Everest Group®

Decentralized Clinical Trial Product Vendor Compendium 2021

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Contents

For more information on this and other research published by Everest Group, please contact us:

Nitish Mittal, Vice President

Chunky Satija, Practice Director

Nisarg Shah, Senior Analyst

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- Background of the research
- Focus of the research

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

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

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Primary sources of information

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

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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

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Fact-based research

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

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

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

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

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

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

This report is based on four key sources of proprietary information

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

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

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

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

Product vendors assessed

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

Source: **The source of all content is Everest Group unless otherwise specified**
Confidentiality: Everest Group takes its confidentiality pledge very seriously. Any information we collect that is contract-specific will only be presented back to the industry in an aggregated fashion

Background of the research

Decentralized Clinical Trials (DCTs), in which clinical trial data is collected through sensors or remote monitoring devices carried by a patient without the need to visit a site, can deliver many benefits to pharmaceutical companies, including cost savings, better patient recruitment and retention, and improved data quality. 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. In recent times, DCTs have proved to be a saving grace to restart paused clinical trials. Additionally, recent technological advances, the proliferation of wearables, and FDA's push to the industry to adopt DCTs following the COVID-19 situation have made the DCT landscape ripe for disruption.

Numerous start-ups that address DCT requirements have recently emerged. The landscape has also experienced heavy fundraising and M&A activity. Through co-innovation, continuous product improvement, and market education, DCT vendors are focusing on increasing trust, speeding trial timelines, and delivering a smooth experience in running DCTs.

In this report, we assess the capabilities of 15 IT vendors specific to decentralized clinical trial products. These vendors are mapped on the Everest Group PEAK Matrix®, which is a composite index of a range of distinct metrics related to a vendor's capability and market impact. We focus on:

- The landscape of vendors for decentralized clinical trial products
- Assessment of the vendors on several capability and market success-related dimensions

Scope of this report

Geography
Global

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

Vendor offering
Decentralized clinical trial products

Decentralized clinical trial products | Scope of the research

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

Scope of assessment

Digital touchpoints				
Patient applications	Physician and nurse applications	Investigator applications	Concierge portals	CRA portal

	Core modules			Auxiliary support services		
Trial start-up	eConsent			Patient screening services	Patient recruitment and enrolment services	
Trial conduct	Wearable technology & BYOD integration + Remote patient monitoring	Medication adherence	eCOA/ePRO	Home nursing services	Patient concierge and engagement services	Medical record review services
		Televisits		Drug and device provisioning	Remote CRA	

Mode of conduct

Completely virtual	Hybrid (Digitally-enabled trials)

Virtual trial platform features

Centralized connected devices, eCOA, and eConsent data	Integration of workflows with traditional clinical development systems	Unified nursing experience	Secure and compliant

Technology enablers

Cloud	Data management	IoT	Reporting & analytics	IT security	Mobility	Automation	AI

Source: Everest Group (2021)

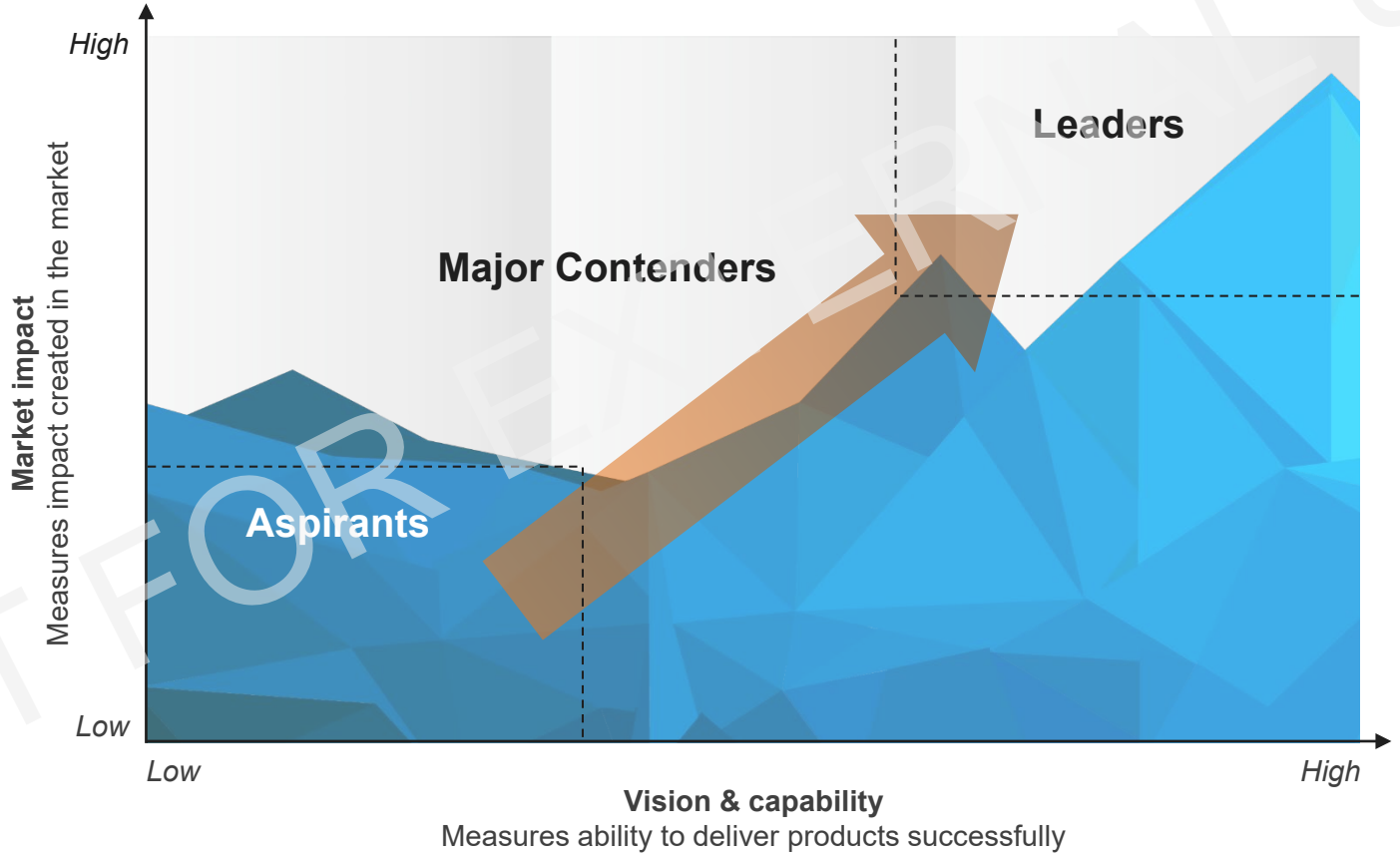
02

Decentralized clinical trial products PEAK Matrix® characteristics

- PEAK Matrix framework
- Everest Group PEAK Matrix for decentralized clinical trial products
- Product vendor capability summary dashboard
- Characteristics of Leaders, Major Contenders, and Aspirants

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

Everest Group PEAK Matrix



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

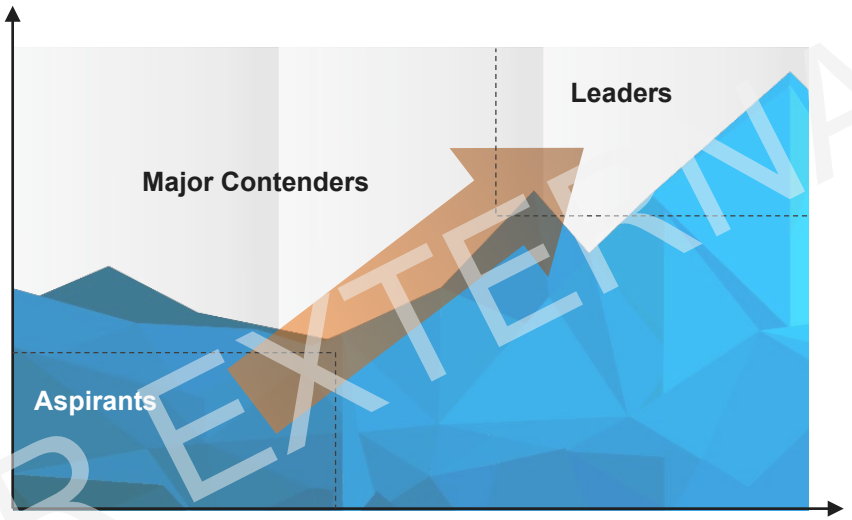
Portfolio mix

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

Market impact



Vision & capability

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

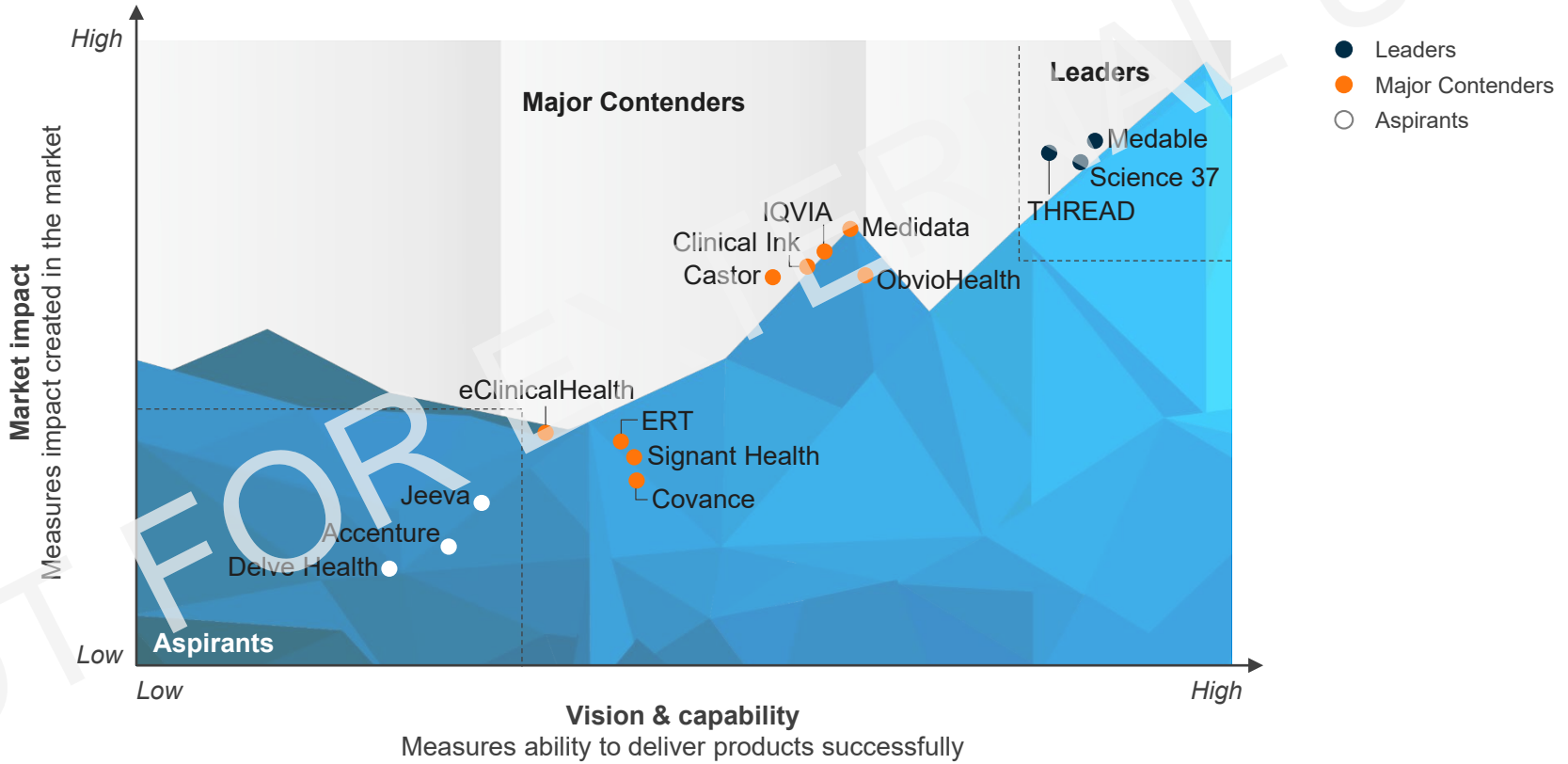
Support

Training, consulting, maintenance, and other support services

Everest Group PEAK Matrix®

Decentralized Clinical Trial Products PEAK Matrix® Assessment 2021

Everest Group Decentralized Clinical Trial Products PEAK Matrix® Assessment 2021[1,2]



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

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

Source: Everest Group (2021)

Decentralized clinical trials products PEAK Matrix® characteristics

Leaders:

Medable, Science 37, and THREAD

- Leaders offer clients an end-to-end modular platform with a unified data model which 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 offer 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 don't exist
- Leader DCT products 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 are also witnessing high growth and are investing in hiring executives for product improvement, growth, and strategy execution
- Clients perceive Leaders to be premium-priced vendors as compared to Major Contenders and Aspirants

Major Contenders:

Castor, Clinical Ink, Covance, eClinicalHealth, ERT, IQVIA, Medidata, ObvioHealth, and Signant Health

- 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
- Similarly, most Major Contenders do not offer the complete spectrum of auxiliary support services (either through partnership or in-house)
- Some major Contenders such as Clinical Ink and ERT offer solutions with technologically superior capabilities such as the ability to manage complex eCOAs as compared to the leaders
- While Major Contenders products are price competitive, they may lack capabilities such as medication adherence or fall behind on desired patient experience

Aspirants:

Accenture, Delve Health, and Jeeva

- While Aspirants may have products for running DCTs, the solutions are relatively new or undergoing pilots and therefore undergoing continuous improvement
- Aspirants do not offer clients the complete suite of DCT products and lack capabilities such as televisits, medication adherence, etc. Individual products also currently lack advanced features as offered by Major Contenders and Leaders
- Aspirants such as Accenture also focus more as a system integrator or custom solution developer for clients, rather than a vendor of DCT products

Summary dashboard | market impact and vision & capability assessment of providers for decentralized clinical trial products 2021

Leaders

Measure of capability: Low High

Product Vendor	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
Medable										
Science 37										
THREAD										

Summary dashboard | market impact and vision & capability assessment of providers for decentralized clinical trial products 2021

Major Contenders

Measure of capability: Low High

Product Vendor	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
Castor										
Clinical Ink										
Covance										
eClinicalHealth										
ERT										
IQVIA										
Medidata										
ObvioHealth										
Signant Health										

Summary dashboard | market impact and vision & capability assessment of providers for decentralized clinical trial products 2021

Aspirants

Measure of capability: Low High

Product Vendor	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
Accenture										
Delve Health										
Jeeva Informatics										

03

Enterprise sourcing considerations

- Leaders
  - Medable
  - Science 37
  - THREAD

Medable | decentralized clinical trial products profile (page 1 of 7)

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 can offer its suite of products as an end-to-end platform with a unified data model – this allows all patient data to be in a single repository, eliminating data silos. Clients have appreciated Medable's ability to offer a single application for everything
- Clients rate Medable's DCT products high on user experience, ease of integration with their existing solution suites, and patient centricity
- Medable offers a superior support experience, with a strong escalation pathway
- Medable offers clients the flexibility to use the products in a SaaS-only model or leverage auxiliary support services such as device provisioning, digital concierge, etc.
- Medable is focusing its investment efforts on leadership hiring to improve product portfolio and improve patient experience

Limitations

- Clients rate Medable as a premium priced vendor for running their DCTs
- The integration between wearables and sensors with Medable's product suite is not seamless, and clients cite integration challenges while collecting data through some sensors or wearables. Similarly, clients state that the eSource integration with EMRs can be improved
- Clients expect Medable's eCOA solution to offer advanced functionalities as offered by specialized eCOA players such as complex eCOA libraries and functionalities
- Medable's primary focus areas are North America and Europe. It has lesser focus on the APAC geography for DCTs as compared to other vendors

Medable | decentralized clinical trial products profile (page 2 of 7)

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

Its vision is to open scientific research to the world, with a platform designed for humans, that accelerates cures and health outcomes for all.

The company is mission-focused to deliver the world's leading global clinical trials platform and demonstrate that it improves access to medicine, human experience, and the mindset around clinical research.

Therapy area coverage

Medable's decentralized clinical trial products cater to all therapy areas including neurology, infectious diseases, dermatology, oncology, endocrinology, gastroenterology, genetic or rare diseases, cardiovascular, ophthalmology, vaccine and virology, psychiatry, sleep, allergy, and reproductive medicine.

Overview of the client base

In 2020, Medable engaged 50+ clients with 100% retention rate. Founded by a clinician and led by seasoned clinical trial operational and science expertise, Medable is trusted by five of the top 10 pharmaceutical companies and 5 of the top 7 CROs. The client base spans CRO, pharmaceutical, and biotech companies. Approximately 25% of 2020 business was with biotech companies.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Medication adherence	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)
eCOA/ePRO	Televisits	

Medable | decentralized clinical trial products profile (page 3 of 7)

Case studies

NOT EXHAUSTIVE

Case study 1	How decentralized clinical trial solutions expand patient access, reduce costs, and improve time to treatment

Business challenge

A precision medicine company focused on the development of new therapies for age-related macular degeneration required a deeper understanding of the disease. However, the study design proved to be too expensive and difficult. Existing study methods required 100+ sites and were limited by a lack of patient proximity to those sites. These limitations led to the study being delayed for years.

Solution and impact

Medable's 5-step decentralized workflow enabled the company to fully digitize the patient screening and eConsent process, enabling greater patient access to the trial while providing a flexible and seamless experience across all users, which improved trial operations and time to treatment. Medable's interoperable technology platform is designed to transform business needs through its ability to rapidly configure new assessments using streamlined, out-of-the-box capabilities that are customizable based on the study's unique protocol needs.

Medable utilized eConsent, eRecruitment, and direct-to-patient shipment services to remove the barriers of extensive site contracting, patient proximity to sites, and, ultimately, a prohibitive cost that had prevented the sponsor from initiating the trial.

For the first time ever, the organization was able to launch its study. Medable's decentralized solution reduced the number of sites needed from 100 to 25 sites, which resulted in saving US$20 million in total trial costs and a 50% reduction in patient enrollment time, from two years to one year.

Case study 2	One of the top 20 global pharmaceutical companies sought to improve patient access to rare disease clinical trials

Business challenge

A worldwide pharma company known for developing and commercializing best-in-class therapies for rare genetic diseases needed to efficiently screen and enroll 1,000 patients. The client required platform flexibility to capture key disease status information, while randomizing into two groups to obtain two blood samples across a six-month period with AE follow-up and reporting. They had a single, central PI with no physical sites. Medable needed to leverage the CRO's assets for a custom-configured E2E decentralized delivery and management solution.

Solution and impact

Medable deployed a decentralized ecosystem solution, including eConsent, ePRO, and televisit, with CRO, local labs, virtual PI network, and direct data capture.

Medable's decentralized workflow simplified the trial for patients. First, patients were recruited through email, completing an eConsent and a digital enrollment questionnaire. This data was then used to confirm patient eligibility and randomization. Next, eligible patients were sent study supplies and blood collection kits, which enabled them to complete digital questionnaires 72 hours in advance of the lab blood draw. Additionally, patients completed ePROs, using televisits when necessary to speak to the central PI, and report safety events.

The ecosystem solution significantly increased patient access, oversight, and engagement, enabling the pharma organization to enroll over 75 rare disease patients within three weeks, using a single platform that enabled remote patient communication and blood sample and signature collection from their home.

Medable | decentralized clinical trial products profile (page 4 of 7)

Offerings

Proprietary digital solutions (representative list)	
Solution	**Details**
eConsent	The eConsent product (Consent Manager) enables a process of informed consent that can be performed remotely, or onsite. This tool also allows a Principal Investigator (PI) and participant to connect remotely to complete the ICF process and ensure comprehension of the study. This remote connectivity functionality also enables both parties to sign remotely and perform other tasks and activities that would typically be done face-to-face. When the tool is paired with Medable's televisit functionality, site staff and participants are even able to review and sign documents while seeing each other in real-time
eCOA	The Medable eCOA platform enables, simplifies, and streamlines COA data collection for sites. The Medable eCOA platform also enables traditional EDC functionality for eCRF data capture, query management, ConMed and adverse event log line capture, and PI signature of the casebook. This is accessible for sites via the site app. The Patient app is an Electronic Patient-Reported Outcome (ePRO), which collects a patient's reported outcome electronically. The patient apps can be used on BYOD or provisioned device. The patient app is device-agnostic and can be used as a native application or on any device with a modern web browser
Remote patient monitoring and integration with wearables & BYOD	Medable supports BYOD and tests back to Android KitKat 4.4 and iOS 9.0. Web browser compatibility testing is done on all current browsers that are supported for the following browsers: Chrome, Firefox, Safari, and Microsoft Edge
Televisits	The Televisit feature enables patients to participate in clinical trials from their home by giving them access to video visits with the researcher (study coordinator, study nurse, investigator, etc.). Televisits are available throughout the patient journey utilizing its unified platform. The solution capabilities are in-house and can be utilized via web or app. Televisits are available both as part of the eConsent process (TeleConsent) or when enrolled in the study via the Site app and Patient app, which allows the site nurse and patient to go through an end-to-end informed consent process or completing eCOA/ePROs from the Site app and patient app. Televisit can be scheduled as an appointment to replace a site visit or can be utilized as patient engagement tool if requested by the patient
Medication adherence	The patient app allows for push notifications and reminders; communication via televisits, emails, and text messages is available as well
Platform	Built with security and compliance at the core, the Medable platform enables virtually any digital, hybrid, or decentralized clinical trial. With a full suite of enterprise microservices and application tooling, the Medable platform supports customized workloads that power global trials at scale. With patient, site, and study management apps built to work on web, iOS, or Android, the Medable platform seamlessly ingests and harmonizes disparate data from informed consents, clinical outcome assessments, sensors, devices, labs, and CRF's. With AI and Machine Learning at the core, the Medable platform shortens the time to capture and strengthens the signals of safety and efficacy endpoints
Digital certification program to enable partners	This recently launched industry-first digital certification program provides life sciences companies with specialized tools, knowledge sharing, and skills development to rapidly scale their decentralized and hybrid trial strategies. Medable's certification program supports partners to codify emerging skills and learning paths that empower individuals and teams to design, build, deploy, and support decentralized and hybrid trials

Medable | decentralized clinical trial products profile (page 5 of 7)

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

Medable | decentralized clinical trial products profile (page 6 of 7)

Recent developments (page 1 of 2)

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
PPD	Partnership	PPD has collaborated with Medable for virtual trials and is deploying new mobile applications that enable patients to connect visually with their clinical study sites. They allow investigators to better complete safety assessments, by supporting the capability to also collect eConsent, eCOA, or data from devices/wearables on the same digital trial platform. PPD is also deploying trial models that enable or augment the use of traditional brick-and-mortar sites with full digital support and decentralized (or virtual) site alternatives to allow the recruitment and retention of patients remotely
MRN	Alliance	Medable empowers MRN's home clinical trial specialists to conduct home and remote visits using Medable's Trial-Fit Telemedicine solution to enable remote patient monitoring, medication administration, patient care, and clinical assessments. These capabilities are especially important for clinical trial continuity despite widespread shelter-in-place initiatives due to COVID-19
AliveCor	Partnership	AliveCor, the leader in AI-based, personal ECG technology, announced a partnership to dramatically scale remote clinical trials by enabling in-home ECGs with AliveCor's KardiaMobile6L, the world's only FDA-cleared six-lead personal ECG. As an integrated capability within the Medable platform, KardiaMobile 6L removes a key barrier to enabling in-home clinical trials
Datavant	Partnership	Medable integrates Datavant's technology into its decentralized trials platform, allowing trial teams to combine real-world health records, claims, diagnostic, and other data sources with their clinical trial data. This will eliminate various manual and time-intensive steps that slow down clinical trials, while also improving patient access and helping trial teams optimize evidence generation during and after studies
Seqster	Partnership	Partnership with Seqster is to integrate real-time, real-world data streams into decentralized clinical trials. This partnership can integrate more data sources and data streams to provide clinicians with a more holistic view of patient health, leading to higher-quality trial results, while simplifying the patient experience
Labcorp/Covance	Alliance	Through an alliance with Medable for digital clinical trials, Covance is expanding its decentralized clinical trials technology ecosystem

Medable | decentralized clinical trial products profile (page 7 of 7)

Recent developments (page 2 of 2)

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
Syneos Health	Partnership	Syneos Health's partnership with Medable increases clinical trial diversity, while improving patient access and experiences to transform biopharmaceutical product development. The partnership enables Syneos Health to reduce physician burden, simplify the patient journey, and collect previously difficult-to- obtain data to speed therapies to patients across the clinical development life cycle. It also delivers a fit-for-purpose decentralized digital solution to Syneos Health customers tailored to their specific attributes and requirements for conducting non-interventional research
Digital certification program	New product launch	Recently launched an industry-first digital certification program that provides life sciences companies with specialized tools, knowledge sharing, and skills development to rapidly scale their decentralized and hybrid trial strategies
Aural Analytics	Partnership	Partnership with Aural Analytics to assess remote data capture and digital biomarkers in cancer patients in an initiative funded by NIH's seven-year Beau Biden Cancer Moonshot research and development program
Series C Extension	Investment	In April 2021, Medable secured its third round of funding (for US$78 million) in less than a year, bringing the total capital raised to ~US$230 million in venture and private funding

Science 37 | decentralized clinical trial products 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 can offer its suite of products as an end-to-end platform with a unified data model – this allows all patient data to be in a single repository, eliminating data silos
- Science 37 allows clients two modes of operation: Metasite™, which has both the platform and auxiliary services; and a SaaS-only option. Clients appreciate this operating model flexibility provided by Science 37
- Apart from being customizable and flexible, Science 37's products have been ranked very high on user experience and user friendliness
- The setup time for Science 37 suite of products is short. The team's speed of work has also been appreciated by clients
- They are competitively priced and flexible during negotiations

Limitations

- Clients cite that Science 37's mobile nursing capabilities need to improve, and that the operations team is not the best for executing remote patient health data collection and visits
- The integration of Science 37's DCT solutions with the internal applications used by their clients have been cited to be a challenge. Similarly, clients have stated challenges with accessing clinical and patient data while integrating with Science 37's solutions
- Science 37 is not able to meet client expectations when it comes to tackling pieces such as running complex eCOAs and associated patient reported outcomes

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

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

Science 37 has the vision of enabling universal access to clinical research and making it easier for patients and providers to participate and accelerate the development of new and innovative treatments that impact patient lives. The company's mission is to enhance workflow orchestration, evidence generation, and data harmonization on a unified, seamless platform – configurable to enable any study and fused with networks of telemedicine investigators, mobile nurses, remote coordinators, patient communities, and connected devices.

Therapy area coverage

Science 37's decentralized clinical trial products cater to various therapy areas such as neurology, infectious diseases, oncology, pulmonary and respiratory diseases, endocrinology, gastroenterology, genetic or rare diseases, vaccine and virology, pediatrics, psychiatry, and nephrology.

Overview of the client base

Science 37 has strategic partnerships with several top 20 pharma companies including Roche, Novartis, Genentech, Boehringer Ingelheim, Sanofi, and Amgen. Approximately 55% of awarded contracts are from small to mid-sized sponsors, and 45% are from large, multi-national sponsors with annual revenue greater than US$1 billion.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography[1]

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Medication adherence	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)
eCOA/ePRO	Televisits	

1 Analyst estimates

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

Case studies

NOT EXHAUSTIVE

Case study 1	Conducting an aggregate study to reduce the effects of lupus in children

Business challenge

The iPERSONAL study is a collaboration between the Duke Clinical Research Institute, CARRA Registry, and Lupus Foundation of America, funded by the FDA Global Pediatric Clinical Trials Network to optimize the use and dosing of HCQ in children.

As a chronic inflammatory disease, lupus can be very painful. Hydroxychloroquine (HCQ) can help in preventing disease flares, reducing damage, and improving chances of survival. But despite widespread use of HCQ in children, there is virtually no evidence to guide HCQ dosing and what impact poor medication adherence has in children. This study is also helping DCRI develop expertise in direct-to-family or decentralized studies.

Solution and impact

By enrolling 25 children/teenagers with systemic lupus, Science 37 helped DCRI run a fully decentralized US study. As part of the study, Science 37 conducted in-home visits by mobile nurses, telemedicine exams, blood and urine sample collection, surveys, and connected devices of electronic pill bottle cap (Pillzy) with reminders and Fitbits. Science 37 is the only partner that combined all these things.

Using a patient registry to identify patients, Science 37 was able to enroll the 25 patients in days. The company is helping speed the overall study timelines, while reducing burden for kids and their families and contributing to accurate dosing and medical adherence for HCQ.

Case study 2	Helping a small biotech company enroll patients for a study indicating the stand-of-care cancer screening

Business challenge

A small biotech company with a cancer-screen blood test began its study with a large CRO, but was having difficulty enrolling patients because of COVID-19. This study in adults did not increase the risk of cancer and just indicated for the stand-of-care cancer screening.

Solution and impact

The client used Science 37 Metasite™ for the problem at hand. For the study, Science 37 leveraged four virtual investigators, eConsent with technology platform, and a Science 37 mobile phlebotomist for in-home blood draws.

The company continues to outperform the traditional sites and was able to enroll 2,000 patients in just one month. By using a Metasite, the sponsor is able to cast a wider net for possible clinical trial participants and helps in accelerating enrollment that can typically take months, even without a global pandemic.

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

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)	
Solution	**Details**
Science 37 Platform	The platform delivers remote eConsent, eSource data capture, eCOA, telemedicine, nursing access, IMP tracking, remote wearable integration, document management, EMR integration, reporting, and data analytics. The platform is modular and sponsors or CROs can use specific features (such as eConsent or telemedicine) paired with other Science 37 capabilities
Science 37 decentralized service models	
Fully Decentralized	With the decentralized clinical study model, Science 37 manages the trial virtually from recruitment to database lock and supports it with the Science 37 platform. High-touch patient services include patient visits conducted via telemedicine and mobile healthcare provider visits, along with study materials (study drugs/devices) that are shipped to the patient's home
Metasite	With the Metasite model, Science 37 is a virtual site among existing site networks to ensure 100% population coverage
Tech+	**Hybrid:** The Science 37 hybrid model is a blend of decentralized and traditional methods to execute a clinical study. Science 37 extends the study's reach into patients' homes with a telemedicine-based approach, which provides patients with convenient access to the study team **Licensing:** The licensing model offers an opportunity for bio-pharmaceutical companies to license the Science 37 Platform to conduct decentralized and hybrid studies globally. Science 37 uses an expansive network of investigators, nurses, coordinators, and patients to deliver a seamless experience over the entire clinical trial life cycle

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

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

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

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
Investment overview	Investment	Science 37 has raised nearly US$150 million since inception, including a US$40 million funding round in August 2020. The funding will be used to support growth, expand the company's technology platform, and accelerate its global expansion efforts. This further strengthens the ability to help sponsors execute decentralized trials and enable patients to participate in trials from anywhere, without the burden of traveling to a traditional clinical site
Science 37 Strategic Partnership Program	Partnership program	Science 37 has established a strategic partnering initiative focused on providing the maximum value to CRO partners and leveraging market-leading capabilities and innovations in the decentralized trial space. This initiative is focused on Science 37 being an enabling platform for CROs who want to work in the decentralized clinical trial space, but are also interested in using a strategic partner than building all capabilities in-house. The initiative includes a dedicated senior-level leader and a Qualified Partner Program (QPP). The QPP will include the following: • Support from the market leader in decentralized clinical trials • Access to Science 37 technology and operational expertise • Training of key people to aid in their ability to go to market with a combined Science 37 solution • Relationship governance with KPIs to measure progress • Clinical expertise for program/protocol development • Standardized proposals/budgets to facilitate the bidding process • Bid-defense support to augment efforts to secure business
Public listing	Investment	Science 37 is becoming a publicly listed company through a merger with New York-based Special Purpose Acquisition Company (SPAC), LifeSci Acquisition II Corp., that gives Science 37 an enterprise value of about US$1.1 billion at closing and a balance sheet of US$250 million in cash to fund its decentralized trial technology platform and extend into adjacencies

THREAD | decentralized clinical trial products 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 can offer its suite of products as an end-to-end platform with a unified data model – this allows all patient data to be in a single repository, eliminating data silos. The solutions are also able to integrate wearable data into a single source of truth
- THREAD is very responsive to client needs and feedback
- Clients view THREAD as an innovative vendor and appreciate the use cases it is launching, such as advanced analytics for predicting patient retention
- THREAD has a good understanding of not only the software, but also the wearables which would be suitable for a study as per the client requirements; THREAD adopts a consultative approach to advice clients on how to decentralize and launch studies and design protocols appropriately
- The solutions are easy and quick to deploy on the client environment

Limitations

- THREAD adopts a technology-first approach while pitching their products that may result in communication gaps. The company tends to focus heavily on the technology stack during deal solutioning, whereas the clients expect a more business-oriented focus in such deals (such as ClinOps, etc.)
- THREAD needs to increase and develop focus on client-facing sales roles as there is presently an over reliance on the CEO during sales pitches
- Clients state that THREAD needs to build more expertise for product and staff teams around clinical data management
- THREAD's telemedicine solution is more expensive; clients also state that THREAD's solutions are priced higher than competitors

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

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

THREAD's 1/5/30 mission is to transform how clinical research is conducted by providing one comprehensive platform with a single experience for every stakeholder that makes research five times more inclusive and 30%+ more efficient.

Therapy area coverage

THREAD's decentralized clinical trial platform and services cater to all therapeutic areas including oncology, neurology, infectious diseases, dermatology, pulmonary and respiratory diseases, endocrinology, gastroenterology, cardiovascular, ophthalmology, vaccine and virology, and pain management.

Overview of the client base

THREAD's major clients in decentralized clinical trials include 90+ biopharma and CRO clients, including ~50% of the top 40 pharma companies and four of the top five CROs.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography[1]

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Medication adherence	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)
eCOA/ePRO	Televisits	

1 Analyst estimates

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

Case studies

NOT EXHAUSTIVE

Case study 1

Developing approaches for hybrid and fully decentralized dermatology trials for a large consumer health company

Business challenge

The client needed to capture study data remotely, but had limited experience with DCTs / hybrid trials and looked to learn more about how to conduct them. It wanted a partner with deep DCT experience and a proven platform to help optimize its DCT/hybrid study approach. The company also required a partner with global DCT expertise, as it looked to scale its DCT approach across the entire portfolio of studies, including those operating across numerous countries.

Solution deployed

THREAD introduced the ability to implement remote approaches that allowed study participants to collect and submit data from home, reducing participant burden using THREAD's experience facilitating DCTs and hybrid studies.

The company implemented a mobile solution that facilitated better participant/clinician engagement and employed a proven DCT platform. It also built a model for DCT adoption and scale that the client could standardize and use to quickly initiate multiple studies.

Impact

- Achieved 95% participant retention rate
- Managed 25% cost savings compared to similar fully site-based study budget
- The client expanded enterprise partnership to a larger study, and multi-year commitment

Case study 2

Developing a global rare disease decentralized registry to improve participant/caregiver experience and increase the overall engagement

Business challenge

For 13 years, the client had kept and managed the registry of patient-reported outcomes for Duchenne Muscular Dystrophy. This registry was web-based and possessed many outdated features, including the inability to collect data remotely, leading to lower-than-desired registration numbers, and limited engagement from registrants. To improve recruitment, inclusion, engagement, and compliance, it needed a platform that provided the remote technology that participants and caregivers wanted.

Solution deployed

THREAD developed a remote approach, allowing data to be collected at the participants' home, thereby reducing participant and caregiver burden. It implemented a mobile solution that facilitated better participant/caregiver/clinician engagement and had experience to create effective participant engagement solutions. The platform was a fully configurable platform for all study stakeholders and had experience with global scale studies.

Impact

- Gathered approximately 2,000 more surveys in 2020 than in previous years of the registry, with a 50% increase
- Boosted the total number of registrants to more than 5,500 – 39% of those are new registrants
- Successfully recruited participants for twelve clinical trials

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

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)	
Solution	**Details**
THREAD eCOA	THREAD's eCOA feature automates and standardizes the use of ePRO, ClinRO, PerfO, ObsRO, and digital endpoint assessments in a variety of globally compliant approaches including capture via on-site, remote, and/or telehealth virtual visit models. THREAD has an extensive eCOA library and supports all service processes to utilize eCOA (translations, license management, etc.). eCOA is fully configurable for fit-for-purpose use via BYOD and/or provisioned device approaches. The feature is available via mobile/tablet app and web
THREAD eConsent	THREAD's eConsent feature standardizes the use of electronic consent in a variety of globally adaptable approaches including capture via on-site, remote, and/or telehealth virtual visits models. eConsent is fully configurable for fit-for-purpose use via BYOD and/or provisioned devices approaches. The feature is available via mobile/tablet app and web. The process includes a globally compliant solution with full compliance, audit trail, reporting, and analytics on key eConsent KPIs
Remote patient monitoring and integration with wearable technology & BYOD	THREAD offers sensor integrations to support more than 300 medical devices and consumer wearables that are pre-integrated in their platform. 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
Televisits	The platform provides a full-suite telehealth feature that can be configured in several ways to support different virtual visit approaches with flexible configurations for global use. Its features enable participants and sites to hold telehealth sessions together, allowing for data capture and an increase in low-friction engagement
Medication adherence	Medication adherence is supported via a series of features including compliance surveys/eDiaries, notifications/alerts, device integrations, and telehealth virtual visit process. It also provides enhanced support for medication adherence through home health partnerships

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

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

THREAD | decentralized clinical trial products profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
Acquisition by JLL Partners & Water Street	Acquisition	Water Street Healthcare Partners and JLL Partners acquired THREAD to capture global clinical trial data and further drive expansion of THREAD and maintain its leadership position in life sciences
THREAD joins DTRA	Industry alliance	Joined an alliance of 50 life sciences and healthcare organizations to accelerate the broad adoption of patient-focused decentralized clinical trials and research. The Decentralized Trials & Research Alliance (DTRA), seeks to unite industry stakeholders, including healthcare companies, regulators, patient groups, and research organizations, with a mission to make clinical trial participation widely accessible by advancing policies, research practices, and digital health technologies in decentralized clinical research
Lokavant	Partnership	Partnered with Lokavant, a major clinical trial intelligence company, to enhance operating DCTs advanced analytics and to deploy advanced clinical operations benchmarking solution to establish industry reference points for DCTs utilizing THREAD
Launched new telehealth features	Product release	THREAD launched new telehealth features, expanding video and audio capture for complex eCOA during virtual visits in decentralized clinical trials. New features allow clinical study stakeholders – including sponsors, caregivers, home health professionals, and raters – to remotely and safely capture video and/or audio recordings in real-time and the solution also supports multiple attendees during a virtual visit and provides a globally compliant solution for participants and sites
UBC selects THREAD	Customer announcement	UBC, a late-stage research and patient-support services organization, selected THREAD to expand its global decentralized clinical research offering
Industry first analytics solution for DCTs	Product release	New solution provides descriptive key performance indicators, predictive measures, and actionable insights to drive informed decision-making and optimized study performance
Trialbee	Partnership	THREAD and Trialbee partner to enhance global decentralized clinical trial inclusivity and recruitment outcomes
THREAD Design	Service offering	THREAD launched new offering THREAD DESIGN, a consultative service that leverages THREAD's deep expertise in facilitating DCTs, THREAD DESIGN helps sponsors and CROs design decentralized studies that are tailored to the specific needs of each protocol to maximize the effectiveness of their research

03

Enterprise sourcing considerations

- Major Contenders
  - Castor
  - Clinical Ink
  - Covance
  - eClinicalHealth
  - ERT
  - IQVIA
  - Medidata
  - ObvioHealth
  - Signant Health

Castor | decentralized clinical trial products 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, innovation, flexibility, and above all, the cost of Castor's product suite
- Castor is quick to address issues that clients might face with the products
- The user experience of the Castor products is rated very good by clients
- Castor has a transparent and standardized pricing model that is dependent on the client (size and industry) and study request (single study vs. bulk vs. subscription); clients state that the product suite is competitively priced
- Castor has strong expertise and previous experience to run Software as a Medical Device (SaMD) trials on its suite of products

Limitations

- Castor positions itself as a self-service DCT provider and has limited partnerships to offer clients auxiliary services; this reduces the value proposition and flexibility to deliver the product and service combination that is beneficial to clients
- Clients state that Castor's delivery capabilities in the US can improve – they desire for a stronger US presence as the time difference can sometimes be a problem when most of their trials are happening in the US. They also note that Castor has taken effort in the last six to eight months to expand its presence in the US
- There is no seamless integration between various Castor solutions such as eCOA and eConsent. Clients state that they desire a single login across these solutions
- In order to be an end-to-end platform vendor for DCTs, Castor needs to offer capabilities for televisits and medication adherence, which are currently on the product release roadmap

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

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

Castor is a leading provider of decentralized and hybrid clinical trial solutions to democratize research. With the highest rated eClinical platform for decentralized and hybrid clinical trials, Castor's plug-and-play platform offers rapid deployment at scale, enabling researchers to create a trial in a matter of clicks, with easy enrollment and real-world data capture. Castor is 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.

Therapy area coverage

Castor's decentralized clinical trial products cater to various therapy areas such as infectious diseases, medical devices (SaMD), rare diseases, cardiovascular, vaccine and virology, and diabetes.

Overview of the client base

Castor is a leading provider of decentralized and hybrid clinical trial solutions to SMB and mid-market clients. Currently, the company has over 400 paying customers, including pharma companies, CROs, medical devices companies such as MedRythms, and digital therapeutic companies such as Click Therapeutics and Akili Interactive.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

- eConsent
- eCOA/ePRO
- Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)

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

Case studies

NOT EXHAUSTIVE

Case study 1	Click Therapeutics

Business challenge

Click Therapeutics, a digital therapeutics company that develops “software as treatments,” was looking for a natively integrated end-to-end decentralized clinical trials platform to run all their studies. For selecting a partner, they compared multiple traditional “legacy” providers as well as newer technology vendors in the space. After sending an RFP, Click Therapeutics selected Castor as a preferred partner. Castor offers an easy-to-use, cost-effective platform with natively integrated product lines, including an integrated EDC to perform decentralized clinical trials.

Solution and impact

Castor provided a range of DCT solutions to Click Therapeutics, depending on the study type. Solutions included: remote enrollment, a patient recruitment landing page, eConsent, EDC, and Castor’s fully functional RESTful API that fully integrates with Castor’s EDC, allowing for all necessary customizations and integrations. In addition, Castor’s flexible solutions allowed for quick adaptations of the implementation based on feedback during the enrollment process. Castor and Click Therapeutics expect to reduce traditional trial duration and costs by at least 30%.

Case study 2	Perspectum Diagnostics

Business challenge

Perspectum, a leading medical imaging company, was looking for a DCT platform that allowed them to run their COVID-19 study, COVERSCAN. This study is aimed at mapping organ health in those following the SARS-CoV-2 infection, as well as identifying at-risk features for the virus, with detailed cross-sectional MRI imaging and genetic studies. Perspectum was seeking an easy-to-use and scalable solution that also minimized COVID-19 exposure to patients and staff.

Solution and impact

Castor offered Perspectum, a fully decentralized solution that consisted of remote enrollment, including remote eConsent and ePRO (online questionnaires), before scheduling a multi-organ scan visit. Over a period of 36 months, the study aims to recruit over 1,500 participants. This is a multi-cohort study that invites healthy volunteers, those who have suffered from COVID-19, and those with an auto-immune liver disease.

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

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)

Solution	Details
EDC	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 calculation, 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 their programs
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. 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
ePRO / mobile apps (Castor Connect)	Castor's ePRO app solution allows study subjects to complete surveys anytime and anywhere from their mobile or tablet. Configurable in-app notifications and a participant "to-do list" presentation showing pending and completed actions ensures 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 EDC's web and 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
Castor APIs	Castor's RESTful API enables users to capture data directly from multiple data sources (eSource) in a secure platform designed for handling and storing sensitive study data. The API has been used to connect to different platforms, including CTMS, medical devices, and wearables

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

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

Castor | decentralized clinical trial products profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
Series A	Investment	Castor announced its US$12 million Series A round in August 2020, led by Two Sigma Ventures, with participation from Hambrecht Ducera Growth Ventures and existing investor INKEF Capital. The company will be able to make significant progress in major areas by continuing to deliver user-friendly, accessible technology that can support remote trials, while ensuring machine-readable output that allows for trial automation and data reuse. In the next 18 months, Castor intends to support customers with patient recruitment and synthetic control arms through better use of their data
DTRA partnership	Alliance	Castor was a founding partner of the Decentralized Trials and Research Alliance, 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
Datavant partnership	Alliance	Castor and Datavant announced a strategic partnership in October 2020, wherein Castor embedded Datavant's technology within its patient-facing products, enabling a more comprehensive solution for linking real-world data for consented patients in both clinical trials and registries
Castor Connect launch	Product launch	Castor announced the launch of Castor Connect in December 2020, allowing clients to deploy native patient-facing apps that could be created by the client (self-service) through Castor's Data Management Platform
Castor Remote eConsent launch	Product launch	Castor launched its remote eConsent solution in 2020 that streamlines and automates study recruitment, screening, and consent. It is designed for decentralized and hybrid research projects to deliver compliant, site-friendly, and patient-centric experiences. The solution offers an integrated video-calling feature that has been built by Castor in-house, eliminating vendor management concerns with third-party video tools
COVID-Red study	Initiative	Castor supports COVID-Red, a fully decentralized 20,000 subject study, in which patients are remotely recruited, screened, and randomized using Castor's platform
World Health Organization Solidarity Therapeutics trial	Initiative	Castor supports the WHO in providing its DCT platform to run the world's largest randomized control trial with 15,000 patients, spanning over 30 countries, 2,145 investigators, and 550+ sites
World Health Organization Solidarity Vaccine trial	Initiative	Castor has worked closely with the World Health Organization to launch the world's first head-to-head COVID-19 vaccine trial. This trial is run completely on tablets using DDC and using Castor's IRT module, integrating with a biometrics identity tracking and messaging application from an external supplier
Click Therapeutics	Partnership	Castor announced its DCT partnership with Click Therapeutics, offering its full suite of DCT solutions to the leading digital therapeutics company to be used for multiple studies

Clinical Ink | decentralized clinical trial products 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 Clinical Ink's ability to offer functionalities and design scales for measuring complex eCOAs. Clinical Ink know the space of eCOA very well
- Clinical Ink is more flexible as compared to its peers; clients have stated the Clinical Ink has a "stellar" tech support
- Clients rate Clinical Ink high on domain expertise and coverage across multiple therapeutic areas; they are also willing to take on complex assessments and tackle hard pieces that other vendors do not
- Clients state that Clinical Ink goes above and beyond its scope of work to improve the engagement. As a result, it is more flexible to client needs and requests
- The real-time data capture and BYOD approach of Clinical Ink is a differentiator

Limitations

- Clients have struggled with getting the data out of the systems in the right formats
- Clinical Ink provisions its own tablets at the site. Site users have stated that there is a big learning curve associated with the tablets and as a result, there have been usage and access challenges
- The company is perceived to be a premium priced player by clients
- Clinical Ink does not offer all the auxiliary support services such as patient screening, patient recruitment, home nursing, remote CRA services which are valuable to run DCTs
- Clients do not believe that Clinical Ink has an end-to-end integrated offering for running DCTs. Also, Clinical Ink needs to use a third-party application for integration of telehealth capabilities

Clinical Ink | decentralized clinical trial products profile (page 2 of 6)

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

Clinical Ink's vision and strategy is to allow for customer flexibility to use and choose the solutions that make the most sense for their study. Clinical Ink aims at allowing customers to choose and allow sites to use existing televisit solutions to connect with patients. It is dedicated to creating an integration framework that will allow for data to flow to and from the platform.

Therapy area coverage

Clinical Ink's decentralized clinical trial products cater to 32 therapeutic areas such as 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.

Overview of the client base

Clinical Ink has worked in over 80 languages, more than 65 countries, and has deployed over 500 unique scales and assessments with different clients.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography[1]

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size[1]

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Medication adherence	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)
eCOA/ePRO	Televisits	

1 Analyst estimates

Clinical Ink | decentralized clinical trial products profile (page 3 of 6)

Case studies

NOT EXHAUSTIVE

Case study 1: Enable remote clinical research and ensure data security

Business challenge

A pharmaceutical company conducting an early phase CNS study required an eSource solution that would allow coordinators to conduct site visits from nursing homes located across the UK, where subjects physically incapable of travel resided.

Solution and impact

Clinical Ink deployed tablets equipped with the study to site coordinators. Before leaving the research site for the nursing home visit, coordinators downloaded individual subject charts on the tablet for offline data capture. While in the nursing home, coordinators moved freely from room to room, capturing subject data directly via tablet. During data entry, built-in edit and logic checks automatically cleaned and validated the data to ensure optimal quality. Upon returning to the research site, coordinators uploaded the data to the Lunexis™ web portal, where it was immediately available online for remote monitoring and review.

Lunexis enabled remote clinical research, allowing coordinators to conduct site visits from various nursing homes supporting a complex CNS study. Designed to facilitate clinical research from anywhere in the world – with or without an internet connection – Lunexis enabled offline research for this study while ensuring the security and privacy of data captured remotely.

Case study 2: Conduct early Phase I study with an electronic data capture solution

Business challenge

A large pharmaceutical company conducting an early Phase I study was looking for an electronic data capture solution that would offer real-time access to study data, eliminate manual data re-entry, minimize data errors, and facilitate the remote monitoring of research sites.

Solution and impact

The sponsor worked with Clinical Ink to develop a customized eSource study to capture subject data electronically during the subject visit. More than 70 site users were trained to capture data using 30 tablets from Clinical Ink's eSource platform, Lunexis™. During the subject visit, data was captured and immediately validated on the tablet before being transferred to the clinical study database, where sponsor study teams used advanced visualization tools to review subject data. Both sponsor and third-party monitors could access study data and the original eSource documents remotely via the web-based portal.

Within an hour of the completed subject visit, the sponsor was able to remotely access and visualize all clinical data using an analytical tool. Receiving study data in one hour was a significant reduction from the nearly two-week wait to access data prior to using Lunexis. This also marked a tremendous improvement in the sponsor's ability to monitor safety data and shorten clinical development timelines. Nearly 80% of the monitoring activities were completed remotely to further reduce R&D costs by eliminating unnecessary time and travel.

Clinical Ink | decentralized clinical trial products profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)

Solution	Details
eConsent	The module allows for the use of audio, video, and photography to be included in the presentation of consenting information to the patient. The patient can create their own PIN code and challenge/response questions and interact with the eConsent content, indicating where they have questions, and then working with site personnel to get their questions addressed
eCOA/ePRO	The module combines audio, video, photography, and electronic inking/drawing, and can support the complex calculations and algorithms all built directly into the eCOA solution. Clinical Ink has deployed the eCOA solution in over 80 languages and in over 60 countries. Clinical Ink also supports ePRO at-home and on-site, using either provisioned devices or BYOD, and this is a key part of its decentralized clinical trial strategy
Remote patient monitoring and integration with wearable technology & BYOD	The module allows customers to be able to remotely review patient data to carry out the necessary monitoring. Depending on the nature of the data collected, monitors can issue queries and apply review statuses to collected data. From an integration of wearable technology standpoint, it offers the ability to kit provisioned patient devices along with wearable technologies, and then allow the customer to be able to look at data on the appropriate portal
Televisits	The solution provides the ability for customers to use and choose whichever televisit solution works best for them and their sites. The company has vetted televisit solutions such as Doxy and Zoom, along with the solution
Medication adherence	The solution enables patients to demonstrate and track their compliance with medication adherence. Reminders and alerts can be configured to remind patients to demonstrate medication adherence and to alert site personnel if the patient has not adhered to medication usage

Clinical Ink | decentralized clinical trial products profile (page 5 of 6)

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

Clinical Ink | decentralized clinical trial products profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
eCOA solutions	Deployment	Deployed industry-leading 500 unique eCOA scales and assessments in 82 languages. eCOA instruments play a critical role in clinical trial conduct and are used in a variety of ways, from screening for inclusion to use as a primary endpoint
Endpoint	Partnership	Partnered with Endpoint Clinical to integrate IRT and eSource in order to create a seamless user experience for investigator sites
Integron	Partnership	Partnered to extend Clinical Ink's mobile device and sensor deployment capabilities to engage and collect data from patients in clinical trials

Covance | decentralized clinical trial products 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

- Covance's acquisition of SnapIoT augments its DCT capabilities, and offers clients products from SnapIoT and auxiliary services owing to Covance's CRO heritage
- SnapIoT also provides clients additional capabilities such as patient randomization, patient diaries, BYOD support, and reporting and insights
- SnapIoT has partnered with vendors such as Actigraph and Clincloud to augment remote patient monitoring capabilities for its products
- SnapIoT focuses on deploying solutions faster and at lesser cost as compared to traditional solutions, thus allowing sponsors and CROs control of their delivery timelines

Limitations

- SnapIoT's products are point solutions, and not an end-to-end DCT platform
- Covance or SnapIoT has limited thought leadership content or consultative capabilities to help clients decentralize their clinical trials or provide insights into DCTs; there are limited case studies or success stories about its work with clients on decentralized clinical trials
- There are limited capabilities to check for patient adherence in DCTs

Covance | decentralized clinical trial products profile (page 2 of 6)

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

Decentralized clinical trial products are disrupting the life science ecosystem with the next generation of powerful self-service clinical science solutions. They are a single platform for any device, mobile, cloud, and operating system.

Therapy area coverage

Covance's decentralized clinical trial products cater to multiple therapy areas including oncology, women's health, and diabetes.

Overview of the client base

Through its acquisition of SnapIoT, Covance serves pharma and medical device companies in their DCTs. There are no publicly listed clients available.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography[1]

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size[1]

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Televisits
eCOA/ePRO	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)

1 Analyst estimates
Note: The analysis includes DCT capabilities through Covance's acquisition of SnapIoT

Covance | decentralized clinical trial products profile (page 3 of 6)

Case studies

NOT EXHAUSTIVE

Case study 1	LabCorp wanted to transform the clinical trial experience and streamline the drug development process

Business challenge

A leading global life sciences company, focused on advancing health and guiding patient care decisions, required new capabilities that could transform the clinical trial experience with the goal of streamlining the drug development process. GlobalCare and SnapIot helped the company with the solution.

Solution and impact

SnapIoT's digitized clinical trials solution provides data interoperability across the trial delivery continuum and optimizes the site workflow by reducing the number of disparate tools and platforms used during clinical trials to one integrated solution. This solution could include functions such as eConsent, ePRO, and eCOA; telehealth and connected devices to improve data collection; and digitization of mobile nursing visits and sample collections to accelerate benefits of DCT, namely faster enrollment, easier engagement, more efficient studies, and quicker data locks.

The result of the solution is that the client can now speed up trial design and implementation while de-risking the execution process by providing complete, integrated solutions from a single partner.

Case study 2	Collaborated with Scripps Research Translational Institute to achieve key milestones in maternal health research study

Business challenge

The client required a technological solution for a study that aimed to improve understanding of factors associated with a healthy pregnancy.

Solution and impact

SnapIoT worked with Scripps Research Translational Institute to develop and implement a native app for android, iOS, and a web-based version for other devices. Maternal health data from the study participants was collected directly from the app along with biometric data from wearables, such as activity trackers and smartwatches, and sent securely to the snapClinical platform where clinicians could monitor results in real-time.

The solution enabled the client to collect frequent and more detailed health data from each participant. This data enabled the client to fill in the knowledge gaps that existed in understanding what factors contributed to healthy pregnancies for all women.

Covance | decentralized clinical trial products profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)	
Solution	**Details**
snapClinical	A powerful self-service platform that allows clinical trial providers to design and deploy apps to their participants with no coding. A disruptive rapid mobile-connected, technology-centric deployment platform for clinical trial solutions
eQualification	To provide customized questionnaires to digitally qualify patients and determine the perfect candidates for clinical trials
eConsent	To break down the informed consent form into smaller, user-friendly segments of information. Use videos and compelling imagery to enhance patient understanding and allow them to make better informed decisions
eDiary	To harness the full benefits of electronic data capture by designing symptom severity or quality of life surveys that run on any phone, tablet, or portal
Recording symptoms	To help patients so that they can take a video or a still image to record symptoms via their mobile device. Video and images are uploaded to the cloud server for immediate review by the trial administrator
snapIoT MDM solution	To make managing any smart device in any clinical trial easy and efficient by aggregating multiple features in one place. MDM features include patient compliance monitoring & alert, application control, location services, remote data wipe out, and reporting and storage of essential information
IoMT	To envision a network of connected devices that sense vital data in real-time

Covance | decentralized clinical trial products profile (page 5 of 6)

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits[1]	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
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Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

1 Available through SnaploT

Covance | decentralized clinical trial products profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
ActiGraph	Partnership	SnapIoT integrated its mClinical platform, snapClinical, with ActiGraph's CentrePoint System. This integration gives sponsors and CROs improved power in data collection and insights for clinical trials. The data collected from ActiGraph's wearables seamlessly uploads to the Cloud, where snapClinical can securely retrieve and store the data. With different types of measurements being collected through the sensors, snapIoT makes visualizing data simple by creating graphs that have the flexibility to overlay data points. snapClinical also allows users to easily compare these data points with other types of collected measurements, such as surveys and diaries
ClinCloud	Partnership	SnapIoT platform was used in a study for adults with mild cognitive impairment, specifically memory-related difficulty, and dementia. Patients, caregivers, and clinical trial candidates, along with their medical professionals, utilized snapIoT's proprietary technology to schedule and conduct virtual pre-screening through the use of snapIoT's proprietary telemedicine offering

eClinicalHealth | decentralized clinical trial products 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

- eClinicalHealth, through its DCT offering, ClinPal, has been helping clients decentralize their studies since 2011
- eClinicalHealth has experience conducting DCTs across multiple therapeutic areas and a wide range of geographies
- ClinPal has partnered with Dreem, Investis Digital, Trials@Home to help clients with carrying out DCTs in various therapeutic areas

Limitations

- eClinicalHealth has not kept abreast with the innovation exhibited by the DCT vendors and does not offer capabilities for televisits
- It does not offer auxiliary support services to clients and positions itself as a self-service platform for running DCTs. There are no partnerships with CROs or home nurse networks that leading vendors engage to augment the value proposition of the platform
- eClinicalHealth has limited thought leadership content or consultative capabilities to help clients decentralize their clinical trials or provide insights into DCTs

eClinicalHealth | decentralized clinical trial products profile (page 2 of 6)

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

Clinpal's mission is to provide a point-and-click studio for study configuration and ensure a rapid, collaborative study design, either self-build or as a service for all its clients. This includes defining the data fields, forms, and logic. Its vision is to enable CROs and self-build clients to quickly and easily design studies with all the features of Clinpal.

Therapy area coverage

Clinpal decentralized clinical trial products cater to therapy areas including neurology, immunology, oncology, pulmonary and respiratory diseases, cardiovascular, diabetes, ophthalmology, obesity, nutrition, and women's health.

Overview of the client base

eClinicalHealth's major clients include a few top 10 pharma companies, a research institute, a major medical device company, and a digital therapeutics company.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography[1]

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size[1]

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

- eConsent
- eCOA/ePRO
- Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)

1 Analyst estimates

eClinicalHealth | decentralized clinical trial products profile (page 3 of 6)

Case studies

NOT EXHAUSTIVE

Case study 1

Phase 3 study involving social media recruitment, eConsent, BYOD, and ePRO

Business challenge

More than 1,000 patients were pre-screened in under four weeks. The study required electronic informed consent / assent for volunteers, parents, and guardians aged 13 and over. The study also required maintaining a daily diary for 12 months.

Solution deployed

To ensure smooth flow of the study, Clinpal recruits were used for pre-screener, referral tracking, and patient engagement. Single system recruitment involving social media ads, a call center, sites, and clinics were all coordinated through the same platform.

The diary structure contained minimal daily impact to volunteers, rewards enabled patient to recognize the value of their diary completion, and reminders with push notification ensured adherence and compliance.

Impact

- Clinpal offered recruitment, electronic informed consent, and patient diaries within one system
- Rapid social media-based recruitment and screening support by Clinpal-configured call center workflow effective
- Ensured automated consent / assent based on candidate's age, combined with separate parent/guardian consent for adolescents

Case study 2

Patient questionnaires in a depression study

Business challenge

The study required Clinpal, supporting 120 patients over 18 months, to conduct hybrid studies combining visits, telephonic visit, and intervention at home with self-reporting. The study required digital therapeutics to be delivered via smartphone and the collected data to be analyzed on Clinpal.

Solution deployed

The company combined eCRF with several patient questionnaires and used Clinpal Randomization and workflow reminders. The entire solution was delivered via the Clinpal app.

Impact

- Only Clinpal offered this solution within one system
- The project was delivered in less than eight weeks. Questionnaires and ECRF developed built an integrated environment in an interactive approach with the clients.
- Use of the Clinpal app kept the costs for patients for the development and deployment below €200

eClinicalHealth | decentralized clinical trial products profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)

Solution	Details
EDC+	The Clinpal EDC+ solution 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
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 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 collection process
Clinpal Engage	Clinpal Engage improves patient and site engagement and communication throughout the study. From initial collection of site information, through start-up, initiation, conduct, and closeout, sites can communicate effectively with patients from the onset of their journey
Clinpal Repository	Clinpal Repository provides immediate access to structured tabular study data, accessible through standard data listing reports. The data can be imported to the sponsor's own relational databases or analytical tools with standard export functionality including a self-service web API

eClinicalHealth | decentralized clinical trial products profile (page 5 of 6)

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

eClinicalHealth | decentralized clinical trial products profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
Dreem	Partnership	Partnered with Dreem, a sleep neurotech company, to carry out remote and large-scale research in sleep analysis and improvement. Dreem is leveraging Clinpal in supporting research over a series of sleep studies based in Europe and the United States
Investis Digital	Partnership	Partnered with Investis Digital, a global digital communications company. The alliance combines Investis Digital's propriety framework, Connected Content™, known for targeting and engaging hard-to-reach patient populations, and Clinpal's cloud-based platform, which connects patients, study teams, and sites during a clinical trial
Trials@Home	Investment	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

ERT | decentralized clinical trial products 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

- ERT's eCOA capabilities are capable of support complex assessments and rater scales and have been adopted across various therapeutic areas such as mental health, oncology, CNS, etc. The eCOA solutions also work with a wide variety of audio and video capabilities that enhances evaluation of a drug's efficacy
- ERT's expertise in imaging capabilities closely integrate with their eCOA solutions to introduce security, improve image identification, and analysis
- ERT's merger with BioClinica offer clients additional capabilities for clinical development such as CTMS, EDC, RTSM solutions
- ERT has good data analytics capabilities and has capabilities to showcase data insights, business intelligence to stakeholders about the eCOA and study progress

Limitations

- ERT's focus is on point solutions, and primarily eCOA solutions. There are limited partnerships to offer clients access to auxiliary support services in DCTs
- ERT does not have capabilities to monitor patient adherence in DCTs. Its virtual visits solution was also recently launched in 2020
- Public reviews by clients have cited communication issues with ERT, which has been a point of delays and hassle

ERT | decentralized clinical trial products profile (page 2 of 7)

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

To minimize risk and uncertainty in clinical trials. Meet clinical development goals and achieve higher quality data, reduced costs, and shortened study timelines with support from ERT.

Therapy area coverage

ERT decentralized clinical trial products cater to various therapy areas such as neurology, immunology, respiratory diseases, cardiovascular, and vaccine and virology.

Overview of the client base

ERT does not have any publicly disclosed clients; but it works with leading biopharma companies on decentralized clinical trials.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography[1]

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size[1]

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Televisits
eCOA/ePRO	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)

1 Analyst estimates
Note: The analysis includes DCT capabilities through ERT's acquisition of BioClinica

ERT | decentralized clinical trial products profile (page 3 of 7)

Case studies

NOT EXHAUSTIVE

Case study 1

Prospective observational study benefits from BYOD eCOA solution

Business challenge

To improve multiple sclerosis outcomes through standardized real-world data collection, aggregation, and insight generation by leveraging digital devices, cloud-based data aggregation, and EMR integration to enable the creation of a longitudinal data repository of deeply phenotype patients to inform clinical research and treatment pathway optimization.

Solution deployed

ERT's post-approval platform delivered the required validated assessments remotely through a native application, downloadable on to patients' own iOS and Android smartphones. To maximize participation, devices were also provisioned to around 20% of patients who did not have an appropriate smart device. Sites were supplied with tablet devices with the assessment app pre-installed to ensure that patients could still complete their assessments during site visits, even if they did not have their device with them. To meet the client's requirement of providing low-level engagement, reminders, guidance messaging, and tailored training were all delivered as part of the app. Finally, the client was able to monitor patient and site progress via the study portal.

Impact

Using a BYOD approach allowed the study to integrate into patients' everyday lives, while the intuitive user experience and interface design with built-in messaging helped maintain participation rates for the duration of the study. For the client, the use of flexible BYOD data capture capability reduced costs in comparison to a fully provisioned model.

Case study 2

Global biotech company leverages patient-reported suicidality assessment to save lives and optimize compound investment

Business challenge

During clinical development, sponsors and CROs need to detect possible Suicide Ideation and Behavior (SIB) related to their drug in the screening, baseline, treatment, and follow-up phases of the study. Suicidal ideation and behaviors are a threat to patient and drug safety, and as such, need to be assessed accurately and in a timely manner.

Data collected during suicide risk assessments will either indicate that the drug has no impact on SIB or that it increases or decreases the risk of suicide – providing the evidence required to terminate trials early, reducing cost and potentially saving lives.

In this group of trials for a multinational biotech company, SIB events occurred, including completed suicide. As a result, the FDA required prospective suicidal risk assessments to be added to their active studies.

Solution deployed

The biotechnology company chose ERT's electronic C-SSRS – a unique monitoring solution that enables patients to self-report their symptoms.

In addition, real-time alerts were built into ERT's web and phone solutions, which notified site staff, caregivers, and supervisors to any positive results. When ERT's eCOA tablets were chosen, alerts were in near real-time, based on data transmission to ERT's EXPERT platform.

Finally, the solution enabled study monitors to access intra-study SIB trending analyses as well as insights across studies in other regions.

Impact

ERT provided the FDA and biotechnology company with evidence of a SIB risk associated with the treatment. The trial was then terminated early – potentially saving further lives.

In addition, any positive scoring on an assessment was sent to clinicians in real-time or near-real time, enabling them to act faster than would otherwise have been possible.

By implementing ERT's eC-SSRS solution, the sponsor and investigative sites also mitigated the burden/ cost of administering clinician interviews during each site visit.

ERT | decentralized clinical trial products profile (page 4 of 7)

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)

Solution	Details
Virtual visits	The telehealth solution gives staff the opportunity to connect with patients in siteless or hybrid trials, where site visits may be fewer or less frequent. It can inform on critical symptom monitoring and data
Home monitoring assessments	The solution captures the compliant and verified data needed to complete the study, without risky or inconvenient site visits. ERT technology makes easy work of the collection of patient data outside of the usual testing sites. At-home assessments can include: eCOA, respiratory, imaging, cardiac safety monitoring, and wearables integration.
Home visit collection	Authorized home clinicians transport all required testing devices and consumables to a patient's home or preferred location and conduct studies following the same protocols they would in-clinic. This option is available for eClinROs, ECG collection, and spirometry
Integration with site-owned devices	Sites can use existing ECG and spirometry equipment instead of ERT-provided devices if there is no time for delivery. Using the ERT portal, the customer can upload an image or PDF of the ECG or spirometry data collected with site-owned devices to be shared with ERT. ERT then uses their precision paper over-reading service to measure the ECG and give a cardiologist's interpretation of the results or provide central overread with acceptability and best test review analysis for spirometry data
In-community imaging scans	A cloud-based imaging solution that can rapidly bring new sites online and closer to patients than their primary investigative site. This allows for compliant image capture from any location and equipment. Once the images are uploaded into ERT's imaging management system, readers and radiologists will be able to access them from any location. To set up these new sites quickly, ERT's site qualification capabilities offer: • Site training • Technician qualification competency testing • Equipment qualification
eCOA multimedia: enhancing data quality	Evaluate drug efficacy with eCOA multimedia, using a single secure device • Compile a more holistic view of a patient's condition, without any additional effort • Track and monitor their progress more accurately and easily over time • Improve compliance using a single device • Achieve standardized, consistent high-quality images and audio recordings

ERT | decentralized clinical trial products profile (page 5 of 7)

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features[1]	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
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Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

1 Available through BioClinica

ERT | decentralized clinical trial products profile (page 6 of 7)

Recent developments (page 1 of 2)

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
iSpiro Virtual Visits	Development (2021)	Launched iSpiro Virtual Visits, which enable real-time coaching during at-home Pulmonary Function Tests (PFT). With iSpiro Virtual Visits, ERT delivers on its commitment to provide customer and patient-oriented innovations that facilitate decentralization
Bioclinica	Merger (2021)	Merged with Bioclinica, an integrated clinical life science solutions provider, to create the global leader in clinical trial endpoint technology
eCOA multimedia	Development (2021)	Launched eCOA multimedia to enhance patient's data captured with photo and audio in clinical trials. The solution allows patients to minimize site visits by enabling them to send important files to the study's database from home.
Data Insights	Development (2021)	Launched Data Insights, a trial oversight solution which is designed to discover variabilities in endpoint data collection and management
Science 37	Partnership (2020)	Partnered with Science 37, the leader in decentralized clinical trials, to deliver high-quality data during virtual trials. The partnership enables ERT's cardiac safety, respiratory, and imaging solutions to be incorporated into the Science 37 virtual, or decentralized clinical trial offering to improve data quality and reduce patient's burden
Cogstate, Ltd.	Partnership (2020)	Collaborated with Cogstate, Ltd, a neuroscience technology company, to enable ERT to expand its electronic Clinical Outcome Assessment (eCOA) solution with digital cognitive endpoint measurement to improve safety and efficacy assessment in clinical trials, including capabilities for at-home testing
Inofab Health	Partnership (2020)	Partnered with Inofab Health, a healthcare technology company designing and developing ultrasonic spirometry technology for in-clinic and at-home use. Through the partnership, ERT expands its portfolio of virtual trial solutions to give clinical trial sponsors and CROs multiple options for continuing life-saving research throughout the pandemic and beyond
APDM Wearable Technologies	Acquisition (2020)	Acquired APDM Wearable Technologies, a next-generation provider of wearables and digital biomarkers. The combined company will generate higher-fidelity and more powerful data to enable clinical trials to be more predictable, cost-effective, and efficient; thereby, reinventing endpoint measurement
Virtual visit solution	Development (2020)	Developed a virtual visit solution that enables the continuation of clinical trials during and after current global stay-at-home mandates

ERT | decentralized clinical trial products profile (page 7 of 7)

Recent developments (page 2 of 2)

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
At-home respiratory solutions	Development (2020)	Provides multiple options that enable trained healthcare professionals to advance respiratory clinical trials by collecting high-quality spirometry data during the patient's home visits. ERT's At-Home Respiratory Solutions enable clinical trial sponsors to continue developing new respiratory treatments while patient access to investigative sites is limited due to COVID-19 stay-at-home mandates
At-home cardiac safety assessment	Development (2020)	A cardiac safety solution that helps biopharmaceutical researchers continue important clinical trials during the current global "stay home" mandates. The solution enables clinician-administered ECG readings – using ERT's provisioned, FDA-cleared devices or other investigative site-owned equipment – to evaluate the safety of new vaccines and medical treatments from patients' homes
ERT SpiroSphere	Development (2019)	Announced ERT SpiroSphere, the first and only spirometer designed specifically for use in global clinical trials. SpiroSphere captures research-grade clinical data that meets regulatory requirements and ensures that quality data is immediately accessible to all clinical trial users

IQVIA | decentralized clinical trial products 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

- Due to its CRO heritage and global footprint, IQVIA can support client requirements for DCTs globally. It is also able to provide a wide combination of technology and auxiliary service offerings depending on client requirements
- Clients appreciate IQVIA's support services and cite that it is quick to resolve queries and action items
- IQVIA has good domain expertise and is able to advise clients on designing their trials from a DCT perspective
- Clients have leveraged IQVIA's product in a fast-paced COVID trial situation; they claim that the size of the study, speed of enrolling patients, and conducting the study was impressive

Limitations

- Clients do not think that IQVIA has an end-to-end platform for running DCTs; they do not have a unified data layer to support the end-to-end perspective. As a result, there are integration issues between various product suites
- Clients cite that IQVIA is a premium priced player and at times, also charges program management fees along with their suite of DCT products
- The product suites' user experience needs to improve. Public patient ratings available on Android and iOS play stores state that the app is designed well but keeps crashing, is slow, and clunky
- Clients state that the planned upgrades are sometimes delayed and there are certain challenges that have arisen post implementation of new updates

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

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

IQVIA is eager to broaden its partnerships with sponsors to work collaboratively as part of next-generation trial execution to support the transformation of sponsor's clinical delivery model through the integration of decentralized trial technologies, services, and processes. It is positioned to support sponsors through the application of its technology whose development was underpinned by IQVIA's extensive decentralized trial experience. IQVIA has deployed technology as well as augmentative decentralized service solutions such as connected devices, home health nursing, and patient recruitment to decentralize trial capability.

Therapy area coverage

IQVIA's decentralized clinical trial products cater to various therapy areas such as neurology, infectious diseases, immunology, dermatology, oncology, pulmonary and respiratory diseases, ophthalmology, vaccine and virology, psychiatry, nephrology, and allergies.

Overview of the client base

IQVIA continues to broaden its partnership with sponsors and has done 1,250+ trials utilizing decentralized platform and services. It has a dedicated decentralized operational team. There are 75+ studies conducted with home health nursing involving over 200,000 subjects. IQVIA has undertaken 10+ therapeutic areas and has 60+ trials underway. Its user base covers 40+ countries worldwide. IQVIA has demonstrated global scalability with its solution, ranging from small studies with 20 subjects to very large studies with over 50,000 participants in multiple countries.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Medication adherence	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)
eCOA/ePRO	Televisits	

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

Case studies

NOT EXHAUSTIVE

Case study 1	Improved compliance through IQVIA's input on design of eCOA sections of the protocol and training during the implementation process for a client

Business challenge

The client's eCOA solution included a handheld device which had to be paired with a Peak Expiratory Flow (PEF) meter, in order to record PEF measurements during completion of the daily diary. The client asked for early involvement during the protocol development and eCOA implementation process.

Solution and impact

During the prototype review, user acceptance testing, and subsequent attendance at the first SIV, it was noted that the device pairing process and the eCOA vendor's standard instruction screens were causing confusion and complications for users. IQVIA suggested updates to the on-screen instructions as well as training material.

The implementation of the solution resulted in less confusion during pairing and 95% compliance with PEF measurements during completion of the daily diary in the live environment.

Case study 2	Increase diversity in a COVID-19 vaccine trial

Business challenge

IQVIA was challenged to vaccinate 40,000 people in eight weeks. Six weeks after the study started, the sponsor changed the study enrollment goals to include a more diverse patient population, requiring a strategy adjustment while the study was in flight.

Solution and impact

IQVIA CORE was used to identify areas near study sites that had the patients needed to meet the diversity and inclusion goal. An agnostic method was used to ensure patient delivery regardless of whether they came from IQVIA, a third party, or the site. Direct-to-patient recruitment campaign and referral program was conducted. Custom dashboard was used to track and monitor enrollment metrics. Also, clinical trial educators were deployed to engage the community, provide training, and support referrals.

It resulted in the vaccination target exceeding 2,000 patients, resulting in 42,000 enrolled patients. Enrollment for underrepresented groups exceeded the OWS average. The sponsor achieved more diverse representation on the study than did all other sponsors of OWS COVID-19 vaccine trials.

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

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)	
Solution	**Details**
IQVIA Decentralized Clinical Trial (DCT) technology platform	The platform enables remote patient and trial team interaction/training via digital communication and televisits. Visit notifications, tasks and alert reminders, real-time access to trial team, and visibility to trial schedule ensure that patients remain engaged throughout the trial. The decentralized platform also incorporates eConsent, essential regulatory document workflow management, eCOA eDiaries, scheduling, reporting, and more to assure seamless patient interaction, operational delivery, and execution of the virtual trial
IQVIA DCT Core Platform	The platform solution is enabled by the Salesforce platform. The solution is a validated CFR 21 Part 11 compliant system that incorporates televisits – video technology to connect patients with the PI and the remote study team. It is also an interactive system that allows the PI and their team to interreact electronically
IQVIA Home Health Nurse (HHN) Services	The service provides mobile research nurse and phlebotomy services for in-home clinical trial visits. All mobile research clinicians undergo a thorough assessment process, which includes an interview and review of the providers' Curriculum Vitae (CV), licensure, and relevant training materials to ensure they have the appropriate skills and proper training to support a clinical trial
Cenduit IRT	For Direct to Patient (DtP) management of clinical trial supplies, the company works closely with third-party vendors to facilitate the supply of IMP and lab kits to patients. This service is proposed in all virtual trials (all remote visits) and some hybrid virtual trials (a mix of on-site and remote visits). Cenduit is an IQVIA company
IQVIA Connected Devices	IQVIA's Connected Devices team is the ideal partner for sponsors to deliver comprehensive device evaluation, validation, logistics, support, and data access. Its currently implemented offerings include Actigraphy/Accelerometry, Ambulatory Blood Pressure, Arrhythmia Monitoring, continuous glucose monitoring, ECG, eCOA/ePRO, scales, Spirometry, Vital Signs Monitoring, and Wearables
IQVIA eCOA	The solution utilizes patient smart devices, trial site tablets, BYOD devices, web-based interactions, and integrated devices. The advanced study build and execution platform helps in deploying real-time, direct-from-patient data collection solutions to amplify the patient's voice in clinical trials and real-world studies. Via intuitive build tools, sponsors can reduce cycle times and enable the setup. The solution offers bi-directional integration capabilities, allowing seamless communications with the sponsor's EDC and IRT systems
IQVIA Complete Consent	The solution is available in both full-service and SaaS models, which support two signature modalities: eSignature and print-to-sign, meeting the regulatory requirements for Informed Consent signature globally. The solution can be integrated with numerous clinical trial systems or other platforms via API. The SaaS offering allows sponsors to create, manage, and automate informed consent forms using internal resources. The technology can be integrated with CTMS, EDC, eTMF, and other common trial-vendor systems
Patient recruitment services	IQVIA patient recruitment services enable engagement, pre-screening, and referral of potentially eligible participants to study investigators for further consideration (consent, screening, enrollment, etc.) in the study. The level and modality of pre-screening support is developed as part of the overall patient recruitment strategy to ensure only high-quality potential matches are delivered to the study site. Recruitment activities are optimized in-flight to maximize response and conversion rates and ensure that enrollment goals are met

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

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

IQVIA | decentralized clinical trial products profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
Patient-centric laboratory solutions	Initiatives	Q^2 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
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, combined with IQVIA's deep life sciences expertise, includes both SaaS and technology-enabled services that automate study processes, drive R&D insights from artificial intelligence and machine learning, and strengthen connections between patients and clinicians
Mulesoft	Partnership	IQVIA's Lexi/Mulesoft capability integrates all applications across the OCT platform, thus creating a unified experience. Lexi will be extended to integrate the OCT platform and the client's existing systems to create seamless data exchange
Amazon Web Service (AWS)	Partnership	OCT Digital Site Suite and Digital Data Suite offer modules that are deployed on AWS in containerized microservices. Scale out is achieved through the container management platform and AWS autoscaling
Cloudera	Partnership	IQVIA and Cloudera have partnered to help pharma and biotech organizations better manage the breadth of data assets and facilitate adoption of a cloud technology framework to achieve their desired business outcomes
NDD MEDIZINTECHNIK AG	Partnership	NDD has partnered with IQVIA Connected Devices to help co-develop world-class Spirometry and pulmonary lung function service line, utilizing NDD EasyOn-PC spirometry devices and EasyOne connect software

Medidata | decentralized clinical trial products 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 quality of services being offered by Medidata for running their DCTs; the Medidata team is also ranked high on domain expertise around DCTs
- The company's DCT solutions are highly rated on governance, security, and compliance
- Medidata's suite of DCT products integrate well with client environment; clients have also cited that they value the ability to create a single form within the Medidata RAVE EDC and supply it to the patient – this single integration is an added plus as they had to code it separately for each application for other vendors
- Its patient insights program is a useful mechanism to improve existing suite of DCT products, while taking the patient and client voice into consideration

Limitations

- Clients state that the user experience of Medidata's DCT products needs to improve
- Medidata is perceived to be a premium priced vendor for running DCTs
- Medidata's DCT products are not end-to-end as they do not have a unified data layer. Clients state that a unified data layer has been designed but not implemented and would still need some work as it is in the early stages of usage as an end-to-end product
- While clients view Medidata as an innovative organization, they cite that DCT-native vendors have caught up in the DCT space and are innovating faster than Medidata

Medidata | decentralized clinical trial products profile (page 2 of 6)

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

Medidata's vision is to develop a broad spectrum of life sciences technologies and services aimed at supporting customers who are revolutionizing the way modern clinical research is done. The company focuses on patient-centricity as well as many of the innovative research methods used during the COVID-19 pandemic and has developed a suite of platform tools both patient-facing and site-/customer-facing that allow customers to choose a level of decentralization they feel is the most appropriate for their patients, sites, and therapeutic area of research.

Therapy area coverage

Medidata's decentralized clinical trial products are designed to support decentralization on any stage of trial or therapeutic area. Medidata has seen significant traction in early uses that cater to various therapy areas such as neurology, infectious diseases, dermatology, pulmonary and respiratory diseases, gastroenterology, vaccine and virology, and psychology.

Overview of the client base

Medidata has been involved in 888 decentralized clinical trials that capture some type of direct eSource data from patients outside of a site visit. This collectively has touched over 653,000 patients, nearly 490,000 sites, and 404 sponsors (including all the top 10 pharmaceutical companies and eight of the top 10 CROs) across multiple disease therapeutic areas, countries, languages, and clinical trial phases of research.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size[1]

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Medication adherence	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)
eCOA/ePRO	Televisits	

1 Analyst estimates

Medidata | decentralized clinical trial products profile (page 3 of 6)

Case studies

NOT EXHAUSTIVE

Case study 1: Better patient engagement for a rare disease research

Business challenge

The research required recruiting and engaging clinical trial patients with rare diseases. The patients were difficult to find across many countries and cultures. One of the top 10 global leaders in rare disease research, recognized the educational and outreach value of providing decentralizing technologies in a unified platform for their rare disease portfolio of studies and entered into an enterprise agreement (EA) with Medidata to deliver a unified approach to their global studies using Rave EDC, eConsent, eCOA, Coder, and Safety Gateway to manage their clinical trials.

Solution and impact

Medidata provided decentralized eConsent and eCOA to deliver direct patient engagement in a hybrid methodology, with some data collected at site and some directly from the patient remotely. The solution allowed for a better understanding of complex disease information for the patient and higher comprehension of their rights and responsibilities, risks and benefits, and expectations of their participation in the clinical trial. It also allowed patients to share data remotely, eliminating some site visits and significantly reducing the site costs as well as the patient burden of traveling to a site to share information.

To date, the company has employed the unified platform to support decentralization on eight studies, supporting 750 global clinical sites and more than 1,500 patients.

Case study 2: Giving patients the choice between remote or site participation

Business challenge

One of the top 20 pharmaceutical companies recognized the opportunity to engage more clinical trial patients through their personal devices and engage with Medidata to provide a “participant’s choice” solution. The patients could opt to consent and participate remotely or in a more traditional site-based setting on a phase III cardiovascular trial with 410 sites and 3,300 participants across 16 countries in North America, South America, Europe, and Asia.

Solution and impact

The client already had an enterprise agreement for the use of Rave EDC, Coder, and Safety Gateway. For this trial, myMedidata eConsent, and myMedidata eCOA were provided to deliver a true BYOD experience for patients wishing to participate from home using their own devices. In addition, site-based eConsent and eCOA were provided to allow patients to come into a trial site for visits. The company anticipated that providing the patient with a choice on how they want to participate will lead to greater patient engagement, patient satisfaction, and a decreased patient burden.

The study provided data points to understand the value of decentralization in a mixed mode trial and helped determine if providing patients with a choice impacted their participation in the trial.

Medidata | decentralized clinical trial products profile (page 4 of 6)

Offerings

Proprietary digital solutions (representative list)	
Solution	**Details**
eConsent	Medidata's eConsent platform is a patient-friendly, electronic informed consent and patient enrollment system for clinical trials that 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. The two modes allow sponsors the option of using one or both modes on a clinical study. eConsent is natively unified with Rave EDC to allow streamlined onboarding of clinical trial participants, while eliminating risk of data transcription errors. A user-friendly configuration tool eliminates the need for engineering resources for set up and allows flexibility in addressing country- and site-specific variations and requirements
eCOA	Medidata's eCOA platform is enabled directly from an EDC through an easy-to-use configuration tool. Sponsors can choose whether they want to use site-mode eCOA for Clinician Reported Outcomes (ClinRO) and ePRO, or if they would like to deliver a BYOD environment for patients through a native iOS, Android, or web-based solution. The Android and iOS platforms allow for off-line reporting on provisioned or BYOD phones or tablets, while the web-based solution provides access for a patient to log in from any internet-connected device with a web-browser to add eSource data in real-time
Remote patient monitoring and integration with wearable technology & BYOD	Medidata's Sensor Cloud provides data ingestion capabilities to capture data from nearly any type of medical and consumer-grade devices. High-frequency, high-volume, continuous, objective data is ingested, normalized, and presented for integration with other data sources to enable analysis and disease-specific clinical insights. From wearable devices that capture physiological data directly from patients, to other connected digital health technologies, such as weight scales or pulmonary function devices, Sensor Cloud ensures accurate and secure remote data collection. Medidata has been executing its roadmap of sensors, which has completed the integration of devices from MC10, Actigraph, BioIntellisense, Biobeat, Indie Health, and Oxitone
Televisits	myMedidata LIVE is a flexible, HIPAA-compliant, and secure two-way web-based live video conferencing platform 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. LIVE supports patient requested and clinician-led telemedicine visits and allows clinicians to provide clinical oversight for remote patients that cannot or choose not to have a physical site visit
Medication adherence	Medidata can track medication adherence via eDiaries and ePRO checks with automated reminders to complete a form or check-in. myMedidata LIVE is used for live two-way interaction between site staff and trial participants, allowing visualization of medication application. Third-party sensors or devices can also be integrated into Medidata's decentralized clinical trial platform to collect real-time or batch data on use of blister packs, bottle usage, dropper administration, and other sensor-driven data. RTSM provides direct-to-patient trial supply management for shipment and tracking of investigational medical products and supplies
Remote Source Review and Detect	Medidata's remote trial oversight tools, RSR and Detect, provide a marked differentiator in the decentralized clinical trial space, allowing sponsors to work collaboratively with sites to both retrospectively review source documents without having to conduct a site visit and also automatically detect anomalies, establishing a robust risk management strategy for effective trial oversight and patient safety

Medidata | decentralized clinical trial products profile (page 5 of 6)

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

Medidata | decentralized clinical trial products profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
MC10	Acquisition	Acquired MC10, a major life sciences company that is deeply 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
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 Decentralized Trials & Research Alliance (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 ACRO DCT Working Party	Partnership	Medidata is the Chair of the Association of Clinical Research Organizations (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

ObvioHealth | decentralized clinical trial products 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

- ObvioHealth gives clients the choice to opt for products along with auxiliary support services; they also excel at designing campaigns for patient recruitment across various social media
- Apart from serving pharmaceutical and medical devices clients, ObvioHealth also has a client roster in the consumer health and nutrition area
- Clients appreciate ObvioHealth's proactive work style and client management capabilities
- Clients view ObvioHealth as an innovative vendor in the DCT space, owing to its real-time dashboards and their capabilities to capture and manage complex rating scales

Limitations

- Clients state that while ObvioHealth is flexible with its pricing, it is not competitively priced and that its price points are higher than peers
- Clients expect a faster setup time for their suite of DCT products
- The user and patient experience of their product suite can improve
- ObvioHealth has a heavy focus on DCTs for small-sized clients and in the APAC market. Therefore, its ability to successfully cater to medium and large clients remains to be tested

ObvioHealth | decentralized clinical trial products profile (page 2 of 6)

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

ObvioHealth's mission is to lead the virtual clinical trial revolution by making the process smoother, easier, safer, and more accurate. The company's vision is to transform health research to help bring more life-improving innovations to the market.

Therapy area coverage

ObvioHealth's decentralized clinical trial products cater to various therapy areas such as cardiovascular, cell/gene therapy, CNS (behavior, neurology, and pain), dermatology, endocrinology, gastroenterology, hematology, hepatology, immune diseases, infectious disease, men's and women's health, nutrition, oncology, oral health, pediatric, rare disease, respiratory, sleep, and vaccine and virology.

Overview of the client base

Key clients include: RedHill BioPharma, Lycored, General Mills, Mizkan, Danone, Abbott, Renovia, Bayer, Janssen, Mithra, Pfizer, GSK, Evolve Biosystems, and MegaFood.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Medication adherence	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)
eCOA/ePRO	Televisits	

ObvioHealth | decentralized clinical trial products profile (page 3 of 6)

Case studies

NOT EXHAUSTIVE

Case study 1: LYCORED: Alleviating lower urinary tract symptoms & prostate discomfort

Business challenge

The client wanted to assess the effectiveness of supplement X on alleviating lower urinary tract symptoms and prostate discomfort after 12 weeks of use. It wanted to evaluate the patient perception, satisfaction, and willingness to recommend and continuously use the product.

Solution and impact

ObvioHealth used a virtual study design, including targeted social media recruiting aimed to enroll 50 men, who were above the age of 40 and reported to suffer from lower urinary tract symptoms most likely related to an enlarged prostate. The screening assessments included medical history, medications, and symptoms related to enlarged prostate. The enrollees received study product shipment and filled out questionnaires assessing changes in symptoms at various timepoints. All health-/medication-related changes were reported to the study team for AE assessment.

About 88% of patients who started the active trial period (IP consumption period) completed the study; 53% of men joined the study to help curb frequent trips to the bathroom and reported the most symptomatically impactful change in 40% of men who took the study product.

Case study 2: RedHill Biopharma: COVID-19 treatment study

Business challenge

This clinical trial required monitoring and clinical assessments of COVID-19 patients to be conducted in their homes to evaluate the safety and efficacy on non-hospitalized COVID-19 patients of an oral investigational drug.

Solution and impact

ObvioHealth is conducting an ongoing study with RedHill Biopharma to test the efficacy and safety of a treatment for COVID-19. Most patients with COVID-19 are, fortunately, not being hospitalized. They are told to self-isolate, rest, and take symptomatic medications. This highlights a significant unmet medical need for an oral, easily administered medication for treatment of symptomatic COVID-19 patients at home.

Participants were enrolled through a clinical site and sent home with the study drug plus several devices. ObvioHealth's platform is collecting both telemetric and patient-reported information. Biomarkers continuously gathered from the devices will include patient's temperature, respiratory and pulse rates, blood pressure, pulse oximetry, electrocardiogram (ECG), and weight.

Home healthcare nurses are scheduled to perform four in-home visits to check in on patients, collect blood samples for certain laboratory parameters, perform virus PCR swabs at home, and assist in certain patient-reported data capture, using devices provided to participants at home. Recruitment is ongoing, and multiple participants have been enrolled.

ObvioHealth | decentralized clinical trial products profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)	
Solution	**Details**
Modular virtual platform	A solution that is both configurable and customizable to meet the needs of virtual and hybrid clinical trial study design, setup, and execution
eConsent & eScreening	The framework ensures enrollment & onboarding on ObvioHealth's major applications with multi-factor identification verification and live chat with the virtual team
Randomization & Trial Supply Management (RTSM)	The framework ensures that the RTSM process is conducted smoothly
ePRO & eCOA	The framework utilizes images, audio, video capture, unstructured and continuous data, bio-sensors and wearables, and digital instruments to integrate them with medical devices
EDC	An internally built proprietary EDC system to capture data throughout the clinical trial
Logistics management	Framework developed to ensure logistical management of home shipments, return of supplies, devices, and global participant payments
Reporting & data visualization	The solution ensures data cleansing & aggregation, can create user customizable dashboard, and studies findings in real-time for sponsors

ObvioHealth | decentralized clinical trial products profile (page 5 of 6)

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
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Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

ObvioHealth | decentralized clinical trial products profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
DIA/ISPOR	Annual meetings	During its annual meetings, ObvioHealth submitted and had five separate abstracts accepted
DPHARM	Annual meetings	ObvioHealth was a finalist in DPHARM idol for next-generation ePRO/eCOA utilizing imaging, video, and audio
Dedalus Group	Business partnership	ObvioHealth entered into a partnership with Dedalus Group to unite real world and clinical trial data. ObvioHealth is bringing clinical trial data fully into the continuum of care through a new strategic partnership with Dedalus Group, the leading healthcare and diagnostic software solutions provider in Europe. The partnership will unite ObvioHealth's proprietary decentralized clinical trial tools with Dedalus's software solutions, connecting the dots between clinical research and Electronic Health Record (EHR) data, while supporting healthcare providers from 6,000+ hospitals and clinics across the world to deliver care to more than 330 million patients
BioIntelliSense, AliveCor, and iHealth	Business partnerships	Entered into a partnership agreement with BioIntelliSense, AliveCor, and iHealth, which allows healthcare providers and trial investigators to monitor up to 20 different clinical-grade vital signs including heart rate, respiratory rate, temperature, blood pressure, oxygen saturation, ECG, coughing episodes, sweat, sleep, activity levels, and body positioning, while ensuring that the patients never have to step into a clinic
Novotech	Business partnership	ObvioHealth, a virtual research organization, and Novotech, the largest Asia Pacific biotech specialist CRO, announced a new strategic partnership to bring innovative decentralized clinical trial capabilities to Asia. This collaboration means ObvioHealth will become Novotech's primary provider for virtual clinical trials in APAC. In return, Novotech will become ObvioHealth's preferred CRO in the region for hybrid and virtual trials. The Asia Pacific region is known globally for its medical research excellence, strong clinical research regulatory support from the government, and access to large diverse patient populations

Signant Health | decentralized clinical trial products profile (page 1 of 5)

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 Health, through the acquisition of VirTrial, is able to serve a broad ecosystem of sites, CROs, and sponsors. The acquisition also augments its existing ePRO capabilities with VirTrial's DCT capabilities in eConsent and televisits
- The company is able to offer clients auxiliary support services such as patient concierge. In addition to this, it provides consulting services to enable decentralization of trials
- Signant Health's televisit capabilities are superior to its peers
- It has created content to help clients navigate across challenges with conducting DCTs in various therapeutic areas such as CNS and dermatology

Limitations

- Signant Health does not have an end-to-end platform for DCTs but rather point solutions which can be deployed on client environment
- The company does not have capabilities to track patient medication adherence via weekly reminders or notifications to patients
- There are limited investments in advanced analytics use cases or patient-centered design

Signant Health | decentralized clinical trial products profile (page 2 of 5)

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

Signant Health's vision is to enhance current research studies by replacing 25-40% of the visits with virtual video visits. The company wants to help sites maximize resources and get faster results for all their clients. Its mission is to ensure that sites have the modern technology and tools they need to advance clinical research, while the industry shifts toward more virtual visits and trial designs.

Therapy area coverage

Signant Health's decentralized clinical trial products cater to multiple therapy areas including neurology, dermatology, oncology, musculoskeletal, and vaccine and virology.

Overview of the client base

Through its acquisition of VirTrial, Signant Health serves pharma and medical device companies in their DCTs. There are no publicly listed clients available.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography[1]

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size[1]

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Televisits
eCOA/ePRO	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)

1 Analyst estimates
Note: The analysis includes DCT capabilities through Signant Health's acquisition of VirTrial

Signant Health | decentralized clinical trial products profile (page 3 of 5)

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)	
Solution	**Details**
SmartSignals eConsent	A PDF-based, clinical trial consent solution offering rapid implementation and a flexible, scalable, and lightweight design. The product helps trial teams quickly set up e-consenting functionality and enables study sites to greatly reduce the effort to route and manage documents for signature
Virtual pre-site	The solution enables pharmaceutical sponsors and CROs to evaluate, qualify, and routinely monitor research sites for studies without physical travel. Virtual pre-site includes delivery of HD live-streaming glasses that enable an on-site Clinical Research Coordinator (CRC) to provide a remote Clinical Research Associate (CRA) access to all aspects of the site virtually

Signant Health | decentralized clinical trial products profile (page 4 of 5)

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence[1]	eCOA/ePRO features	Televisits[1]	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

1 Available through VirTrial

Signant Health | decentralized clinical trial products profile (page 5 of 5)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)

Event/company name	Type of event	Details
uMotif	Partnership	Partnered with uMotif, a patient-centric data capture platform provider, to combine DCT technologies in one seamlessly integrated solution. Signant Health's telemedicine platform provides compliant video consultation capabilities to effortlessly connect site and patient. The uMotif platform's patient-friendly design empowers participants to submit large volumes of high-quality eCOA/ePRO data via BYOD or provisioned devices. Combining these two proven solutions enables sponsors and CROs to offer patients an easy and potentially fully remote trial experience
Signant Health	Acquisition	Signant Health, one of the leading enablers of evidence generation for modern clinical trials, acquired VirTrial. By adding the capabilities of VirTrial, Signant Health plans to expand its software stack to further digitally enhance trial sites and offer sponsors superior evidence generation across traditional, decentralized, and hybrid trial models
BlueCloud by HealthCarePoint	Partnership	Entered into a global collaboration with BlueCloud by HealthCarePoint (HCP) that enables international investigator sites to become VirTrial technology competent and also become ready for the benefit of sponsors, CROs, universities, regulatory agencies, and other industry stakeholders
SnapMD	Acquisition	Acquired SnapMD, a provider of telemedicine tools and services that improve patient engagement. The acquisition bolsters VirTrial's capabilities with access to SnapMD's telemedicine platform and technical expertise. In addition, the acquisition enables integration of additional features and capabilities into VirTrial's Virtual Care Management (VCM) platform

03

Enterprise sourcing considerations

- Aspirants
  - Accenture
  - Delve Health
  - Jeeva Informatics

Accenture | decentralized clinical trial products 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

- Accenture's consulting expertise enables it to counsel clients to decentralize clinical trials; it offers consulting expertise around a wide range of areas such as protocol design and business casing for DCTs
- Its system integrators capabilities allows it to implement vendor solutions for DCTs, custom build capabilities for clients' DCT requirements, and offer data expertise and integrations to enable smooth communication between DCT and traditional clinical technology products
- As the products are part of the overall INTIENT platform, Accenture DCT products offer clients good data management capabilities, the ability to integrate with EMR and device data, and a good overview of clinical data insights

Limitations

- Accenture's INTIENT solution does not support televisit capabilities for conducting DCTs. It has recently released their eConsent and eCOA capabilities (in April 2021) that indicates limited success stories for these products
- Clients state that Accenture tends to focus heavily on the technology stack during deal solutioning. Clients desire a more business-oriented focus in such deals through effective business casing of the existing technology use cases
- Accenture's DCT products do not have advanced analytics use cases or the innovation that peers are driving in the space; its focus is that of a system integrator or custom solution provider, rather than a DCT product vendor

Accenture | decentralized clinical trial products profile (page 2 of 6)

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

As technology has advanced and decentralized, trial capability has matured; Accenture sees multiple advantages of decentralized trials for sponsor organizations such as creating more diverse cohorts by expanding the reach of the trial, the ability to increase patient engagement during a trial to reduce drop-out and increase adherence, and the capability to collect higher fidelity data in near real-time.

Therapy area coverage

Accenture's decentralized clinical trial products cater to various therapy areas such as vaccine and virology and infectious diseases.

Overview of the client base

Accenture has developed a revolutionary technology platform called INTIENT in partnership with Google Cloud, which consists of 400+ engineers, designers, and testers. The solution was deployed to a large biopharma company in 2015. INTIENT was also deployed to a large pharmaceutical company in 2018.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography[1]

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size[1]

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Medication adherence
eCOA/ePRO	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)

1 Analyst estimates

Accenture | decentralized clinical trial products profile (page 3 of 6)

Case studies

NOT EXHAUSTIVE

Case study 1	A large biopharma company required Multiple Sclerosis Partners Advancing Technology And Health Solutions (MS PATHS)

Business challenge

To improve Multiple Sclerosis outcomes through standardized real-world data collection, aggregation, and insight generation by leveraging digital devices, cloud-based data aggregation, and EMR integration to enable the creation of a longitudinal data repository of deeply phenotype patients to inform clinical research and treatment pathway optimization.

Solution and impact

Accenture teamed with the biopharma company to develop a cloud-based, data-driven digital health solution that included a Multiple Sclerosis Performance Test (MSPT) medical app/device used to assess patient vision, mental processing, and dexterity as well as collect demographic, health, and medical information. The solution is built on the Accenture INTIENT Platform, which manages consent, data acquisition, enterprise master patient index, data tracing, transformation, staging, and analytics.

The impact of the solution resulted in development of clinical guidance, evidence-based standards of care, and personalized medicine for the approved utilization of the world's largest aggregated, de-identified data set by researchers from the world's leading MS research institutions including the Cleveland Clinic, NYU, and Johns Hopkins University.

Case study 2	A large pharmaceutical company required decentralized trial digital health platform pilot

Business challenge

To assess how to operationalize the use of medical devices and remote monitoring in a clinical trial ensuring that the data is accurate and patients are adhering. Additionally, to combine the real-time device data collection with clinical data directly from an EMR to better identify patients for clinical trials earlier in their disease progression.

Solution and impact

Accenture teamed with the large pharmaceutical company to develop a platform solution that collected patient information and automated the device registration and set-up process. The platform then collected real-time data on registered devices to monitor patients and curated a persistent HL7 repository, which allowed the linkage across data sets more easily.

The platform solution streamlines the logistics of getting devices to patients and setting up those devices. When adding digital tools to healthcare, consider the patient and site experience to help drive adherence and be thoughtful on how best to scale support for patients using digital technologies. This platform can also be applied to devices deployed in a clinical setting outside of a trial.

Accenture | decentralized clinical trial products profile (page 4 of 6)

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)

Solution	Details
INTIENT platform	The INTIENT platform is designed to support the full scope of an enterprise digital clinical study needs. The various components of the platform are: • Patient identification application: A tool for sites to easily identify patients that are eligible for studies. It is a service to generate unique hash-key based on a client secret using a master patient index, which helps identify patient's data across sources in de-identified domain for a complete patient 360-degree view in driving insights – Search for programs and studies – Integrate with EHR/EMR system – Identify patients that match a program or study criteria – Review match criteria for each individual patient – Define status of patient (qualified, excluded, etc.) • Clinical Research Engagement Application: To coordinate the enrollment experience, including device registration and data collection. The application provides the ability for sites (PIs and coordinators) to onboard, manage, and monitor patients in a study. It provides ability for the sites to better assess the status of the study and monitor their enrollment, protocol adherence, device connectivity, and device readings for timely intervention. It also provides timely notifications in helping manage efficacy of the study – Manage and track enrollment of patients to a study across sites – Configure and provision devices natively through the portal • Data Fabric Framework: To aggregate patient data via various channels. It enables ingestion, storage, and processing of data from incoming streaming and batch health data sources with standardized interfaces. Also enables a consistent standard for data processing, validation, profiling, catalog, lineage, error handling, and archival mechanisms – EMR – Labs – Devices – ePRO • Clinical Operations Application: For a real-time view and support of the study portfolio. It allows sponsors to view an administrative view of the trial. Helps coordinate to improve efficacy by serving live data and insights to coordinate across sites and sponsors – Able to monitor connectivity and data across all sites – Create, update, and publish reports for collaborative management of active trials – Gain insight into aggerated, de-identified study metrics such as enrollment, connected devices, and ePRO in real-time – Track adherence to protocol and intervene before it is too late – Leverage insights to uncover ways to promote an even better patient experience

Accenture | decentralized clinical trial products profile (page 5 of 6)

Features of key offerings

NOT EXHAUSTIVE

Available | Available via third-party integration | Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

Accenture | decentralized clinical trial products profile (page 6 of 6)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)		
Event/company name	**Type of event**	**Details**
Google cloud	Partnership	Accenture partnered with Google cloud to develop a platform called INTIENT. The platform helps both the companies in supporting over 25 global pharma leaders

Delve Health | decentralized clinical trial products 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

- Delve Health has partnerships in home nursing and patient screening to provide auxiliary support services to clients
- Its ePRO solutions have capabilities to measure ePerfO, eClinRO, and eObsRO

Limitations

- Delve Health has limited capabilities for medication adherence and does not have adequate capabilities for remote patient monitoring via wearable integration. Some capabilities such as eConsent and virtual visit solutions have been recently released in 2020
- Apart from Apple Watch, Delve Health products have limited capabilities to integrate with other wearables for capturing sensor data
- Delve Health has limited consultative capabilities and thought leadership to help clients decentralize their clinical trials

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

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

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.

Therapy area coverage

Delve Health's decentralized clinical trial products cater to therapy areas including sleep, infectious diseases, oncology, ophthalmology, and cardiovascular.

Overview of the client base

Delve Health has managed, designed, and executed over 100 studies across multiple disease states. The company joined xCures and Cancer Commons to support the Beat19 data initiative to conquer COVID-19.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography[1]

Asia Pacific	Europe (excluding UK)	Middle East & Africa
North America	South America	United Kingdom

Decentralized clinical trial products revenue split by buyer size[1]

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
Large (annual revenue = US$5-10 billion)	Very large (annual revenue > US$10 billion)

Decentralized clinical product offerings

eConsent	Televisits
eCOA/ePRO	Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)

1 Analyst estimates

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

Case studies

NOT EXHAUSTIVE

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 their 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.

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 the blood pressure monitor and managed the activation of blood pressure monitors across the US and EU, and utilized ePRO to collect patient-reported outcomes via cell phones. Patients received SMS or WhatsApp for ePRO notification based on their geographical regions. Delve Health collected data from the blood pressure monitor.

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

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

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)

Solution	Details
Clinical StudyPal	A cloud application to manage decentralized clinical trials, allowing sponsors and CROs to continue their clinical trials in hybrid and virtual modes. The solution follows the clinical patient from recruitment through pre-screening, consent, and randomization; and then once in the study, the system has a patient communication portal with secure messaging to provide patients with up-to-date study information and allow them to communicate with their doctors. The application also has televisit technology to allow live video interaction with investigators and other site personnel to discuss their consent or conduct a virtual visit. It also automates drug supply tracking and provides complete patient progress and status visibility across study partners
Perta	A cloud-based end-to-end platform, helping researchers and scientists visualize scientific and biomedical information. It links publications, clinical trials, public biomedical information, and internal private data sources to provide more robust evidence-based research
In-home nurses	To help improve patient retention, lower patient risk, and make it easier for patients to be part of clinical trials, this solution has been developed by Delve Health. An experienced team helps to identify the right level of in-home services, and whether a nurse or phlebotomist is needed based on the protocol design. The company partners in-home nurses with Clinical StudyPal to provide full transparency of the data collected at that visit and ensure data compliance throughout the trial

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

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
Available to download on patient phone; Android/iOS support	Weekly reminders	Question builder and analytics tools	Text, email, and appointment scheduling features	Data authentication and accuracy features
Reconsent capabilities	Facial recognition	Visualization functionality	Screening tools	Data management capabilities
Multimedia support (audio, video, etc.)	Sensor integration	Available to download on patient phone; Android/iOS support	Available to download on patient phone; Android/iOS support	Integration with multiple wearables such as phone and glucometers
Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

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

Recent developments

NOT EXHAUSTIVE

Key events (representative list)		
Event/company name	**Type of event**	**Details**
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

Jeeva | decentralized clinical trial products profile (page 1 of 5)

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

- Clients state that Jeeva Informatics is willing to customize its solutions as per their requirements. Their experience while using the products is that the suite is less complicated, easy to use, and the webpages are less congested versus the other peers
- Clients appreciate Jeeva Informatics' quick support services and continued support even post business hours; their issues are resolved almost immediately

Limitations

- Jeeva Informatics' suite of products are still undergoing pilots with academic research organizations and hence, there is limited patient and user feedback from sponsors and sites
- Jeeva Informatics currently has no capabilities for televisits and medication adherence
- There are limited partnerships to offer a holistic portfolio of products and services; currently Jeeva has positioned itself as a self-service offering for running DCTs

Jeeva | decentralized clinical trial products profile (page 2 of 5)

Overview

NOT EXHAUSTIVE

Company mission/vision statement for decentralized clinical trial products

Jeeva eClinical Cloud helps clinical researchers, CROs, and biopharmaceutical sponsors accelerate remote patient enrollment significantly faster compared with traditional methods. 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. Modular software design allows 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.

Therapy area coverage

Jeeva's flexible decentralized clinical trial products are disease-agnostic and cover various therapy areas such as chronic diseases, neurology, genetic or rare diseases, and psychiatric diseases.

Overview of the client base

Jeeva's suite of products is currently being used by leading academic research organizations.

High (>25%) Medium (10-25%) Low (<10%)

Decentralized clinical trial products revenue split by geography[1]

Asia Pacific	Europe (excluding UK)	Middle East & Africa
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Decentralized clinical trial products revenue split by buyer size[1]

Small (annual revenue < US$1 billion)	Medium (annual revenue = US$1-5 billion)
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Decentralized clinical product offerings

- eConsent
- eCOA/ePRO
- Remote patient monitoring and integration with wearable technology and Bring Your Own Device (BYOD)

1 Analyst estimates

Jeeva | decentralized clinical trial products profile (page 3 of 5)

Offerings

NOT EXHAUSTIVE

Proprietary digital solutions (representative list)	
Solution	**Details**
Jeeva eClinical Cloud SaaS	Comprehensive set of modules and features supported by Jeeva. Customer can pick all or some 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.
Jeeva TRIALMAGNET	It enables rapid patient enrollment from numerous channels. Its features include remote screening, form builder, eConsent, reconsent, bi-directional communication, recorded video, reminders, and multi-site studies with centralized monitoring dashboards
Jeeva compliant remote electronic informed consent (eIC)	It has features such as pre-screening, remote eConsent, patient reported outcomes, drag-and-drop workflow builder, Bring Your Own 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 | decentralized clinical trial products profile (page 4 of 5)

Features of key offerings

NOT EXHAUSTIVE

Available Not available





eConsent features	Medication adherence	eCOA/ePRO features	Televisits	Remote patient monitoring and integration with wearables/BYOD
Multi-lingual eConsent	Available to download on patient phone; Android/iOS support	ePRO functionality	EHR-/EMR-agnostic	Overview dashboards and analytics capabilities
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Dedicated dashboards and visualization tools		ePerfO, eClinRO, and eObsRO capabilities	Usage analytics	

Jeeva | decentralized clinical trial products profile (page 5 of 5)

Recent developments

NOT EXHAUSTIVE

Key events (representative list)		
Event/company name	**Type of event**	**Details**
KiwiTech LLC	Partnership	Partnered with KiwiTech for product development and access to its investors / start-ups ecosystem
AWS	Partnership	Partnered with AWS for infrastructure, microservices, technology stack, and elastic cloud services

04

Appendix

Glossary

Glossary of key terms used in this report

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

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With you on the journey

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Dallas (Headquarters)
info@everestgrp.com
+1-214-451-3000

Bangalore
india@everestgrp.com
+91-80-61463500

Delhi
india@everestgrp.com
+91-124-496-1000

London
unitedkingdom@everestgrp.com
+44-207-129-1318

Toronto
canada@everestgrp.com
+1-647-557-3475