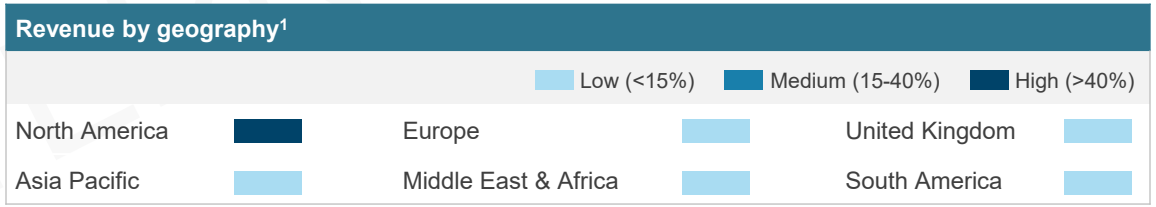
Overview of the client base

YPrime has clients from small biotechnology firms to large global pharmaceutical companies, CROs, etc.

Revenue by buyer size[1]



Revenue by geography[1]



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YPrime | decentralized clinical trial platforms provider profile (page 3 of 6)

Case studies

Case study 1	A case of lost genealogy

Business challenge

The sponsor was faced not only with data quality issues but also lost access to a valuable research genealogy.

Solution

Data were managed by a combination of paper notebooks, a laboratory information management system (LIMS), a chromatography data system (CDS), a scientific data management system (SDMS), and a materials assessment system (MAPP).

Impact

The process got improved as a result of linking the existing data for rediscovery efforts

Case study 2	Solving data overload problem

Business challenge

The sponsor was not able to scale up efficiently due to data overload.

Solution

The data acquisition assessment analyzed inbound and some outbound interfaces for the web-based system, in order to design a strategy that would improve interfaces and reduce costs.

Impact

A long-term strategy was developed to address the company's future integration needs using a flexible architecture.

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YPrime | decentralized clinical trial platforms provider profile (page 4 of 6)

Offerings

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Proprietary solutions (representative list)	
Solution	**Details**
eCOA platform	Robust platform includes both customized and pre-validated adjustable authoring environments to fulfill each study unique protocol-specific demands. Iterative development approach allows sponsors to see the system at key phases of design and development, ensuring that their needs are addressed in a timely and efficient manner.
IRT for DCT	The platform provides remote, hybrid, and onsite visit scheduling for individual patients, and the discrepancy management tool allows for return confirmation without the use of a CRA.
DCT	Decentralized Clinical Trial (DCT) models allow participants to participate in clinical trials from the comfort of their own homes, reducing the need for patients to travel to a central investigator site.

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YPrime | decentralized clinical trial platforms provider profile (page 5 of 6)

Features of key offerings

Functionality available | Functionality not available

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eCOA/ePRO	ePRO functionality	Question builder and analytics tools	Visualization functionality	Autogenerated regulatory and project documentation	ePerfO, eClinRO, and eObsRO capabilities
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YPrime | decentralized clinical trial platforms provider profile (page 6 of 6)

Recent developments

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Key events (representative list)

Event name	Type of event	Details
TransCelerate	Statistical Analysis Framework	Statistical analysis of clinical trial data must enter the modern era. TransCelerate introduced the Modernization of Statistical Analytical Framework as a model technique to show health authorities that regulatory submissions produced with any analytical program, including atypical analytical tools, deliver essential reliability.

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04

Appendix

- Glossary

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Glossary of key terms used in this report

AI	Artificial Intelligence is the simulation of human intelligence and decision-making capability by machines
Aspirants	Aspirants are the third set of platform providers rated by Everest Group, according to Everest Group's proprietary scoring methodology. They have moderate experience and delivery capability
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 Trials 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 is 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 allows 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 to connect to a doctor remotely, via video and audio connection either on a smartphone or a computer

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