Everest Group®

Clinical Development Platforms Product Provider Compendium 2022

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Contents

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Introduction and overview

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- Key information on the report
- Background of the report
- 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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Robust definitions and frameworks

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

02

Primary sources of information

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

03

Diverse set of market touchpoints

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

04

Fact-based research

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

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

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

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

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

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

This report is based on two 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 the scope of work (updated annually)
- The database tracks the following elements of each contract:
  - Buyer details including size and signing region
  - Contract details including provider, contract type, TCV & ACV, provider FTEs, start & end dates, duration, and delivery locations
  - Scope details including share of individual buyer locations being served in each contract, Line of Business (LoB) served, and pricing model employed

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

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

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

Product vendors assessed[1,2]

accenture, anju LIFE SCIENCES SOFTWARE, ArisGlobal We Bring the Future to Life, CALYX, CLARIO., DATATRAK Enterprise Cloud, CliniOps, cognizant, ennov, flatiron, generis, IQVIA, labcorp Drug Development, MEDIDATA, MEDnet, merative, NAVITAS LIFE SCIENCES, ORACLE, SAP, SIGNANT HEALTH, tcs TATA CONSULTANCY SERVICES, Veeva

1 Assessments for Calyx, CliniOps, Datatrak, Generis, Ennov, Labcorp Drug Development, Merative, Navitas Life Sciences, Signant Health, and Veeva Systems 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 clinical development platform product buyers

2 Analysis for Flatiron Health is based on capabilities of Protocol First before both the companies combined, analysis for Clario is based on capabilities after the merger between Bioclinica and ERT to form Clario, analysis for Merative is based on IBM's clinical development capabilities, before Merative became a new standalone company

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

Clinical development platforms continue to evolve with technological advancements and scientific breakthroughs. However, the recent pandemic has had a tremendous impact on how clinical trials are designed and conducted, catalyzing the adoption of digital technologies, products, data science, analytics, and automation tools, enabling remote services, and preserving the continuity of care. Nevertheless, data silos, complex clinical trial technology landscape, traditional methods of data analysis, concerns with data privacy and security, and regulatory complications hinder efforts to accelerate the trials and enhance the experience for patients, sites, and physicians.

A unified clinical development platform with improved data architecture and analytics capabilities aims to accelerate the drug development process and enrich the experience for sponsors, patients, and physicians. Interestingly, the industry has gone from questioning the existence of an end-to-end platform to creating a near-term vision for adopting such platforms. There is an increase in willingness among sponsors to shift from a traditional best-of-breed landscape to a simplified best-of-breed approach. Everest Group's Clinical Development Platforms Products PEAK Matrix® Assessment 2022 looks at the current vendor landscape and platforms and presents in-depth analysis and insights into such platforms.

In this report, we assess the capabilities of 22 clinical development platform vendors. 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 clinical trial platforms and products
- Assessment of the vendors on several capability and market success-related dimensions

Scope of this report

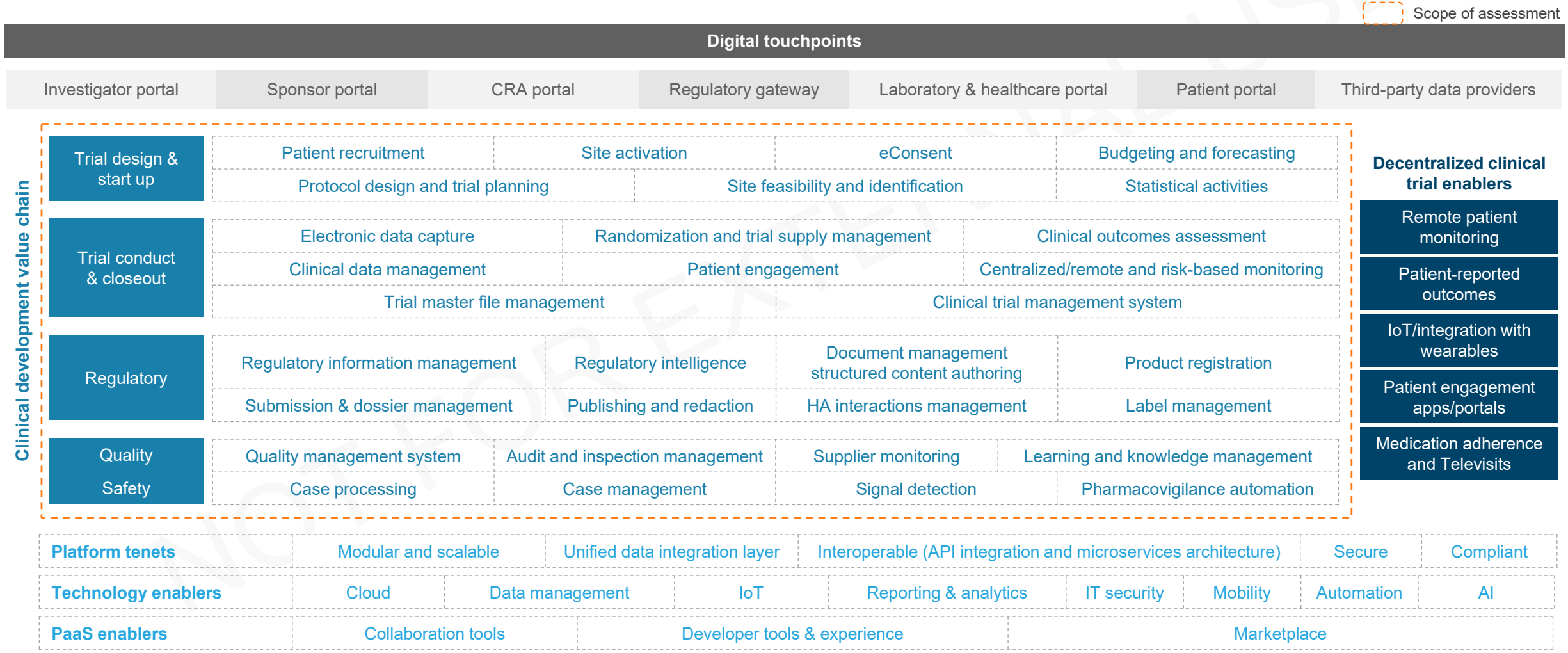
Geography
Global

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

Vendor offering
Clinical development platforms

Focus of the research

In this report, Everest Group focuses on the entire spectrum of the clinical development value chain



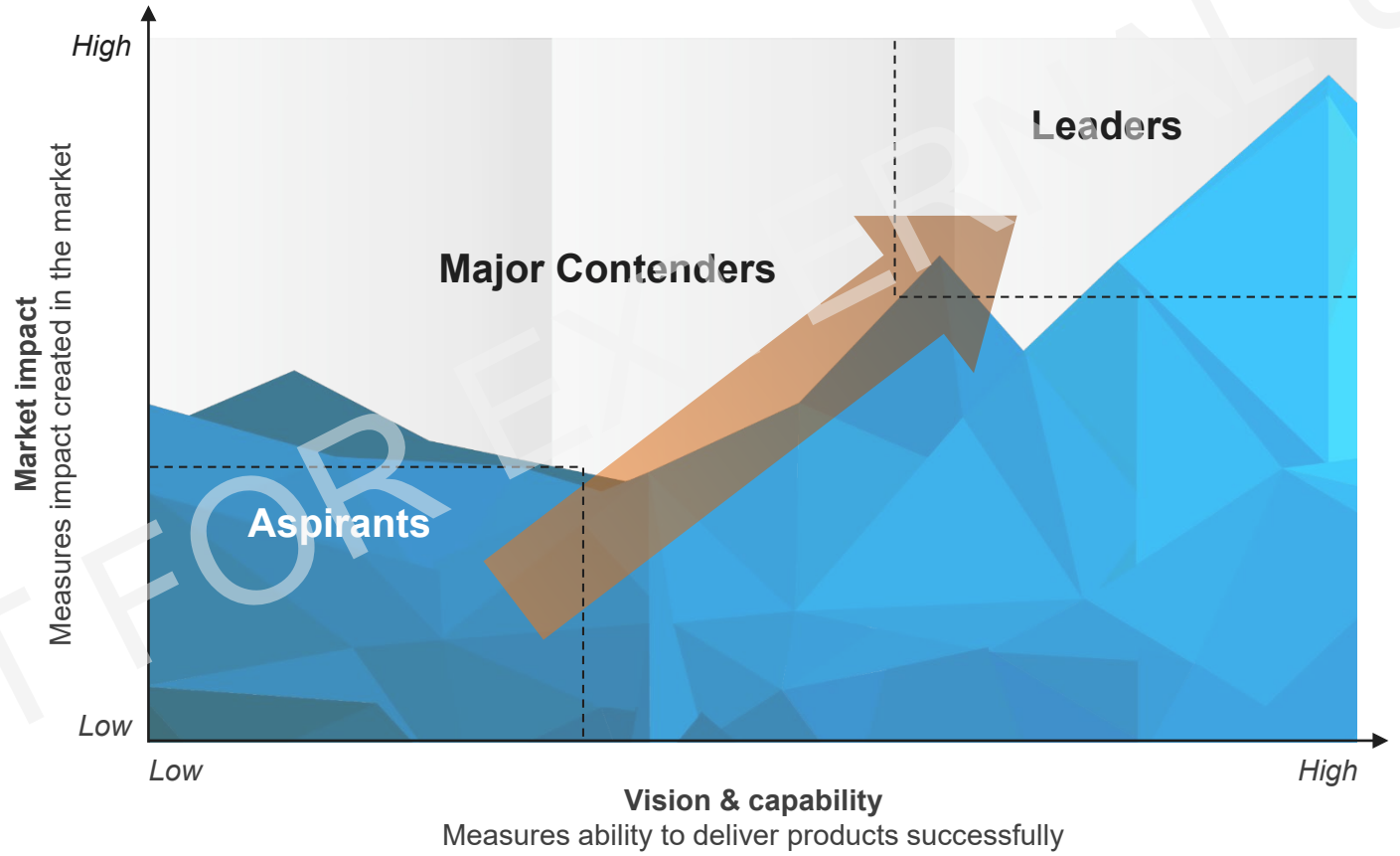
02

Clinical development platforms products PEAK Matrix® characteristics

- PEAK Matrix framework
- Everest Group PEAK Matrix for clinical development platforms
- 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

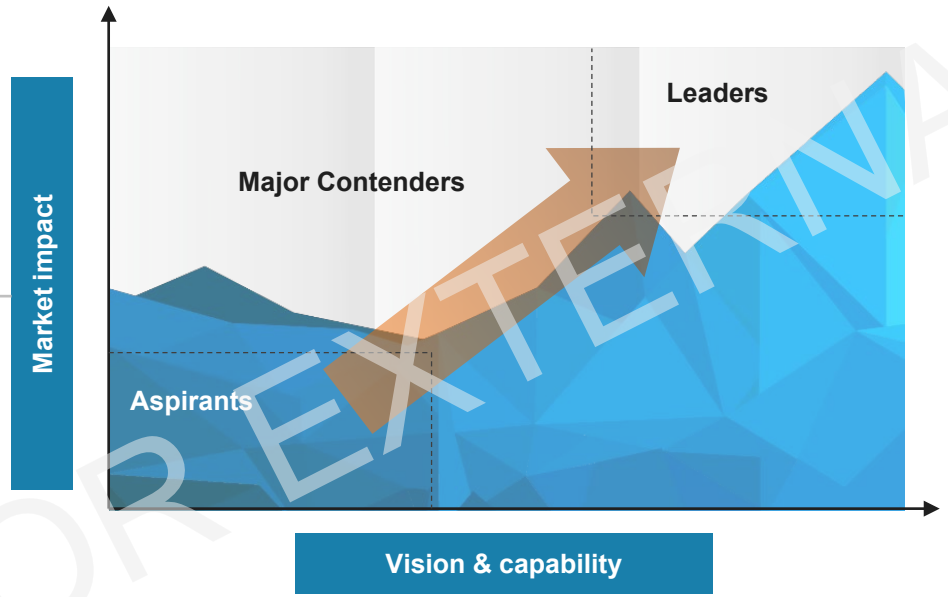
Number of clients, revenue base, and YoY growth

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



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

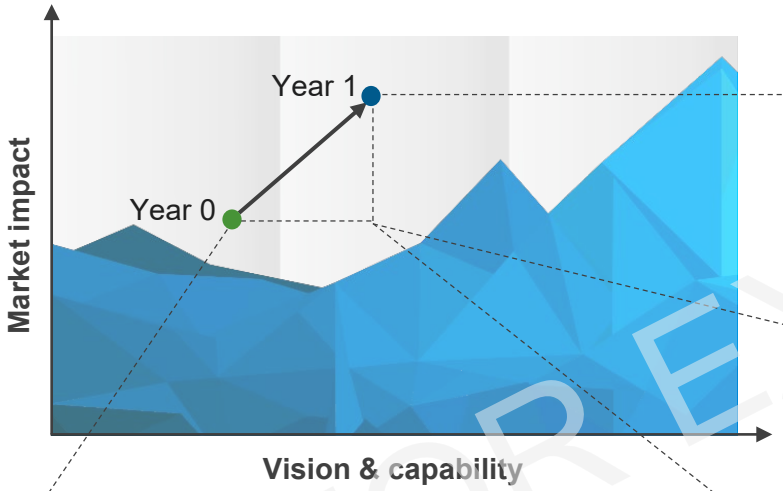
Support

Training, consulting, maintenance, and other support services

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

Methodology

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



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

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

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

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

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

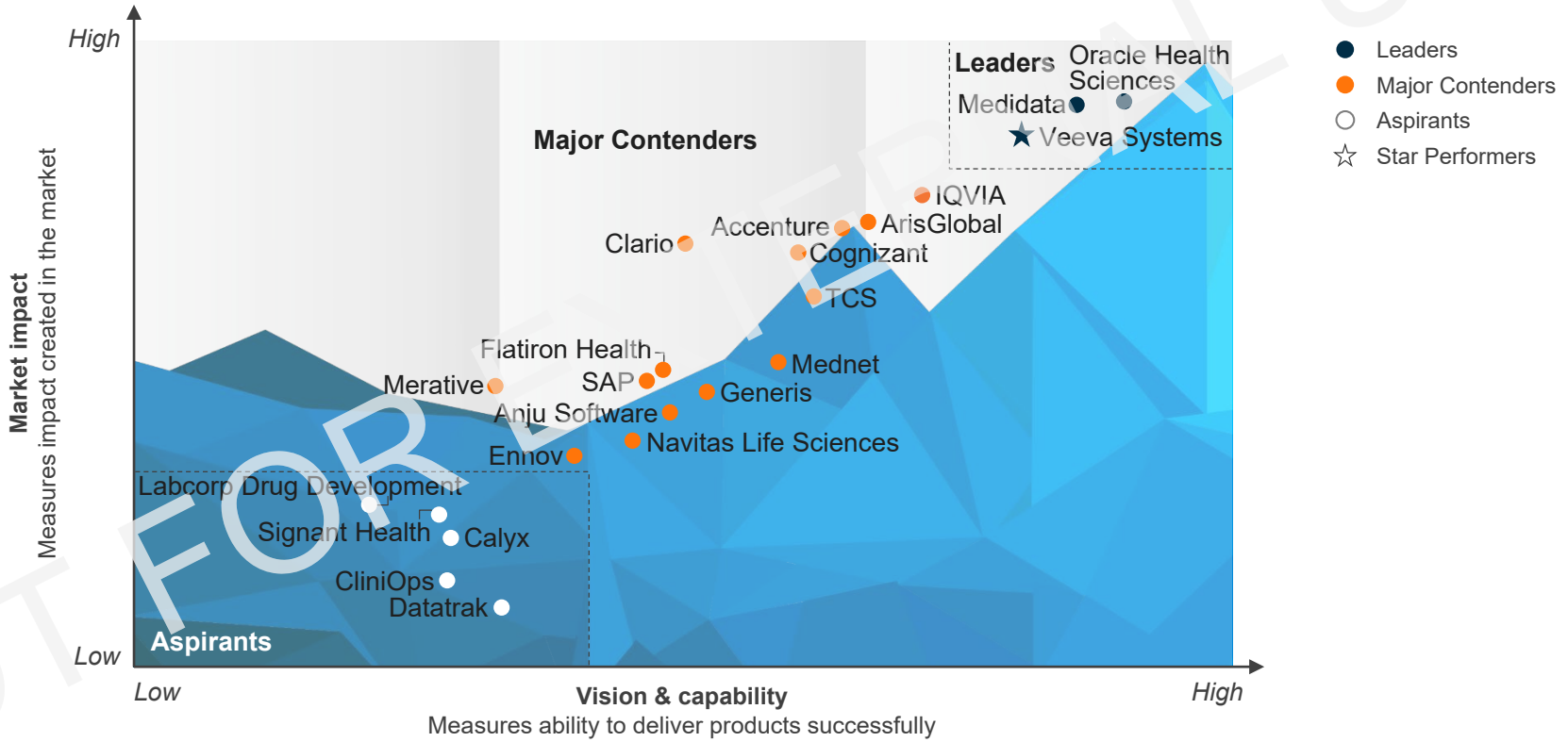
- The maximum number of top-quartile performance improvements across all of the above parameters AND
- At least one area of top-quartile improvement performance in both market success and capability advancement

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

Everest Group PEAK Matrix®

Clinical Development Platforms Products PEAK Matrix® Assessment 2022

Everest Group Clinical Development Platforms Products PEAK Matrix® Assessment 2022[1,2]



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Source: Everest Group (2022)

Summary dashboard | market impact and vision & capability assessment of providers for clinical development platforms 2022

Leaders

Measure of capability: Low High

	Market impact				Vision & capability					
Vendors	Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
Medidata	●	◔	◔	◔	◔	◔	◔	◔	◔	◔
Oracle Health Sciences	◔	●	◔	◔	●	●	◔	◔	◔	●
Veeva Systems	●	◔	◕	◔	◔	●	◔	◔	◔	◔

Summary dashboard | market impact and vision & capability assessment of providers for clinical development platforms 2022

Major Contenders (page 1 of 2)

Measure of capability: Low High

Vendors	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										
Anju Software										
ArisGlobal										
Clario										
Cognizant										
Ennov										
Flatiron Health										

Summary dashboard | market impact and vision & capability assessment of providers for clinical development platforms 2022

Major Contenders (page 2 of 2)

Measure of capability: Low High

Vendors	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
Generis										
IQVIA										
Mednet										
Merative										
Navitas Life Sciences										
SAP										
TCS										

Summary dashboard | market impact and vision & capability assessment of providers for clinical development platforms 2022

Aspirants

Measure of capability: Low High

	Market impact				Vision & capability					
Vendors	Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support	Overall
Calyx										
CliniOps										
Datatrak										
Labcorp Drug Development										
Signant Health										

Clinical development platforms products PEAK Matrix® characteristics

Leaders:

Medidata, Oracle Health Sciences, and Veeva Systems

- Leaders enjoy the highest brand recall among biopharma enterprises when it comes to the idea of a unified end-to-end clinical development platform
- Majority of the sites and personnel involved in clinical trials are well-versed with the products and solutions from these players
- These players have established a wide partnership network with System Integrators (SI) and CROs, enabling them to broaden their offerings and increase enterprise mindshare
- Continued investments in the next-generation technologies, such as Artificial Intelligence (AI), Machine Learning (ML), and Natural Language Processing (NLP), allow these players to bring in intelligent automation, exploit the power of data, and accelerate the drug development process

Major Contenders:

Accenture, Anju Software, ArisGlobal, Clario, Cognizant, Ennov, Flatiron Health, Generis, IQVIA, Mednet, Merative, Navitas Life Sciences, SAP, and TCS

- Major Contenders have an integrated approach in certain areas of the value chain, offering best-in-class solutions in that segment, for example, Generis (end-to-end regulatory information management) and ArisGlobal (safety solutions)
- Some of these players are trying to increase the enterprise mindshare and enter the leaders' market through their state-of-the-art and digitally-mature offerings
- The CRO heritage of some players enables them to offer Business Process as a Service (BPaaS) solutions to their clients; however, it also raises skepticism around their abilities as technology vendors
- Some of the Major Contenders use their partner network for implementation and customization services, while a significant proportion of these players rely heavily on their internal team for these services

Aspirants:

Calyx, CliniOps, Datatrak, Labcorp Drug Development, and Signant Health

- These vendors offer point solutions in specific segments of the value chain
- These players are limited by their scale and niche offerings; hence, they partner with SIs and CROs to scale and enhance their geographic presence

Everest Group has identified one product vendor as the 2022 Star Performer

Clinical development platforms Star Performer	Distinguishing features of market impact in 2022	Distinguishing features of capability advancements in 2022	Change in PEAK Matrix® positioning for clinical platforms
Veeva	• Growth in Vault Clinical Trial Management System (CTMS) adoption – Veeva Systems announced in May 2022 that more than 150 global enterprises and fast-growing companies are advancing clinical trial operations with Veeva Vault CTMS. Sponsors and CROs are using Vault to manage over 300,000 research sites and support more than 1 million patients • Announced that biotechs and top 20 pharmaceutical companies are enriching employee learning with Vault Training • Fortune Magazine ranked Veeva Systems as one of its fastest-growing companies for the fifth year	• Focus and vision toward building a unified clinical development platform • Veeva Systems has been able to disrupt the regulatory landscape and is gaining good enterprise mindshare in the quality and clinical operations segment as well • With three product releases every year, Veeva Systems is modernizing key trial operations that can accelerate studies. Some of the new features of Vault CTMS include – – Risk-based study management – Site monitoring enhancements – Study oversight features to manage protocol deviations	**Entered the Leaders category**

Source: Everest Group (2022)

03

Enterprise sourcing considerations

- Leaders
  - Medidata
  - Oracle Health Sciences
  - Veeva Systems

Medidata | clinical development platforms profile (page 1 of 9)

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

- Medidata has good end-to-end capabilities, with offering solutions covering the trial design, start up, and conduct segments of the value chain
- Clients cite that Medidata has an established reputation and sites are well-versed with its products and solutions, increasing the flexibility and ease of use for its solutions
- It showcases strong analytics and reporting capabilities through Acorn AI, working with top pharma clients on AI and ML techniques to drive a range of use cases using historic clinical trial data and real-world data
- It leverages its past experiences to educate client teams on domain knowledge, study build, and trial execution processes
- It has a wide partnership network with SIs, CROs, and academia with focused investments on next-gen technologies like AI, ML, and NLP

Limitations

- Clients state that Medidata's price points are higher than the existing solutions and that the contract negotiation process is complicated and time-consuming
- Clients often face challenges when it comes to integration with existing legacy systems or other third-party platforms
- It should look to accelerate migrations from EDC and customizations on the CTMS solutions, avoiding unexpected delays
- It needs to work on the user interface (UI) of its solution, making it simple, user-intuitive, and ensuring easy navigation
- Clients cite that the platform does not have sufficient standard reports and AI-based dynamic search across fields

Medidata | clinical development platforms profile (page 2 of 9)

Overview

Company mission/vision statement for clinical development platforms

Medidata's vision is to be an end-to-end platform for clinical development in order to bring therapies to market faster and at lower cost. Their mission is to power smarter treatments and healthier people. Medidata's strategy is to remain focused on three key pillars:

- Accelerating, transforming, and modernizing the clinical trials process
- Utilizing an analytics-first approach that turns data into insights
- Ensuring that the patients are fully able to access and actively engage in their own healthcare and clinical trials

Overview of the client base

- Medidata's customers include global pharmaceutical companies, innovative biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations
- Previous year, Medidata was involved in the release of two-thirds of all new drugs. The top 20 pharma and biotech companies are customers, and nearly all the top 10 CROs are partners

Clinical trial platforms revenue (excluding services)[2]

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1]

Low (<10%) | Medium (10-35%) | High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1,2]

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

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

Revenue by value chain element[1,2]

Low (<10%) | Medium (10-20%) | High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

Medidata | clinical development platforms profile (page 3 of 9)

Case studies

Case study 1	Enabled Medidata Rave Electronic Data Capture (EDC) for the treatment of orphan diseases

Business challenge

PhaseBio, a clinical-stage biopharmaceutical company developing biotherapeutics for the treatment of orphan diseases, was challenged by a rare disease or condition affecting less than 200,000 persons in the US. Despite the smaller pools of affected patients, these drugs still required safety and efficacy regulatory approval.

Solution

Medidata enabled Medidata Rave EDC that helped PhaseBio to address current and future needs as they advanced and improved their therapies. Rave EDC's flexible architecture supported data management trial demands as PhaseBio advanced from one site to multi-site studies across the globe.

Impact

- Accelerated trial process
- Enabled data management and analysis

Case study 2	Automated clinical trial monitoring workflows to increase efficiency

Business challenge

Enterin's clinical monitoring team manually created reports, confirmation letters, and follow-up letters. To increase efficiency, Enterin wanted to automate the generation of letters and reports, automatically notify Clinical Research Associates (CRAs) and other stakeholders when site visits were due and make it easier to share data with senior leadership and site managers.

Solution

With Medidata Rave Clinical Trial Management System (CTMS), a cloud-based solution for end-to-end trial management, Enterin streamlined its clinical monitoring workflow. Medidata's Rave electronic Trial Master File (eTMF) was also used to create a single source of truth for all clinical trial documents.

Impact

- Time saved from automated report and letter generation
- Site visit reminders based on activities and site history
- Supported remote source data verification during the pandemic

Medidata | clinical development platforms profile (page 4 of 9)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Acorn AI platform	Analytics-as-a-Service solutions pushing innovations from clinical trial planning through launch as a collaborative partner using unparalleled clinical trial data, deep industry and human expertise, advanced analytics, and predictive modeling. Solutions include Synthetic Control Arm®, trial design, Medidata link, intelligent trials, and commercial data solutions
Clinical Data Capture & Management	Eliminates complex manual processes and delivers data for faster decision-making and real-time inspection readiness. The solutions drive critical reductions in study build time, query volume, data correction rates, and reporting turnaround time
Medidata Clinical Cloud®	The Medidata Clinical Cloud is a cloud-based unified platform dedicated to clinical research. All Medidata's clinical trial solutions are a part of the platform and are unified on the same underlying architecture. Once data is entered into the platform, it is available for all products, eliminating the need to manage integrations and reconcile data. At the same time, the platform is flexible enough to work with an enterprise's existing systems, processes, and partners, and can scale from individual studies through large global programs.
Patient Cloud	Suite of powerful patient-facing solutions that make it simple and engaging for patients to participate in any clinical trial. Built into the Medidata Clinical Cloud platform, patient cloud solutions combine Medidata's leading clinical trial technology with unmatched patient-centricity by design
myMedidata	A single destination patient portal enabling patients to virtually enroll and participate in clinical trial activities. Built directly on Rave EDC, myMedidata extends all the capabilities of Medidata's patient-facing solutions for eCOA, eConsent, wearable and biosensors, live video visits, patient registries, and enablement of hybrid and virtual trials
Medidata eCOA	A full-service, flexible solution that easily and accurately captures outcomes data from patients, caregivers, and clinicians. Available as an iOS or Android app or web-based solution, Medidata eCOA provides a single-system deployment model for capturing patient data that can simplify your builds, accelerate study timelines, and lower costs
Medidata eConsent	Whether on-site or remote, Medidata eConsent automates the patient enrollment process and onboards patients directly into Rave EDC improving overall consent tracking management, reducing informed consent errors, and easing the administrative burden for sites and study teams. It also enhances the patient experience with easy-to-understand clinical trial information while improving participant compliance and boosting patient engagement
Sensor Cloud	Provides cutting-edge data ingestion capabilities focused on transforming the clinical trial experience for patients, sponsors, CROs, and research sites. Its common data model and proprietary algorithms enable rapid ingestion, normalization, and analysis of patient data resulting in better clinical decision-making, faster timelines, and a more patient-centric experience
Rave Coder	A cloud-based, centralized medical coding tool that unifies and streamlines coding and EDC business processes by simplifying dictionary upgrades and streamlining coding query management and code verbatims from external systems
Rave EDC	A Software-as-a-Service (SaaS) web-based solution with an intuitive user interface that facilitates the capture and cleaning of clinical trial data with robust and scalable functionality that operates on a true unified platform
Rave eTMF	A collaboration platform that sponsors, sites, and CROs can use to manage Trial Master File (TMF) content to actively maintain inspection readiness. It simplifies the filing and oversight of TMFs ensuring completeness and compliance through artifact pre-population, role-based workflows, and intuitive reporting and dashboards
Rave Imaging	Manages all aspects of a medical image-based clinical trial including image acquisition, de-identification, structured data collection, edit checks, image distribution, and the image review process

Medidata | clinical development platforms profile (page 5 of 9)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Rave Safety Gateway	An electronic process providing an online and secure solution that is more efficient and accurate than manual processes for reporting Serious Adverse Events (SAEs)
Rave RTSM	It has a single unified data store (Rave EDC), improves data quality, reduces risk, and provides the flexibility needed for mid-study changes. Rave RTSM provides cost benefits in reduced resource use, accelerated study start, and real-time mid-study change capabilities with edit live design
Rave CTMS	Clinical software that provides study teams with the ability to plan and manage all trials in a consistent and harmonized manner, standardizing activity planning and management at the study, country, and site level. Activities include study/site team creation and activation, patient enrollment, milestone tracking, site monitoring, and issue management
Medidata Risk Management	A digital solution to identify, document, score, prioritize, and monitor potential risks of a clinical trial, devise monitoring and mitigation strategies for those risks, and adjust as the trial progresses. The solution identifies and evaluates risks across critical processes, critical data, and Critical to Quality (CtQ) factors to ensure patient safety and data quality
Medidata Detect	Medidata Detect provides end-to-end data and risk surveillance and includes capabilities that aid planned risk monitoring, such as Key Risks Indicators (KRIs) and Quality Tolerance Limits (QTLs), centralized monitoring with embedded machine learning capabilities to identify unexpected, data anomalies and trends, targeted analyses to identify site performance, fraud and misconduct, as well as features to support robust data interrogation at the individual patient and at the aggregated level
Rave TSDV (Targeted SDV)	A digital solution that targets critical data to be checked during on-site monitoring and reduces the amount of Source Data Verification (SDV) conducted in a clinical study. This allows teams to take a risk-based approach to data monitoring, reducing effort without sacrificing regulatory compliance or data quality strategies
Medidata Remote Source Review	A cloud-based solution that rapidly and remotely enables monitors to acquire critical documents, automates document sharing workflows to the right monitor for the right study and site, and allows review of documents to support SDV and SDR
Rave Trial Assurance	A managed service, powered by Medidata Detect, that evaluates the integrity and quality of all clinical and lab data within a clinical trial inclusive of a comprehensive analysis, report, and presentation for results
Rave Clinical Trial Financial Management	A suite of applications that provides an end-to-end solution to clinical trial financial management to enable operational efficiencies and financial compliance, collaborative data-driven decision-making and greater transparency over financial planning and execution. The suite of applications includes clinical study design, study budget planning, and site payments processing and tracking
Medidata Adjudicate	A cloud-based clinical endpoint adjudication management solution that follows all clinical events from beginning to outcome. Designed to support investigator sites, sponsors, CROs, and the Clinical Endpoint Committee – who collect, manage, organize, adjudicate, and submit clinical endpoint data
Site Cloud: End of Study	An end-to-end solution that seamlessly generates, distributes, and manages sites' study files at the end of a study. Sites' study files are accessible and downloadable via a secure unified platform eliminating the need to create and distribute physical media and deal with paper acknowledgment forms
Medidata Decentralized Clinical Trials	Solutions to virtualize the entire clinical trial end-to-end including patient participation, data monitoring, and oversight activities as well as patient drug dispensation and supply management. The Medidata DCT Program provides flexible, composable capabilities that can be adjusted to optimize the level of in-person or virtual patient participation and study oversight that is right for any trial

Medidata | clinical development platforms profile (page 6 of 9)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring and source review	Direct-to-patient drug delivery	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Medidata | clinical development platforms profile (page 7 of 9)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	Study data tabulation model (SDTM) support	Real-world data (RWD) integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Identify critical data to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Inbuilt checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Document the conduct of risk review activities according to trial risk plan
Trial master file management	Plan expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	Informed consent form (ICF) distribution, tracking, and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Note: Have included only current capabilities

Medidata | clinical development platforms profile (page 8 of 9)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	Health authority (HA) interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Manage the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integrate data from different sources	

Medidata | clinical development platforms profile (page 9 of 9)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Circuit Clinical	Industry partnership	In 2022, partnered with Circuit Clinical to expand and strengthen Decentralized Clinical Trial (DCT) capabilities
AllStripes	Industry partnership	In 2021, partnered with AllStripes to connect patient-centric rare disease research with clinical study workflow and data solutions
Expansion of R&D resource capacity	Industry partnership	In 2020, partnered with 3DS India, established a dedicated captive offshore development center to accelerate and expand existing development capacity by 100%
MC10's Patient Sensor Technologies	Acquisition	In 2020, acquired MC10's Patient Sensor Technologies to extend Medidata's offerings around the integration of sensor data from multiple sensors becoming more and more popular in clinical research settings
Cognizant	Alliance	In 2019, partnered to develop new solutions for pharmaceuticals biotech, medical device company, contract research organizations, sites, and investigators
Acorn AI	Investment	In 2019 invested in innovation unit to drive platform AI and analytics
Dassault Systèmes	Acquisition	In 2019, merged with Dassault Systèmes, as a fully owned subsidiary. They merged a family of technologies that design and simulate therapies and medical devices, supporting creation, development, production, and treatment
SHYFT	Acquisition	In 2018, acquired SHYFT, and entered the post clinical market through commercial and real-world data analytics solutions

Oracle Health Sciences | clinical development platforms profile (page 1 of 8)

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

- Oracle's ClinicalOne has broad coverage across the clinical trial landscape and enjoys good enterprise mindshare
- Clients appreciate Oracle for the speed of its database build and almost zero downtime for new launches and customizations, causing no unnecessary interruptions or delays
- Certain products, such as Oracle Inform, are commended for the ease of use, quick navigations, and intuitive queries. Clients mention that users were able to use the platform without any prior training or technical knowledge
- Clients have stated that Oracle leverages its experience with large biopharma companies and brings in new perspectives and shares industry best practices in its subsequent implementations
- It made focused investments around new technologies such as ML and predictive analysis tools for trial oversight, control, and monitoring

Limitations

- Clients quote that customizations are often very tedious and time-consuming, going through a full validation cycle for every single change
- Some clients have stated that Oracle may tend to overpromise and under-deliver with respect to its reporting functionalities. It lacks advanced analytics capabilities and sometimes report formats are not compliant with the regional regulations
- While clients appreciate the speed of database built, they sometime face challenges due to system outages without prior notification or communication
- Clients face difficulties in integrating one product with another, especially Oracle products with other third-party solutions

Oracle Health Sciences | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Oracle Health Sciences' vision is to unify people, processes, and data to simplify and accelerate the clinical trials – digital, decentralized, patient-centric – for pharmaceutical, biopharma, and medical device companies, and CROs around the world. It delivers this through a comprehensive suite of integrated solutions and a new unified platform, Clinical One, which is built using over two decades of experience, to support the most complex trials in the simplest, most user-friendly way.

Overview of the client base

Oracle Health Sciences customers include 28 of the top 30 pharma companies, the top 10 biotech, and the top 10 CROs. In addition, Oracle Health Sciences solutions are used by countless emerging and midsize biopharma companies around the globe.

Clinical trial platforms revenue (excluding services)[2]

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1]

Low (<10%) Medium (10-35%) High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1]

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

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

Revenue by value chain element[1,2]

Low (<10%) Medium (10-20%) High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

Oracle Health Sciences | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1 | **Enable data integration with enhanced patient experience**

Business challenge

Bayer Pharmaceuticals wanted to expand the ability to collect data from multiple sources such as regulatory-approved wearables, patient apps, and sensors that would allow real-time data flow, while also improving the patient experience by making it less burdensome by employing remote monitoring and reducing physical site visits.

Solution

Oracle developed a platform integrator that supports data integration, data collection, data management, and advanced analytics.

Impact

- Modernized medical models and workflows
- Advanced data collection and aggregation

Case study 2 | **Enhance the IRT system and accelerate drug development**

Business challenge

A large US pharma company wanted to replace its old, antiquated IRT system, which was difficult to use and required vendors and programmers for the initial study build and all mid-study changes during study conduct. This added months to the process and cost the client tens of thousands of dollars for every change.

Solution

With Oracle Health Sciences Clinical One Randomization and Trial Supplies Management Cloud Service, it was able to build a study in three days instead of three months and make mid-study changes in real-time, deploying them in minutes. There was no need for reliance on vendors and programmers and no costs. Using Clinical One has helped the client uphold the trial timelines and incur no additional costs with every mid-study change.

Impact

Reduction in RTSM deployment and delivery

Oracle Health Sciences | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Clinical One	It is a unified eClinical platform that harmonizes data, streamlines workflow, and saves time from study start up to study closeout. It allows to collect data sets from any source – such as wearable sensors, patient apps, electronic health records, labs, and eCOA – and harmonize them in a single place to draw valuable clinical insights.
Argus	A solution for processing, analyzing, and reporting adverse event cases originating in pre- and post-market drugs, biologics, vaccines, devices, and combination products. It provides compliance with drug, vaccine, and device regulations in all regions of the world, including E2B(R3), E2B(R2), eVAERS, eMDR, and IDMP.
Empirica	A solution for detecting, analyzing, and managing safety signals for investigational and authorized medicinal products. Empirica supports end-to-end life cycle signal management from clinical trials through post-marketing surveillance.
Safety One Intake	It uses deep learning, natural language processing, and image processing algorithms to turn safety source documents – both structured and unstructured – into E2B files for easy ingestion into any safety case management system.
Select	A study start up solution that enables site selection based on data-driven performance metrics, ensuring a match to study. Select combines internal and external data sources to create a complete target site profile that enables evidence-driven site selection processes.
Activate	It streamlines and automates study start up, cutting cycle time by over 30%. Activate improves operational efficiencies with real-time monitoring of items on the critical path to ensure that the key milestones are met with real-time access to documents and automated, compliant workflows.
Analyze	A study start up analytics solution that provides sponsors, CROs, and sites access to the same information in a secure and controlled manner
Analyze Insight	Analyze Insight improves transparency, communication, and collaboration with CROs, leading to enhanced performance and governance of outsourced clinical trials. It provides real-time access to a wealth of data across study portfolio and CRO partners, replacing the need for manual preparation of routine reports, facilitating communications on study progress, and bottleneck resolution to deliver faster study start up and eliminating time wasted on non-productive activities.
Siebel CTMS	It is a centralized clinical trial management system, which enables sponsors & CROs to collect & track data, perform site management activities, and make product monitoring trip reports.
Data Management Workbench (DMW)	DMW is the only clinical data management platform that provides a trustworthy, single source of truth for all trial data. DMW can aggregate data from any source for data processing activities. The platform provides complete traceability and reduces study set-up costs by centralizing data in a single library.
InForm	InForm is the only EDC system that offers advanced capabilities for trials today and the foundation of data capture for the future. InForm allows study teams to rapidly build and deploy studies via a robust design library that not only speeds up the build process but allows the reuse of standard forms.
ClearTrial	ClearTrial can reduce the end-to-end planning process from weeks to hours by providing visibility into industry standards, detailed tasks, timelines, costs, and resources.

Oracle Health Sciences | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Oracle Health Sciences | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Oracle Health Sciences | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Oracle Health Sciences | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
HSBU customer success group	Investment	In 2021, launched HSGBU's customer success program that helps in accelerating a customer's path to achieving the targeted business outcomes by maximizing the impact of their solutions
Medable	Industry partnership	In 2021, in partnership with Medable, launched digital trial data collection to enable a single source of data for the site and sponsors.
Oracle patient monitoring system in response to COVID-19	Investment	In 2020, launched a patient monitoring system that allows healthcare systems to gather data from their subscribers around symptom tracking, contact tracing, and laboratory test results.
Oracle therapeutic learning system in response to COVID-19	Investment	In 2020, launched a COVID-19 Therapeutic Learning System that allows physicians and patients to record the effectiveness of a promising COVID-19 drug
Digital and decentralized trials	Partnership	Expanded Oracle's Core eClinical Suite, a single source of true, unified data model, and enhanced analytics reporting for consumption of vendor's full digital and decentralized clinical trial platform and capabilities. (Medable, Apex PRO, mHealth adaptor, etc.)
Data management AI	Partnership	Combined Data Management AI with DMW, Clinical One, and Inform to advance discrepancy management

Veeva Systems | clinical development platforms profile (page 1 of 8)

Everest Group assessment – Leader and Star Performer

Measure of capability: Low High

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

Strengths

- Clients mention that Veeva has a wide ecosystem coverage, offering solutions with an end-to-end approach across the clinical development landscape
- Clients appreciate Veeva for its client-centric approach throughout the project duration with on-time query resolutions and proactive pitching of ideas and solutions
- It has significant enterprise mindshare in the regulatory and quality value chain segments and can leverage it in other areas as well, especially safety and Decentralized Clinical Trials (DCT)
- It has extensive SI and CRO partnerships enabling them to broaden its offerings and expand its geographic reach
- Veeva applications and solutions are user-friendly, and clients appreciate the intuitive UI and ease of customization

Limitations

- Veeva price points are higher than other existing solutions in the market
- It has limited capabilities around trial design, site feasibility and selection, patient recruitment and retention
- Clients cite that Veeva can work on improving its capabilities around predictive analytics and machine learning when it comes to areas of integrated trial quality and risk management
- Clients state that the safety solutions are not mature enough, especially to deal with trials on a global scale

Veeva Systems | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Veeva Systems' vision is to be the leader in cloud-based software for the global life sciences industry. It wants to strategically partner with medical affairs for improved medical audience engagement and communications and to build the industry cloud for life sciences to support the critical functions within clinical trials processes to help companies of all sizes bring products to market faster and efficiently.

Overview of the client base

Some of Veeva Systems' clients include Illumina, Kronos Bio, Sanofi, GSK, KCR, ConvaTech, Vertex, Bioforum, Alcon, Insmed, and Celerion.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

Low (<10%) | Medium (10-35%) | High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1,2]

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

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Revenue by value chain element[1,2]

Low (<10%) | Medium (10-20%) | High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1,2]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

Veeva Systems | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1	Technology transformation in clinical environment

Business challenge

One of the top 20 pharma companies wanted to improve trial efficiency, quality, and speed. It also wanted to streamline clinical operations to get drugs to market faster with improved modernized technology.

Solution

The modernization team prepared time and budget estimates that included productivity dollar savings, reduced cycle time, and improved quality and compliance. A big-bang approach was implemented, and standardization was done for over 4,000 users to avoid the risk and complexity of maintaining two systems and sets of integration.

Impact

- Improved speed and quality of studies through proactive trial management and enhanced productivity
- Achieved 50% reduction in time to author monitoring visit reports
- Enabled 5% reduction in time for issue management across all active sites

Case study 2	Built clinical center of excellence with Veeva Medtech solutions

Business challenge

A global medical device diagnostic company wanted to establish a clinical Center of excellence (CoE) as an initiative that encompasses people, processes, technology, and partners. The goal was to set the industry gold standard for the conduct of clinical diagnostics execution. The client needed to collaborate, track, and scale trials more efficiently, while improving data quality, reporting capability, and compliance.

Solution

It selected Vault Clinical Operations and Vault CDMS for its new Clinical Trial Center of Excellence. Veeva's connected suites enabled clinical leaders to take a unified approach to clinical operations and data management.

Impact

- Fast and efficient study management
- Flexibility to respond to changing EDC needs

Veeva Systems | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Veeva vault clinical suite	It transforms clinical operations and clinical data management with a suite of clinical solutions, offering EDC, coding, data management, study start up, eTMF, CTMS, and payments on a single cloud platform.
Vault electronic data capture (EDC)	It provides an interface for capturing and reviewing data from sites, eliminates constraints, and runs the trial one wants with a modern EDC system.
Veeva vault coder	It provides an interface with innovations for fast and accurate coding of adverse events, medical histories, and medications using MedDRA and WHODrug dictionaries.
Veeva CDB	It is a clinical data platform that aggregates and harmonizes all data sources, to get clean, well-organized data that is ready-to-use faster.
Veeva RTSM	A robust, reliable, and user-friendly randomization and trial supply management solution that helps in simplifying complex processes and expedites clinical trials. A modular and highly configurable architecture delivers study set-up times in as little as three to four weeks and allows customizations to be built quickly and easily.
Veeva vault platform	A cloud application development platform for customizing, integrating, and extending Vault applications, or to create one's own applications.
Vault CTMS	It unifies clinical information, documentation, and processes globally to reduce complexity, increase transparency, and speed time to critical decision-making.
Vault payments	The solution speeds up payment processes within existing trial management workflows and ensures that sites get paid on time.
Veeva site connect	It automates the flow of trial information between Veeva clinical applications used by sponsors and CROs, and Veeva SiteVault, a compliant eISF application for clinical research sites.

Veeva Systems | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Veeva Systems | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
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Veeva Systems | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
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Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Veeva Systems | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Veeva link	Investments	In 2020, developed Veeva link, a new solution that gives commercial and medical teams accurate customer data and real-time insights for key account management
MyVeeva for clinical trials	Investments	In 2020, developed MyVeeva for clinical trials, a new application for clinical research sites. With capabilities for virtual visits, patient adherence, ePRO, eConsent, eSource, and an easy-to-use patient portal, MyVeeva for clinical trials makes it easier for clinical research sites to deliver a patient-centric and paperless clinical trial experience for patients and sponsors.
Veeva vault product surveillance	Investments	In 2020, developed Veeva vault product surveillance, a new cloud application for medical devices and diagnostics, to simplify and standardize the post-market surveillance process
MuleSoft	Partnership	In 2020, partnered with MuleSoft to leverage MuleSoft connector for Veeva Vault to make it faster and easier for life sciences companies to connect Veeva Vault applications with other enterprise systems
Vault site connect	Investments	In 2020, developed Veeva Vault Site Connect, a new application that connects sponsors and clinical research sites during trials. Vault site connect automates the flow of information between Vault clinical applications used by sponsors and Veeva SiteVault, a compliant eISF application used by sites for source document management and remote monitoring.
Physicians world	Acquisition	In 2019, acquired Physicians World, a provider of speakers bureau services, to meet the industry's need for a complete solution to plan and execute live and virtual events for healthcare professionals
Crossix	Acquisition	In 2019, acquired Crossix, the leader in privacy-safe patient data and analytics. Crossix operates as an independent business unit under its current brand.

03

Enterprise sourcing considerations

- Major Contenders
  - Accenture
  - Anju Software
  - Aris Global
  - Clario
  - Cognizant
  - Ennov
  - Flatiron Health
  - Generis
  - IQVIA
  - Mednet
  - Merative
  - Navitas Life Sciences
  - SAP
  - TCS

Accenture | clinical development platforms profile (page 1 of 8)

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

- Accenture excels as a system orchestrator with modular, plug-and-play capabilities in the INTIENT platform, integrating different clinical development systems under a single roof
- Clients appreciate Accenture's project management capabilities and that project managers and the team stay with clients throughout the entire duration of the project
- Clients rate Accenture high for its support model, especially appreciate the support during the hyper-care phase
- Its INTIENT platform is rated high for its smooth and simple UI, easy navigation, and context-driven queries
- Clients appreciate the INTIENT platform for its seamless integration capabilities with existing enterprise solutions for clinical development

Limitations

- Accenture should focus on talent management having more resources with deep technical expertise and domain knowledge in clinical development
- Clients believe that most of the offerings around clinical development and operations are service-oriented rather than being product-oriented
- It is perceived as a premium-priced vendor and sometimes clients feel that the projects/solutions are overbudgeted
- It has limited capabilities around regulatory and quality value chain segments

Accenture | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Accenture's vision for INTIENT is to be the market leading cloud solution for the enablement of new science. This involves bringing clinical development capabilities together with a focus on humanizing healthcare through better trial experiences (investigators, patients, etc.), powered by advanced analytics and AI capabilities that enable clients to use INTIENT to move from insights to impact.

Overview of the client base

INTIENT clients represent:

- Out of Fortune 500 pharmaceutical companies, 55% are clients
- Around 80% of the Top 20 pharmaceutical and biopharmaceutical companies in the world as measured revenue
- Three of the 10 most innovative biotechnology companies of 2021, according to fast company

Clinical trial platforms revenue (excluding services)[2]

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1]

Low (<10%)	Medium (10-35%)	High (>35%)
Biopharmaceuticals	Medical devices	Others

Revenue by buyer size[1]

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

Revenue by value chain element[1]

Low (<10%)	Medium (10-20%)	High (>20%)
Trial design and start up	Trial conduct and closeout	Quality management
Regulatory	Safety	

Revenue by geography[1]

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

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

Accenture | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1	Enabled INTIENT clinical platform to help simplify and speed drug development processes

Business challenge

A multinational pharmaceutical company wanted to simplify and speed up its drug development processes.

Solution

Accenture INTIENT Clinical platform, part of Accenture INTIENT, rapidly integrated new technology, advanced analytics, and applied intelligence to support the delivery of patient treatments. Bayer also joined the Life Sciences Cloud Coalition, which was developed to enable pre-competitive collaboration between pharmaceutical companies with the goal to more quickly and cost-effectively advance clinical development.

Impact

Improved efficiency

Case study 2	Improving drug development timelines with INTIENT Clinical

Business challenge

The client was an early adopter of INTIENT Clinical capabilities and has relied on INTIENT since 2014 to store, process, and manage clinical trial data for a portfolio that spans eight therapeutic areas.

With the explosion of data sources and increased pressure to deliver products to patients faster, the client needed to scale advanced cloud technologies as part of an effort to transform the client's clinical architecture and data flow.

Solution

Rapid technology advances have created opportunities to improve the ways clinical data is collected and used, offering a remedy to improve drug development timelines that can make a big difference to patients.

The extension of INTIENT will support a foundational upgrade to the latest INTIENT capabilities and platform, as well as upgrade the existing DMW application. This will enable the client to improve the ways clinical data is collected and used, offering a remedy to improve drug development timelines that can make a big difference to patients.

Impact

The client expects to realize over 1,600 weeks of efficiency gains per year in clinical data management. This will equate to approximately US$4 million in productivity savings per year at peak.

Accenture | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
INTIENT Clinical	INTIENT Clinical provides solutions to run clinical trials by enabling data aggregation, performing data analysis, and driving study and operational insights. With Google Cloud, it includes: • Study evidence repository: ingests and aggregates data into a single source of truth and enables easy, managed access to patient data • Study Data Engine: accelerates data transformation processes to conform collected data to submission datasets, leveraging an intelligent data transformation approach, which increases efficiency, reduces cycle times, and improves first-time quality • Managed Analytics Environment: a next-generation statistical computing environment that provides a centralized data science platform with dynamic, cloud-scalable compute and support for multiple programing languages to analyze clinical data for submission • Clinical Control Tower: integrates with data providers to empower portfolio, study, and site management to oversee clinical trial execution using KPIs and metrics, enabling continual monitoring with predictive modeling to identify actions to keep a trial on track
INTIENT Patient	INTIENT Patient is the supporting technology for Accenture's suite of outcomes-based patient services throughout their health journey. Within Clinical Development, this is helping life sciences companies provide more informed, connected patient support throughout the clinical trial experience. INTIENT Patient provides: • Health data management with connectivity using industry standard protocols for monitoring devices, apps, EMRs, medical images, and other digital health sources • Applied intelligence with robust rules engine, algorithms, and clinical care modeling to unlock the value of integrated patient data • Patient and caregiver mobile application framework: a native iOS and Android starter app, intended for customization to meet the specific use cases containing common patient and caregiver workflows, interacting with the platform to send and receive data, and being fully skin-able • Patient Identification Engine: enables PIs to more easily identify eligible patients for studies; integrated to EHR/EMR system to recruit patients within clinical workflow • Cohort Manager: application that enables a user to explore robust FHIR healthcare data sets for research and other purposes so that a company can determine how many patients are affected by a certain health condition in a specific demographic • Decentralized Clinical Trial capabilities including a mobile application for patients/caregivers and a portal for clinical research site staff to support clinical trial participants. This solution is integrated with third-party vendor solutions for eConsent and patient reimbursement and will continue to integrate with other capabilities to enable sponsors to achieve enterprise scale by connecting to an ecosystem of DCT partners
INTIENT Pharmacovigilance	INTIENT Pharmacovigilance provides earlier insights, better data transparency, improved accuracy and consistency in reporting, and more timely discovery of potential adverse events. With Google Cloud, INTIENT Pharmacovigilance offers: • ML models for medical entity extraction • Auto-ML natural language API to enable custom machine learning models that analyze documents • Vision OCR technology that uses industry-leading deep learning neural network algorithms to perform text, character, and image recognition with exceptional accuracy

Accenture | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Accenture | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Accenture | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Accenture | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
INTIENT platform	Initiatives	In 2019, launched INTIENT Platform and roadmap with 200+ clients in-person
Google partnership	Industry partnership	In 2019, partnered with Google to use Google Cloud as the main technology partner
Training investments in cloud and data science	Investment	In 2020, over 70,000 people were trained in technology services, including cloud and data science, by clients. Their technology licensing arrangements with major software firms allow access to a full range of technical training and application certification programs, which help employees with their long-term career progression.
Next-generation product	Investment	Advances capabilities relative to five strategic imperatives for the industry: 1. Velocity and diversity of clinical research 2. Enablement of global decentralized trials 3. Next-generation of collaboration in precision medicine 4. Advanced integration of life sciences and digital health 5. Rise of intelligence everywhere
Expanded partnership network	Investment	In 2018, invested in new distinct and large datasets within the genomics, clinical, and healthcare space. It procured genetic and phenotypic data, clinical trial operational data, longitudinal claims data, and SDOH data. These data sets have been used to 1) develop, train, and verify several tools and capabilities across the INTIENT platform, and 2) deliver more than 25 analytics initiatives with clients, leveraging the said data and the underlying analytical tools of the INTIENT platform. Partnership investments: At the core of INTIENT platform strategy, the company invested in expanding partnerships with over 100 independent software and hardware vendors, dedicating resources and effort to ensure their technologies integrate seamlessly with the INTIENT platform. Within that list, there are at least 10 software technologies that it has invested in or purchased licenses for to ensure that key aspects of INTIENT are delivered to clients as native to the platform; most of these software tools are leveraged by every INTIENT client. It also made equity investments in innovative start up businesses such as IXlayer, Geneyx, and TripleBlind.
Innovation hubs and technologies	Investment	Since 2017, Accenture has invested in the creation of Centers of Innovation, The DOCK in Ireland, and Liquid Design Studios at Accenture offices around the globe, where Accenture enables clients to ideate and co-create. The investments in innovation technologies – such as applied intelligence, machine learning, and natural language processing – can streamline processes, remove redundancies, eliminate manual data manipulation, and ease the data exchange between safety and regulatory stages.
Accenture INTIENT Summit 2022	Initiatives	• Accenture is determined to drive transformation in life sciences and beyond, deeper into the healthcare supply chain, by collaborating with biopharma and ecosystem partners. Through the INTIENT platform of platforms and the network of services, it provides solutions to organizations designed to accelerate new clinical research and patient treatments • At this year's global INTIENT summit, the third of its kind, a hybrid format (in-person and virtual), it brought together 133 participants including innovators, leaders, and influencers from across the life sciences and healthcare industries. It advanced itself as a thought leader by presenting and facilitating deep-dive discussions around three of the most prominent matters challenging these industries – humanizing healthcare, Innovation in Clinical Trials, and Advancing Cell & Gene Therapies

Anju Software | clinical development platforms profile (page 1 of 8)

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 cite that systems and solutions from Anju Software are simple and easy to operate without having to understand the technical nuances and testing mechanisms behind them
- Anju Software's price points are very reasonable and especially suitable for the small and medium segment of clients (annual revenue <US$1-5 billion)
- Clients appreciate Anju Software for its quick and responsive support services
- Clients are happy with the regular product releases and cite no issues with downtime and release management

Limitations

- Anju Software lacks an end-to-end vision toward developing a modular and interoperable platform for drug development
- Clients mention that the reporting system has limited functionalities and customizing reports becomes complicated
- Clients have mentioned that Anju Software might not be ready to deal with sites with a diverse patient population set
- It has limited partnerships with SIs, resulting in insufficient capabilities around cloud migrations and custom development

Anju Software | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Anju Software's vision is to deliver true, quantifiable value to customers with a comprehensive product portfolio complemented by commitment to innovation and exceptional customer support. It plans to continue to provide improvements that help with patient engagement, decentralized and hybrid trials, data visualization and actionable insights, easier user management, and integrations.

Overview of the client base

Anju Software partners with some of the top biopharmaceutical companies and contract research organizations (CROs) around the world. The goal is to provide the best tools for success to get life-saving treatments to patients faster.

Among its clients are:

- Ten of the top 10 global pharmaceutical companies
- 16 of the top 20 global pharmaceutical companies
- Eight of the top 10 CROs around the world

Clinical trial platforms revenue (excluding services)[2]

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

Low (<10%) | Medium (10-35%) | High (>35%)

Biopharmaceuticals | Medium devices | Others

Revenue by buyer size[1,2]

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

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

Revenue by value chain element[1,2]

Low (<10%) | Medium (10-20%) | High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1,2]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

Anju Software | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1	Development of a self-service web portal enabling physicians and patients to obtain information

Business challenge

A leading pharma company needed a self-service portal that could be used by medical professionals to obtain information, thereby allowing its own staff to focus on higher value activities.

Solution

Anju Software's Information Request Management System (IRMS) Care integrates seamlessly with IRMS and makes pre-approved information within the platform available via the portal to IRMS Care users. Results from IRMS Care's initial customers show an immediate and significant reduction in routine case volume calls to MedInfo internal staff or call centers.

Impact

- Decrease in calls by 10-15% from physicians
- Personalized experience of obtaining information and content anytime from anywhere and on any device

Case study 2	COVID-19 treatment study build using eClinical Suite

Business challenge

A pharma company wanted to set up a study for COVID-19 treatment within a very short span of time.

Solution

Anju Software was able to compress the timeline from project initiation to study go live to just under ten days with four days of design, two days of configuration, and one day of quality and compliance checks.

Impact

Study built and operational within ten days

Anju Software | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
eClinical suite	An easy-to-use solutions suite for the conduct and management of clinical trials enabling informed decision-making, risk-based monitoring, and an accelerated clinical trial life cycle. • Trial master – EDC/ePRO solution that streamlines the collection, processing, analysis, and submission of clinical trial data • CTMS master – the premier clinical trial management system that keeps trials on track with streamlined workflows and intuitive trial tools • RTSM master – complex subject randomization and trial supply management • ETMF master – regulatory-compliant creation and management of trial master file (TMF) • RBQM master – data aggregation and analytics platform including risk plan management, clinical data and operation insights, along with cross-study metrics • EPS master – early phase source and site automation solution for bed-side clinical sites
Medical affairs suite	Adaptive, connected, and patient-centric solutions that offer comprehensive, purpose-built capabilities, which together unify and enhance capabilities of medical affairs organizations. • IRMS Max – IRMS MAX is the definitive gold standard of medical information solutions offering unsurpassed capabilities • iCare Max – allows HCPs and consumers alike access to approved, published content via a secure company-branded, searchable website • Pubstrat Max – enables to reach target audiences faster to maximize the value and outcomes of scientific publications and medical communications and the team that produces them
Data science suite	• A clinical and medical intelligence solutions suite that provides actionable data insights, powerful analytics, and seamless data integration that can be customized to organization's needs • TA Scan – comprehensive clinical intelligence tool that aggregates and analyzes clinically relevant public and private data to facilitate and accelerate data-driven decision-making for all aspects of clinical study planning and implementation

Anju Software | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Anju Software | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Anju Software | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Anju Software | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Industry partnership (Top five pharma)	Co-innovation	Co-development of a new product that is not available in the market by any vendor. Anju Software and pharma companies shared their expertise and collaborated in product development, which is now implemented globally in 26 countries with over 2,500+ users
Innovation hub/lab	Investment	Invested in creation of an Innovation Hub and is working with various biotech companies to incubate and conceptualize new products (e.g., genomics, precision medication, and text narration analytics)
Alliance	Industry alliance (Microsoft)	Works with Microsoft to incorporate data factory concepts and tools for ANJU Data Platform
Alliance	Industry alliance (Gartner)	Works closely with Gartner life sciences analysts to uncover new trends in life sciences clinical, MI, and data segments
OmniComm Systems	Acquisition	In 2019, acquired OmniComm Systems to add EDC to ANJU CTMS product suite. The OmniComm product was on-premise software and ANJU transformed that into a cloud native with added features such as edit checks and self-service reporting, dashboards using ANJU DV, BUS, and improved the time for study set up.

ArisGlobal | clinical development platforms profile (page 1 of 9)

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

- LifeSphere is a proven solution in the safety domain. ArisGlobal is focusing on improving and adding capabilities to the platform in the areas of data integration, process automation, data fabrication, and analytics
- Clients appreciate the domain expertise and process knowledge along with the strong support services
- It has a flexible and modular solution with the ability to customize according to client needs across all segments (large, midsize, and small biopharma) of the market
- The Safety Advisory Board, Regulatory Advisory Board, and Industry Standard Practices bring clients on a common platform with the aim of standardizing processes, discussing challenges and best practices, and co-innovating solutions in clinical development
- It utilizes the CRO partnerships as a strategic channel to scale its products globally

Limitations

- ArisGlobal relies heavily on its internal team for deployment, migration, and implementation services. A good partnership with SIs can help it accelerate deployment and scale faster
- Clients call out long implementation cycles for regulatory and safety products
- It can look to improve the testing cycle for its products, making it more rigorous and conducting end-to-end platform testing over the siloed approach

ArisGlobal | clinical development platforms profile (page 2 of 9)

Overview

Company mission/vision statement for clinical development platforms

ArisGlobal wants to progress into five categories: progress developing and applying automation, depth of functionality, end-to-end coverage and expertise, approach to building with the industry, including advisory boards and ISP groups, and deeper subject matter expertise. It has documentation on its innovation roadmap that highlights some of the progress it is making in these areas.

Overview of the client base

The company currently provides technology solutions to the top five pharma companies, seven out of the top 10, and 40 of the top 50 biopharmaceutical companies, in addition to six government health authorities, including the FDA, Health Canada, and the NMPA.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1]

Low (<10%) Medium (10-35%) High (>35%)

Biopharmaceuticals	Medical devices	Others

Revenue by buyer size[1]

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

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

Revenue by value chain element[1]

Low (<10%) Medium (10-20%) High (>20%)

Trial design and start up	Trial conduct and closeout	Quality management
Regulatory	Safety	

Revenue by geography[1]

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

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

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

ArisGlobal | clinical development platforms profile (page 3 of 9)

Case studies

Case study 1	Enabled fast and high-quality submissions to the FD

Business challenge

Fujirebio wanted to ensure fast and high-quality submissions to the FD, as traditional data entry and review processes using spreadsheet trackers and paper were no longer sufficient. Simultaneously, concerns grew about the increased risk of human error, quality issues, and delays as faster, shorter studies with higher complexity were planned. As a result, there was need for faster, more accurate data, and a more streamlined data management process.

Solution

The Fujirebio Diagnostics Clinical and Data Management team worked with unified LifeSphere CTMS and LifeSphere EDC. This eliminated delays caused by manual data production and review. Studies could be launched much sooner, and the team could look at data across studies.

Impact

Faster and accurate data management

Case study 2	Developing next-generation cloud and automation capabilities

Business challenge

Boehringer Ingelheim was experiencing growing adverse event and medical inquiry volumes, and its on-premise technology stack had limited flexibility and was expensive to maintain.

Solution

The client adopted LifeSphere Medical Information, cloud medical information inquiry management solution. Following deployment, the client elected to migrate its existing pharmacovigilance systems to the new LifeSphere Safety suite. It also adopted LifeSphere Reporting & Analytics and LifeSphere Signal and Risk Management solutions.

Impact

There was 77% efficiency gain with LifeSphere MultiVigilance

ArisGlobal | clinical development platforms profile (page 4 of 9)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Clinical	LifeSphere Clinical is a cloud platform for clinical operations and data management, which accelerates studies, ensures transparency, and streamlines collaboration across customer organizations. It offers unified solutions for clinOps and data management teams of all sizes. The offering within the platform includes: • LifeSphere CTMS is a trial management solution that helps clinical operations teams accelerate timelines, stay organized, and reduce complexity • LifeSphere EDC delivers sponsors and CROs a cost-effective way to capture, manage, and report clinical research data • LifeSphere eTMF is a cloud-based system used for clinical trials to manage trial master file(s). This system ensures efficient collaboration and inspection readiness • LifeSphere Safety Document Distribution automates manual processing and distribution of safety documents for time saving, compliance, and acknowledgment of oversight, e.g., SUSAR comms
Safety	LifeSphere Safety is a unified, intelligently automated, end-to-end platform that helps PV teams save time, achieve scalable compliance, and make better decisions. Its integrated cloud applications help collect safety data efficiently, process it accurately in a single global database, and act on deeper insights with advanced analytics. Three key products are: • LifeSphere MultiVigilance is an intelligently automated, end-to-end case management solution. It incorporates the latest cognitive automation technology to deliver groundbreaking efficiency gains to PV teams. Its capabilities enable scalable, efficient, and globally harmonized case management • LifeSphere Signal and Risk Management is an intelligently automated, unified solution for signal and risk management. Its capabilities enable faster signal detection by seamlessly bringing big data together, reduce false positives with AI/ML-enhanced analysis tools, and accelerate patient safety by making signal data readily available during benefit-risk analyses • LifeSphere Safety is used by 300+ firms, including 7 of the top 10 biopharma companies and leading health authorities, with 19+ deployed cloud implementations
Regulatory	LifeSphere Regulatory delivers end-to-end regulatory information management that allows for seamless transitions between regulatory affairs, operations, HQ, and affiliates offering interoperability and intelligence to a global organization. The offerings within the LifeSphere Regulatory platform are: • LifeSphere RIMS delivers end-to-end regulatory information management to plan, execute, and track all regulatory activities in a single application with seamless access to regulatory documents and full support for all major eCTD submission requirements • LifeSphere Publishing is a submissions management application that enables life sciences organizations to easily compile, publish, and validate regulatory submissions with full support for all major global eCTD requirements • LifeSphere IDMP is a simple-to-use ISO IDMP cloud application that addresses the challenges of implementing IDMP and eXVMPD standards

ArisGlobal | clinical development platforms profile (page 5 of 9)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Medical Affairs	LifeSphere medical affairs is a cloud platform that helps life sciences organizations deliver timely information, stay compliant, and streamline collaboration between global stakeholders. The offerings within medical affairs platforms are: • LifeSphere® Medical Information enables teams to deliver better engagements at the point of need. Using an automated, multi-channel, and data-centric approach, it helps deliver timely information, stay compliant, and streamline collaboration • LifeSphere® Reporter is a simple digital engagement portal that enables medical affairs and safety teams to connect with stakeholders in real-time. Using secure mobile and web applications, healthcare providers, field teams, and patients can submit and track inquiries, report adverse events, and record product complaints – anytime, anywhere • LifeSphere® Product Complaints is an efficient way to log, track, and manage complaints from multiple channels, speed up inquiry assessment, and quickly respond with approved information. Out-of-the-box integrations and automation improve efficiency, productivity, and cost savings
Document and content management	LIFESPHERE® EasyDocs provides document and data management in a modern, easy-to-use cloud platform, delivering efficiency, compliance, and enhanced collaboration across drug development workflows. The EasyDocs platform features are: • Allows R&D teams to work from a common set of documents that are always up to date with the most recent changes, reducing data integrity issues • Structured Content Authoring is a standalone platform to automatically generate, author, review, and finalize clinical narratives. It can also develop a structured narrative from a given output, including from literature articles • Protocol Authoring can be readily created, reused, updated, and managed to ensure fewer amendments and direct feeding and set up of downstream systems and documents • User, role, and group-based security rules ensure consistent, reliable security across organizations of any size or outsourcing model

ArisGlobal | clinical development platforms profile (page 6 of 9)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

ArisGlobal | clinical development platforms profile (page 7 of 9)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

ArisGlobal | clinical development platforms profile (page 8 of 9)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

ArisGlobal | clinical development platforms profile (page 9 of 9)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Organizational readiness center of excellence / talent	Investment	Invested in building a Center of Excellence (CoE) and team focused on **organizational readiness**. This is a scalable, productized offering for organizational change management that includes the provision for structured training programs, digital/physical change management content creation, coordinated workshops, etc. It invested in this offering to help customers with their transition to new technology. In 2019, this offering enabled it to successfully onboard Johnson & Johnson users and team members during and after one of the largest safety system implementations in the industry (2,300+ users onboarded/trained).
AI center of excellence	Investment	Invested financial resources and time in establishing and developing its CoE for AI in life sciences. The results have been impactful within pharmacovigilance.
Expansion of R&D resource capacity	Investment	• In 2019, Nordic Capital acquired ArisGlobal for nearly US$800 million with the intent of investing heavily in further scaling the business • In 2021, Nordic Capital made significant additional investment with the company valuation at US$2 billion; the company is investing an incremental $80M toward R&D and commercial excellence directed toward clinical and regulatory business areas
Global technology & delivery center investment	Investment	Invested in expanding global technology and delivery footprints. It is building technology centers of excellence in Portugal, Hungary, and South America, including developer pods and delivery resources. It is also investing heavily in its US-/EU-based delivery and support footprint.

Clario | clinical development platforms profile (page 1 of 8)

Everest Group assessment – Major Contender

Measure of capability: Low High

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

Strengths

- Clario has deep expertise in electronic Clinical Outcome Assessment (eCOA) solutions and can handle complex requirements while sharing best practices for optimal outcomes and data collection
- Clients consider contract management and the overall partnership as strengths for Clario
- Clients appreciate Clario for its simple and easy-to-use solutions that require minimal technical expertise and training
- It offers cost-competitive solutions, with solutions at a flat fee compared to the per-site fee model for other peers considered
- Clients rate Clario high for its implementation services in terms of guidance and bringing in industry best practices

Limitations

- Clario can focus more on solution designing around an end-to-end unified platform and look to partner with SIs to enhance and accelerate deployment of solutions
- It should focus on talent management to ensure uninterrupted client support and bring on board digital experts who can work to distinguish the offerings
- Clients expect Clario to improve its dashboarding and reporting capabilities with more standardized and user-intuitive reports, KPIs, and queries
- The quality and mode of delivery for training materials can improve, starting with video training materials
- Clients state that Clario discusses ideas around governance and security of the platform but sometimes falls behind in executing them

Clario | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Clario's vision is to provide a broad, integrated platform for the collection of high-quality evidence. Its focus is on both collection of high-quality data, regardless of location (at site, at home, or in the community) as well as improving the user (customer, site, or patient) experience and increasing the speed/efficiency of delivery through integration of novel technology (e.g., AI/ML) that will enhance value for customers and improve clinical development processes. Sponsors will be able to leverage medical imaging, cardiac safety, respiratory, eCOA, and connected device data capture and analysis alongside eConsent, EDC, RTSM, supply optimization, CTMS, payments, subject eligibility, and adjudication, integrated from a single vendor, configured to leverage Clario's deep therapeutic, and endpoint collection experience and expertise.

Overview of the client base

Clario's client base is primarily pharma/biotech, with a small portion represented by medical device companies. Clario has ongoing or recent business with the top 30 largest global pharma companies, and >80% of the top 100. It also has a significant customer base of small and emerging pharma companies, which makes up >30% of the annual revenue.

Clinical trial platforms revenue (excluding services)[2]

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1]

Low (<10%) | Medium (10-35%) | High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1]

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

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

Revenue by value chain element[1,2]

Low (<10%) | Medium (10-20%) | High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

Clario | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1 | **Expedited start up processes for a pharma company**

Business challenge

A pharma company needed support and analysis over weekends. It was facing challenges with short start up timelines and non-standard additional operations support.

Solution

Clario worked with the customer to implement expedited start up processes, review cycles, and weekend support to operations teams to meet their needs. It also utilized proprietary LINK to site solution, which allowed sites to utilize their own equipment to reduce cost and shipping timelines. To fulfill the need for real-time data access, it utilized innovative central data exchange service to push data into their EDC system directly.

Impact

- Cost was reduced
- Timelines were expedited
- Logistical challenges declined

Case study 2 | **Enabled collection of clinical data**

Business challenge

A pharma company needed to create a new operational and commercial contracting path to support traveling nurse studies across multiple sponsors to accommodate aggressive timelines, budgetary constraints, and logistical challenges.

Solution

Clario worked with the customer to develop an equipment provisioning solution that could quickly deploy equipment and supplies globally with expedited timelines.

Impact

- Cost savings
- Expedited timelines
- Simplified business processes

Clario | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Medical imaging	It is powered by AI to ensure data upload compliance, and efficient trial execution including pre-processing, quality control, and analysis; delivers comprehensive site training on clinical trial image protocols; KPI dashboards and milestone notifications to ensure near real-time study tracking; secure and compliant data store for all trial Imaging; exclusively certified radiology technologists to QC image data; unparalleled team of medical experts and globally recognized KOLs across TAs; provides 29 imaging modalities, three millions+ images processed, and over 30 years of experience working with the FDA, EMA, and other regulatory agencies.
eCOA	Innovative Trial Anywhere eCOA are solutions that give patients choice; project assurance, training, and logistics teams deliver trials worldwide at scale; expertise across all TAs and 500+ indications to develop assessments. It has supported 3,000+ studies, at 200 thousand+ sites and reached 1.3 millions+ patients.
Cardiac safety	It provides real-time access to all safety and efficacy data to monitor key performing indictors and key risk indicators; devices plus training and support for variable trial modalities; supported over 10 thousand cardiac safety trials at 400 thousand+ sites and reached 2.5 million+ patients
Respiratory efficacy & safety	They are customized and integrated solutions that deliver quality respiratory endpoint data across all study phases; more endpoints supported with integrated devices and training tailored to customer's protocol; coaching innovations that reduce the incidence of implausible data and changes in function; specialists to provide guidance on how to unlock better evidence; supported 1,000+ respiratory studies for over 500 thousand patients, and 90% of new respiratory drug approvals
Precision motion	It is a use-anywhere solution for the capture of digital biomarkers; single or multi-sensor precision monitoring device that adapts to patient needs, provides procession motion analytics, measures patient function, and can be integrated with other endpoint solutions; precise assessment of functional mobility to support meaningful diagnosis and progression insights; objective, high frequency data specific to the patient population and therapeutic area; one of the largest validated outcomes libraries in the industry; 140+ validated outcome measures, 500+ scientific publications recognize Opal; 1,000+ researchers use Opal technology
Trial enablement	A full suite of advanced eClinical solutions to handle essential trial management tasks, including the ability to integrate and analyze data seamlessly to enable staff to focus on study conduct; cloud-native AI that automates QC assessments of complicated data; solutions include eConsent, Telehealth, EDC, CTMS, RTSM, site & patient payments, source document manager, eligibility, and clinical adjudication.

Clario | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Clario | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Clario | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Clario | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Acquisition	Industry acquisition of Bioclinica	In 2021, acquired Bioclinica to combine its imaging, eClinical, and drug safety capabilities with ERT's eCOA, cardiac, respiratory, and wearables expertise, to create the most comprehensive and robust endpoint data collection portfolio in the industry
Acquisition	Industry acquisition of APDM	In 2020, acquired APDM, a leading provider of wearables and digital biomarker solutions for clinical trials
Acquisition	Industry acquisition of Saliency	In 2021, acquired Saliency, AI-powered software platform that speeds up analysis of medical images and is used to support trials of pharmaceuticals and medical devices
AliveCor	Industry partnership	In 2020, partnered with AliveCor and released a home ECG solution for the clinical trial market that allowed customers to continue developing new medical treatments during the COVID-19 pandemic, regardless of whether trial patients had physical access to investigative site personnel
Cogstate	Industry partnership	Partnered with Cogstate to offer joint customers the eCOA experience for CNS clinical trials. Both teams developed an integration so both apps could be on one device for clinical trials.
Core endpoint product investment	Investment	Invested in core endpoint to improve speed, flexibility, and efficiency of Clario's eCOA platform
Core product investment	Investment	Additional investment (above normal R&D) made to support the continued build of a unified platform/ecosystem of solutions

Cognizant | clinical development platforms profile (page 1 of 8)

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

- Cognizant brings in its expertise from working in other industries and introduces innovation and new technologies (AI, ML, and NLP) for life sciences clients to expedite the clinical study and conduct processes
- It excels as an SI unifying point solutions in an end-to-end clinical development platform fulfilling client expectations
- Some of the solutions, such as RBM, TMF, and structured authoring, have been appreciated by clients and ranked higher than similar solutions in the market
- Its solutions are more open to integration with third-party vendor solutions in contrast to most leading platform providers in this space
- Clients rate Cognizant high for its commercial constructs as it brings in co-innovation and flexibility in its pricing models

Limitations

- Cognizant can look to capture more enterprise mindshare as an end-to-end system orchestrator by redefining its marketing strategies and showcasing more business cases and success stories
- While clients appreciate the idea behind the Shared Investigator Platform (SIP) solution, they are looking for improved user experience and out-of-the-box (easy and fast) integrations to common site systems, making it easy for sites and accelerating study start-ups
- It can help enterprises adopt new platforms and solutions through robust and successful change management strategies
- It has limited product capabilities beyond trial operations. It can look to build more in-house products/solutions, reducing the partnership-based engagement models

Cognizant | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

The Cognizant Products and Platforms' vision is to be the leader in helping clients transform clinical development through digital transformation, enabling cross-platform connectivity to unlock the intelligence in their own data, developing new technology to address clear market gaps, and providing services to enable optimization of platforms. Cognizant works with leading biopharma firms to identify unmet needs in clinical development, i.e., needs that are not satisfied by current technology platforms. These needs are then met by customization of standard platforms and building of appropriate APIs and proprietary platform technologies to ensure that clinical trial sponsors have a full suite of end-to-end offerings enabled by Cognizant.

Overview of the client base

- Cognizant is engaged with global life sciences clients that include biopharma, medical devices & diagnostics, generics, and small/midsize innovators across business segments. Within life sciences, the company works with all the top 30 biopharmaceutical companies and 18 of the top 20 medical device companies
- When appropriate, Cognizant engages in life sciences consortium(s)-led engagement of biopharma and related clients to ensure that technology platforms and appropriate features are identified and enabled within the appropriate regulatory and legal framework

Clinical trial platforms revenue (excluding services)[2]

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1]

Low (<10%)	Medium (10-35%)	High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1,2]

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

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

Revenue by value chain element[1,2]

Low (<10%)	Medium (10-20%)	High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

Cognizant | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1	Enhanced efficiency of the trial process

Business challenge

A top-3, global pharma company based out of Europe had a long turnaround time from send to receipt of the Feasibility Survey questionnaire that led to a bottleneck and reduced efficiency in the clinical trial process.

Solution

The Cognizant team helped the client enable out-of-the-box (OOTB) functionality offered by the SIP Survey module.

Impact

The turnaround time for receipt of surveys from sites reduced from an average of 13 days to four days only in twelve months, leading to a 70% average increase of efficiency.

Case study 2	Developing a solution for development of clinical documents

Business challenge

A UK-based pharma company wanted to develop a solution to manage clinical development documents and to be able to transform clinical document content into a digital asset to reuse information in downstream processes and systems.

Solution

The Cognizant team deployed the Document Accelerator – a proprietary platform. The Document Accelerator enabled the client to create a digital clinical document suite with the ability to auto-generate up to 80% of clinical protocols and other documents.

Impact

This resulted in creation of higher quality clinical documents with a 30% to 40% reduction in time.

Cognizant | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Event name	**Details**
Shared Investigator Platform	An open industry collaboration platform that streamlines trial activities and data sharing for and between sites, sponsors, and related stakeholders, resulting in improved operational efficiencies and accelerated timelines. It is being widely adopted across the industry as a preferred site collaboration platform
Clinical Data Insights	A clinical data repository that can ingest operational data and patient data from Electronic Data Capture (EDC) and other sources and leverage advanced data visualization to provide key insights back to CDM stakeholders. This product has a performance management solution that provides real-time, proactive, and regulatory-compliant risk assessment, as well as global trial oversight
Clinical Metadata Hub	A cloud-based proprietary tool that uses protocol definition from protocol authoring tools, such as Cognizant Document Accelerator, to automate all specification creation for data acquisition, analysis, and reporting systems for clinical trials leading to automated configuration of data capture systems
Document Accelerator	A digital documentation experience tool designed for researchers and investigators to produce clinical trial protocol documents in a collaborative manner
Cognizant LEAF	A unique, evolutionary AI platform that uses advanced evolutionary algorithms and deep learning to produce actionable results from complicated, multi-variate problems. LEAF supports biopharmaceutical companies to assess potential therapeutic outcomes based on individualized interventional strategies
Patient Health Suite	An interactive application suite using AI and ML for comprehensive exploration and insights generation of disease diagnosis and patient treatment
Rapid Pro	A proprietary Veeva Vault Certified Migration toolset that has been used for performing enterprise scale migration onto the Veeva Vault and other toolsets. The comprehensive enterprise migration framework covers content discovery, data clean-up, data verification, source data lock, validation, data reporting, etc.
Cognizant Neuro	A proprietary interoperable, modular platform that binds the client's segmented processes and technologies together to enable them to adapt, scale, and evolve to an ever-changing environment in a better, faster, and more streamlined way. It simplifies and accelerates time to business value through one inclusive automation fabric that connects to every aspect of the business

Cognizant | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality present via platform partners

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Cognizant | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality present via platform partners

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Identify critical data to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Inbuilt checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Document the conduct of risk review activities according to trial risk plan
Trial master file management	Plan expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking, and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Cognizant | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality present via platform partners

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Manage the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the Supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integrate data from different sources	

Cognizant | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Partners	**Type of event**	**Details**
Philips Healthcare (Philips Health Suite Digital Platform)	Industry partnership	In 2021, partnered with Philips Healthcare to gain support in consulting and digital engineering capabilities. This allowed biopharma and medical device manufacturers to define digital health use cases and business models, such as decentralized clinical trials or remote patient management, enabling it to deliver secure, compliant, and scalable solutions
Generis Corporation	Industry partnership	Partnered with Generis, CARA for structured content management and authoring along with Fonto XML for regulatory content management. This helps drive regulatory, structured as well as unstructured, content management, along with reduced turnaround time in regulatory submissions, reducing silos, generating document/content track-ability and traceability
RxLogix	Industry partnership	Partnered with RxLogix to drive end-to-end safety & PV transformation through adoption of their platform combined with Cognizant's industry-leading IT consulting & safety operations
Veeva	Industry partnership	Partnered with Veeva to expand capabilities in clinical data management. The partnership helps us modernize regulatory information management, safety & PV process, and quality document management by driving digital transformation and end-to-end platform adoption
Medable	Industry partnership	In 2022, partnered with Medable to drive adoption of their Decentralized Clinical Trials (DCT) Platform to expand DCT & clinical offerings. Medable's digital platform streamlines design, recruitment, retention, and data quality for decentralized trials, replacing siloed systems with integrated digital tools, data, and interfaces to accelerate trial execution. Medable connects patients, sites, and clinical trial teams to improve patient access, experience, and outcomes
Florence	Industry partnership	In 2021, partnered with Florence to integrate Florence Healthcare's eBinders electronic Investigator Site File (eISF) platform and SIP platform to streamline collaboration between clinical sites and sponsors and enhance connectivity and communication
Medidata	Industry partnership	Partnered with Medidata to offer end-to-end clinical capabilities including IRT-as-a-service, ePRO, payments, randomization, and trial supply management. This partnership drives Cognizant's capabilities and service offerings across AI & analytics and industry platforms in the clinical space
Oracle	Industry partnership	Partnered with Oracle to transform end-to-end clinical development technology, sponsor experience through integration with Cognizant's Shared Investigator platform and Oracle's Study Start Up, as well as platform modernization in safety & PV

Ennov | clinical development platforms profile (page 1 of 8)

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

- Ennov showcases good capabilities across the regulatory, safety, and quality areas of the value chain
- Clients have appreciated the UI/UX of its solutions in their public reviews
- It offers easy-to-deploy solutions backed by good support services
- It also serves other industries like medical devices, animal health, chemical, and food and beverage with its trial management solutions

Limitations

- Ennov's offering around unified platform is limited to regulated content and information management, not much focused across the entire breadth of the clinical trial value chain
- It has limited capabilities across trial start up and conduct
- Its portfolio of solutions does not support decentralized trials

Ennov | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Ennov has been developing innovative and easy-to-use software for regulated content, data, and process management. The company designs and builds solutions to support the life sciences R&D continuum that includes clinical, regulatory, quality, pharmacovigilance, and commercial value chains.

Overview of the client base

Ennov serves over 150 companies and 150,000 users around the world, which includes many pharmaceutical, biotech, medical devices & diagnostics, and healthcare companies. Some of the clients include the top 25 pharmaceutical companies, such as Aguettant, Amgen, Almedis, Boehringer Ingelheim, GSK, Novartis, Takeda Pharmaceuticals, and Inserm.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

	Low (<10%)	Medium (10-35%)	High (>35%)
Biopharmaceuticals			
Medical devices			
Others			

Revenue by buyer size[1,2]

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

Revenue by value chain element[1,2]

	Low (<10%)	Medium (10-20%)	High (>20%)
Trial design and start up			
Trial conduct and closeout			
Quality management			
Regulatory			
Safety			

Revenue by geography[1,2]

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

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

Ennov | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1: Providing a robust CTMS solution to a Russian life sciences player

Business challenge

ALMEDIS, a Russian life science market player, was looking for a vendor that could provide a complete, affordable, and easy-to-use clinical data management solution.

Solution

ALMEDIS implemented Ennov clinical data management solution, which helped the company evolve from a niche CRO into one of the major players in the Russian life sciences market.

Impact

- Increase in company revenue and market share
- Improvement in brand awareness
- Broadened area of expertise for the company

Case study 2: Helping client implement a pharmacovigilance solution

Business challenge

PDS, a specialized consultancy that provides pharmacovigilance and regulatory services to life sciences companies, was looking to identify and implement a standard pharmacovigilance solution to replace a legacy system that had become too burdensome to maintain.

Solution

Ennov provided PDS with a comprehensive drug safety solution that required no IT resources or expertise to implement.

Impact

The solution met all the PDS requirements for:

- Pharmacovigilance case processing
- PV reporting
- MedDRA coding
- Signal detection
- Medical writing of the PSUR and other safety reports

Ennov | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Ennov EDC	It is a comprehensive clinical data management solution that allows clinical research personnel to easily define EDC studies and collect subject data without the worry of missing or inaccurate data.
RTSM	It is a solution that manages randomization and clinical trial supplies. An integrated Interactive Web Response System (IWRS) allows clinical investigators and site personnel to access study data from any location at any time and execute their study-specific activities using an intuitive web-based interface. It is also used to manage the Investigational Medicinal Product (IMP) from the initial shipment to the investigating centers to dispensing and replenishment.
ePRO	The software automates the capture of electronic patient data through the use of online questionnaires that patients can complete from the privacy of their own home. The data is checked for validity, consistency, and completeness and is made available to the investigators and site personnel responsible for monitoring patient compliance and safety.
Clinical Trial Management Software (CTMS)	The software facilitates the end-to-end management of clinical trials. It allows sponsors to be more efficient, make better decisions, ensure compliance, monitor patient recruitment, and manage finances.
Electronic Trial Master File Software (eTMF)	It is an electronic trial master file solution to collect and manage essential trial documents in a centralized repository and makes them available to clinical teams, via the internet, from any location at any time. The benefits of using Ennov eTMF include streamlined processes, increased transparency, simplified tracking, and enhanced security.
Clinical eLearning	It is a solution that addresses the problem of training large and geographically dispersed clinical teams on the use of Ennov EDC software. Ennov Clinical eLearning provides clinical team members with an interactive learning experience that keeps them engaged and ensures consistent and uniform training for all clinical staff.

Ennov | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Ennov | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Ennov | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Ennov | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Afcros clinical research day	Others	In 2022, partnered and sponsored the 10th edition of the AFCROs (French Association of CROs) clinical research day.
Clinical quality oversight forum	Others	In 2021, announced sponsorship of Clinical Quality Oversight Forum that was held at Hilton Philadelphia City Line Avenue Hotel
Release of version 8.6	Others	In 2020, announced the release of Version 8.6 of unified compliance platform. The release includes many new features and functions including enhancements to Ennov Doc, Ennov Process, Ennov Dossier, and Ennov RIM.
FME life sciences	Industry partnership	In 2020, partnered with FME Life Sciences, a provider of business and technology services. The partnership provided an expanded portfolio of content and data management services to the company's regulatory clients.
Genpact	Industry partnership	In 2019, partnered with Genpact to provide data management services in support of Ennov's regulatory information management solution. The partnership provided expanded portfolio data management services to the company's regulatory clients.
TMF summit and CROWN congress	Global conference	In January 2020, the company sponsored the ninth Trial Master File Summit and CROWN Congress held in Orlando, Florida. Both conferences focused on improving clinical operations through the use of technology and optimized processes.

Flatiron Health | clinical development platforms profile (page 1 of 8)

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 lightweight EDC platform with a short set-up time for study databases, enabling speedy platform migration and deployment
- Flatiron Health is adaptive to client requirements and brings in high-quality program managers ensuring adequate support and guidance all through the project duration
- Clients rate its products high on their security, governance, and compliance abilities
- Its price points are competitive and transparent, and clients have realized significant cost savings in the engagements

Limitations

- Clients cite that adding new features to the solution will slow down deployment, creating a situation wherein there is a trade-off between the short set-up time and the ability to customize the solution
- It has limited capabilities in trial start up and execution, and clients expect it to diversify and broaden the product portfolio
- It can consider partnerships with CROs as a good starting point to bolster efforts around training and change management services
- It can look to improve on the reporting capabilities of its platform, adding more standard reports, KPIs, and queries

Flatiron Health | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Flatiron Health has developed a core representation of the protocol structure that, together with novel cloud-based technologies and data standards, can generate breakthrough efficiencies in all aspects of the trial, connecting medicine to research.

Overview of the client base

About 14 of the top 20 pharmaceutical companies and three of the top five CROs use Flatiron Health's applications.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1]

Low (<10%) Medium (10-35%) High (>35%)

Biopharmaceuticals	Medical devices	Others

Revenue by buyer size[1,2]

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

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

Revenue by value chain element[1,2]

Low (<10%) Medium (10-20%) High (>20%)

Trial design and start up	Trial conduct and closeout	Quality management
Regulatory	Safety	

Revenue by geography[1,2]

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

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

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

Flatiron Health | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1	Remote Monitoring and Protocol dissemination/management for a complex program

Business challenge

Beat AML wanted EDC, Remote Monitoring and Protocol dissemination/management for a large and complex program (>1,000 subjects at major academic institutions) in early phase oncology–anticipating multiple sub–studies, +40 amendments, and interim data cuts.

Solution

- Clinical–pipe allowed for data to be transferred from EHR to EDC. The sponsor indicated full SDV is not needed when the data source is EHR
- Source Upload enabled remote monitoring on data manually entered from EHR into EDC (data not able to be transferred via Clinical Pipe)

Impact

- Fast study and amendment builds
- Data present in FHIR observation domain (e.g., labs, vital signs) able to be transferred without manual transcription from EHR to EDC
- Deployment of 11 protocol amendments across Flatiron EDC+ in less than five business days after final protocol
- Time and cost savings by sponsor for deploying remote monitoring solution, reducing travel to sites

Case study 2	Built EDC to simplify complex hematology and oncology protocols

Business challenge

Prelude Therapeutics had very complex hematology and oncology protocols that required multiple study amendments as new indications were uncovered.

Solution

Flatiron built and deployed an EDC system across Prelude Therapeutics' entire clinical development program – currently being used on six studies.

Impact

- Enabled configuration EDC to the Nth degree of branching and versioning
- Eradicated migration data between versions

Flatiron Health | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Flatiron EDC+	It is designed from its inception to solve the baked-in flaws of legacy EDC systems. This technology was created to address complex trials, especially in oncology with complex branching and treatment cycles, and seamlessly collect and manage data. This suite of powerful benefits elevates the traditional list of features found in other EDC systems, allowing to deliver speed and accuracy not found with any legacy EDC system.
Source upload	Flatiron Health's Source Upload solution, which runs (on a different screen) alongside any EDC system (Rave, InForm, IBM, Medrio, etc.) allows site coordinators to upload unredacted source data at the click of a button. The CRA/Monitor can remote monitor the data, mark it as reviewed, issue queries to the site, and download metrics reports for management, CTMS, or eTMF. Flatiron Health just released in October 2021 a standalone version of Source Upload (SU.com), which allows in-app redaction of identity-rich data so as to meet global regulatory requirements. Additionally, SU.com is connected to Rave and P1 EDC just like Clinical Pipe is – allowing for a real-time connection and no need for configuration beyond what was configured in the EDC.
Clinical pipe	An EHR-to-EDC connector that uses the latest SMART on FHIR standards to transfer data from one system to the other. The app seamlessly connects to leading EHR and EDC systems. The current manual transcription process is expensive, time-intensive, and error-prone (up to 9% according to a recent Duke study). Depending on the therapeutic area, 50-80% of data can be pushed from one system to the other. This is the first scalable integration of EHR and EDC. It represents huge leap toward unlocking the power and value of technology within the life sciences industry.

Flatiron Health | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Flatiron Health | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Flatiron Health | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Flatiron Health | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Protocol First	Acquisition	In 2021, Protocol First reversed merged into Flatiron. It aims to reduce the operational complexity of data collection and validation in clinical research, by leveraging proven technologies and standards.

Generis | clinical development platforms profile (page 1 of 8)

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

- Generis excels in end-to-end Regulatory Information Management (RIM) with the CARA platform
- It is adaptive to client requirements and brings in top-notch CARA experts for designing tailor-made solutions for its clients
- CARA comes with a highly configurable UI for the administrators/power-users to deploy new changes easily and effectively
- Clients appreciate Generis for its comprehensive training program for developers

Limitations

- Generis can look to improve the integration of its solutions with new-generation technologies and platforms
- Clients mention that the user experience of the platform with respect to its look and feel and navigation can be enhanced
- It has limited capabilities in the trial start up and trial conduct value chain segments
- Clients cite that the documentation of the releases and updates can be improved

Generis | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Generis' vision is to provide industry-defining implementations that are fast and intuitive in order to bring customers an enjoyable and efficient experience that allows them to focus on their work.

Overview of the client base

It is used by over 60,000 professionals worldwide. Some major clients are AstraZeneca, Bayer, Pfizer, Merck, and Roche.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

	Low (<10%)	Medium (10-35%)	High (>35%)
Biopharmaceuticals		Medium (10-35%)	
Medical devices		Low (<10%)	
Others		Low (<10%)	

Revenue by buyer size[1,2]

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

Revenue by value chain element[1,2]

	Low (<10%)	Medium (10-20%)	High (>20%)
Trial design and start up			High (>20%)
Trial conduct and closeout		Medium (10-20%)	
Quality management			High (>20%)
Regulatory			High (>20%)
Safety		Medium (10-20%)	

Revenue by geography[1,2]

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

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

Generis | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1 | **Updated legal system through CARA**

Business challenge

Pfizer wanted to update its system as it was using legacy systems for regulatory submission documents and for quality documents, with poor performance and functionality. It did not have specific functionality for labelling, or for their legal department for managing contracts and records.

Solution

It used CARA during the selection process, to facilitate both cost advantages and performance/usability benefits. CARA was rolled out across the globe for users in multiple areas.

Impact

- Reduced cost
- Streamlined in-house infrastructure and support team requirements
- End-users had the major benefit of a consistent user interface for multiple systems, which therefore required less training
- The legal department was able to benefit from managing controlled records of contracts and other legal documents, including features such as comparison and redaction

Case study 2 | **Implemented CARA for simplifying multiple user platforms**

Business challenge

Bayer wanted to simplify its system as there were multiple systems in place for handling regulatory, safety, and quality documents. There was no connection between the systems and ultimately users had to learn multiple systems to do their work.

Solution

Implemented CARA for 500 users for Regulatory Correspondence Management, and following the success of the system, moved on to implement three systems for global regulations / SOPs management, as well as a global regulatory submissions documents system. This was then followed by a system for archiving (in consumer health) and one for PV case content management, integrated with ARGUS.

Impact

- Reduced cost
- Streamlined the system and work environment

Generis | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
CARA life sciences platform	• It provides a foundation of regulatory information, managing data to make it easy to identify and reuse across the organization • CARA provides a range of user experiences from simple portals to functionality-rich business tools • Metadata is used for content creation and data handling. CARA has more than 40,000 configuration settings. Category-based security down to the document, group, and user-level can be attained in CARA. AI and intelligence are used for integrating algorithms

Generis | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Generis | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
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Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Generis | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
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Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
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Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Generis | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
German biotech company	Collaboration	In 2022, a German biotech company Affimed selected CARA™ Life Science Platform to support its clinical R&D teams in the management of Trial Master Files.
intilaris Life Sciences	Industry partnership	In 2021, partnered with intilaris Life Sciences, a consultancy specializing in clinical development operational excellence, to add clinical trial management optimization to CARA™
Kyowa Kirin	Collaboration	In 2021, Kyowa Kirin, a global specialty pharmaceutical company, selected the Generis CARA™ Life Science Platform to enable it to respond quickly and consistently to regulatory correspondence and reduce time-to-market.
Planet Pharma Solutions	Industry partnership	In 2021, it partnered with Planet Pharma Solutions, a Japanese life sciences software provider, to take the Generis CARA™ Life Science platform into the Japanese market.
Data Conversion Laboratory	Industry partnership	In 2021, it partnered with Data Conversion Laboratory to apply structured content management and structured content authoring to legacy information and existing documents.

IQVIA | clinical development platforms profile (page 1 of 9)

Everest Group assessment – Major Contender

Measure of capability: Low High

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

Strengths

- IQVIA focuses on system orchestration through the Orchestrated Clinical Trials (OCT) platform. It is designed to enable each suite and product to play to its strengths and orchestrate a best-of-breed solution
- It has good capabilities covering the entire breadth of the clinical trial landscape with reputed domain and process expertise
- It has made good investments around AI, ML, NLP, and automation for clinical development
- Clients have appreciated the responsiveness of IQVIA's 4-tier support model in public reviews
- Its CRO heritage enables it to offer BPaaS solutions to its clients

Limitations

- Clients have cited difficulties in setting up workflows with the RIM and Risk-based Quality Management (RBQM) solutions
- IQVIA's CRO heritage sometimes create skepticism in enterprise minds about its abilities as a technology vendor in the clinical development space
- Clients face complications due to long implementation hours and cite challenges while navigating through the IQVIA solutions

IQVIA | clinical development platforms profile (page 2 of 9)

Overview

Company mission/vision statement for clinical development platforms

IQVIA's vision is to combine technologies, global healthcare data, data curation, and modern data science for the healthcare industry. It provides a range of solutions used across the clinical development life cycle, from design and planning, to site and patient engagement, trial management, safety, regulatory and quality, and a clinical data analytics platform providing connected intelligence to transform clinical development. It focuses on providing technology to change workflows that empower orchestration.

Overview of the client base

IQVIA's major client base has revenue of >US$10 billion, followed by clients with revenue of US$1–10 billion. One-fourth of its client base consists of clients with revenue of <US$1 billion.

Clinical trial platforms revenue (excluding services)[2]

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

Low (<10%) | Medium (10-35%) | High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1]

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

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

Revenue by value chain element[1]

Low (<10%) | Medium (10-20%) | High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

IQVIA | clinical development platforms profile (page 3 of 9)

Case studies

Case study 1 | **Vaccinating a diverse & global patient population in an accelerated time frame**

Business challenge

As a part of Operation Warp Speed, an initiative taken by the United State government to accelerate a COVID-19 vaccine trial, a biopharma sponsor needed to vaccinate 40,000 people in eight weeks.

Solution

The sponsor leveraged IQVIA's leading-edge decentralized trial platform and patient engagement & recruitment services including clinical trial educators, CRA mobile app, call center, chat-bot scheduling, and COVID-19 predictive analytics.

Impact

- The sponsor was able to enroll and vaccinate >40,000 patients within eight weeks
- The trial was conducted across eight countries, involving 210 sites
- Collected more than 1.7 million e-diary records during the trial

Case study 2 | **Clinical support across a diverse portfolio**

Business challenge

A major global biopharmaceutical company wanted to streamline end-to-end early clinical support through a CRO. It also wanted operational and scientific expertise to develop programs across a pipeline of several therapeutic areas.

Solution

IQVIA's subject matter experts participated in sponsor strategic planning sessions, and in-house symposia was enabled for clinical research staff to brainstorm with IQVIA therapeutic experts. For centralized oversight and continuous process improvements, they proactively streamlined study-specific risk mitigation through failure modes and effects analysis.

Impact

The company established cross-functional capabilities all in one place, which allowed to provide the sponsor with comprehensive support and personal attention across its portfolio for:

- Simplified oversight
- Simplified contracting
- Earlier insight into compound viability

IQVIA | clinical development platforms profile (page 4 of 9)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Grant plan	It allows sponsors and CROs to forecast, budget, and generate Fair Market Value (FMV) analysis for investigator grant costs in 132 countries. (Over 76% of global clinical trials are conducted by Grant Plan subscribers, global coverage offering up-to-date benchmarks for over 100 countries, budgets that represent Fair Market Value expedite speed to First Patient In (FPI)).
Investigator portal	It provides a single destination to activate sites, manage training, securely exchange documents, and receive and acknowledge safety notifications.
Clinical trial payments	It provides a reliable and efficient way to pay sites, submit invoices, and track payment progress and history by generating a centralized dashboard for all site payment activities.
ETMF	It is a cloud-based clinical content management solution that offers precision planning and automation tools to help plan, manage, monitor, and maintain an inspection-ready eTMF.
Patient portal	It provides patients with a single site where they can access study and visit guides, receive notifications about visits and events, and complete patient data returns, surveys, and other documents supporting decentralized trial participation.
Virtual and decentralized trials	It helps in increasing patient engagement and decentralized trial participation to maximize engagement. Extensive solution-oriented approach including DCT platform, televisit capabilities, eCOA, eConsent, connected devices (patient wearables), e-diary, IRT, remote monitoring, and numerous patient services. In H1 2022, IQVIA experience in DCT trials involved over 225,000 patients with more than 90 trials for >30 indications across 15 therapeutic areas in over 60 countries.
Complete consent	It automates the consent processes to reduce compliance errors with informed patient consent and investigator contracts, improves patient retention, and accelerates the path to approval.
eCOA	It manages all patient assessments and outcomes reported by patients, clinicians, observers, and caregivers to optimize real-time, direct-from-patient data collection, while enhancing the patient experience and improving data quality.
Connected health	It removes the limits to traditional clinical research, opening new possibilities for novel endpoints, digital biomarkers, digital therapies, and new evidence generation.
RTSM (Cenduit, IRT)	It accelerates study start up & amendment, optimizes site experience, reduces trial supply costs, and improves study decision-making (over 1,700 clinical trials, over 80,000 sites, over 100 countries and 200 languages, over 1 million patients, and over 450 active trials (live, built-in, awarded))
CTMS	It helps in achieving transparency through digital automation designed around persona experiences.
RBQM	It helps in intuitive automation and intelligent recommendations with configurable risk assessment and mitigation tools. It includes central monitoring capabilities, tied to CRA automation, to increase monitoring efficiencies (14% reduction in subject visit data entry lag, 25% cost savings, four days faster database lock vs. non-RBM trials, 28% less SDV backlog for RBM studies vs. non-RBM studies, 4X Lower error rate in critical data in RBM studies vs. traditional 100% SDV)

IQVIA | clinical development platforms profile (page 5 of 9)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
RIM smart	It delivers fully integrated, technology-led intelligent management of the complete regulatory life cycle. The only solution with embedded regulatory intelligence, it automates high volume tasks, boosting speed, accuracy, and efficiency, lowering costs, and improving data quality.
Vigilance platform	It is a comprehensive, AI-driven system that automates safety workflows and simplifies regulatory reporting – including the identification and processing of adverse events – significantly reducing the cost and complexity of the entire pharmacovigilance experience across the life cycle.
Clinical data analytics suite	It is a SaaS-based product, designed to help strategic R&D decision-makers make smart, data-driven, and timely decisions to improve trial design, improvise trial strategy to achieve better outcomes, and optimize their life science workflows with automation and intelligence. It uses advanced AI-/ML-enhanced analysis to identify more predictive and previously hidden insights, empowering stakeholders to make smarter decisions across the trial journey.

IQVIA | clinical development platforms profile (page 6 of 9)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

IQVIA | clinical development platforms profile (page 7 of 9)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

IQVIA | clinical development platforms profile (page 8 of 9)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

IQVIA | clinical development platforms profile (page 9 of 9)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Foundry Health	Acquisition/ Partnership	Partnered with Foundry Health to support the development of the next-generation Connected Devices Digital Platform, for use in all service lines and all clients.
Amazon Web Service (AWS)	Technology provider (partner)	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. IQVIA's Platform-as-a-Service (PaaS) offering, built on Cloudera technology, offers clients the ability to deploy data lake environments on demand.
MuleSoft	Technology provider (partner)	Integrated IQVIA's Lexi/MuleSoft capability across the OCT platform to create a unified experience. Lexi extended to integrate the OCT platform and client's existing systems to create seamless data exchange. OCT provided real-time / near real-time data access and transparency, support process automation, and functional collaboration across clinical operations.
Salesforce	Technology provider (partner)	In 2018, IQVIA partnered with Salesforce to build a clinical solution for life sciences on Salesforce Health Cloud. The IQVIA-Salesforce partnership is the largest technology partnership in the healthcare industry.
IQVIA Orchestrated Clinical Trial (OCT Platform)	Investment	Deployed a three-part approach of build, buy/acquire, and partner for technology growth strategy, which has seen over a US$3 billion investment since the merger of Quintiles and IMS Health in October 2016. The Orchestrated Clinical Trial platform has been integrated to transform traditional clinical research for patients, sites, and sponsors to adopt a more modernized digital trial experience, which further accelerates value, minimizes risk, and optimizes outcomes.

Mednet | clinical development platforms profile (page 1 of 8)

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

- Mednet displays client-centric behavior through close relationships and active support and quick resolution of queries
- Clients appreciate the ability to set up and build the study platform easily, without much technical knowhow from their end
- Although the UI needs a little revamp, yet, clients cite that it is very intuitive, user-friendly, and easy to navigate and workaround
- Clients mention reasonable price points and flexible contracts as major factors differentiating Mednet

Limitations

- Mednet has limited capabilities around Direct-to-Patient (DTP) solutions and conducting decentralized trials
- It has limited focus outside the clinical trial conduct and closeout value chain segment
- Clients often face difficulties in data port and exchange between Mednet systems and other clinical development systems
- It can look to enhance its Patient-reported Outcome (PRO) capabilities, ensuring data integrity at endpoints and catering to the demands of complex eCOA requirements

Mednet | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Mednet's mission is to provide innovative, efficient, and effective eClinical solutions to accelerate clinical development, allowing life sciences customers to focus on what matters – improving healthcare for people worldwide.

Overview of the client base

Mednet supports a wide variety of CROs and life sciences companies, including pharmaceutical, biotechnology, and medical device organizations. The bulk of Mednet's growing customer base consists of small to midsize research organizations; however, Mednet's experience spans all study types and phases and across all therapeutic categories.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1]

Low (<10%) | Medium (10-35%) | High (>35%)

Biopharmaceuticals	Medical devices	Others

Revenue by buyer size[1]

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

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

Revenue by value chain element[1]

Low (<10%) | Medium (10-20%) | High (>20%)

Trial design and start up	Trial conduct and closeout	Quality management
Regulatory	Safety	

Revenue by geography[1]

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

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

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

Mednet | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1	Enabled auto-management of payments

Business challenge

A CRO noted that in its previous study it had to hire a full-time person to manually manage payments.

Solution

Mednet advised the client to use the Payments module in iMednet, allowing payments to be auto-managed in the system, eliminating the need for full-time staff, and making payment management much more efficient.

Impact

Improved efficiency and reduced the need for a full-time person to manage payments on the study for significant cost savings

Case study 2	Maximized efficiency in the database development process with significant reduction in labor

Business challenge

Statistics and Data Corporation (SDC) wanted to maximize efficiency in data management by streamlining the database development process for similar studies within a given clinical program.

Solution

To quantify the labor savings provided through iMednet, SDC retrospectively evaluated two examples of the database build and validation process – one using the previous EDC solution, and one using iMednet. One area where the client noticed exceptional labor savings was in reproducing studies – developing new databases for existing clients by utilizing form libraries and reusing previously created workflows, processes, and reports.

Impact

SDC found that the database build and validation process utilizing iMednet resulted in over 50% reduction in labor vis-à-vis the former EDC system.

Mednet | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
iMednet	It is a comprehensive, cloud-based, clinical data management system, centered around a robust EDC and built from the ground up with key native modules. The platform enables research teams to meet the rapidly evolving requirements of clinical research, while supporting a wide range of study types and designs. iMednet is flexible and intuitive, enabling users to get studies up and running quickly, while ensuring easy onboarding of the entire research team and clinical trial sites.
Electronic Data Capture (EDC)	iMednet EDC helps sponsors and CROs streamline study build, execution, and management. Core features include AE con med linking, lab normals, medical coding, monitoring trip reports, redaction tool, reporting, and targeted SDV. iMednet EDC allows for quick study replication from templates to reduce study build times, allowing partners to manage post go-live protocol changes. Intelligent build tools, such as study design wizards, include date comparison and workflow manager. Studies can be set up in a matter of days.
Randomization and Trial Supply Management (RTSM)	iMednet Randomization can be configured rather than programmed to meet the specific needs of a study, making it quick and easy to randomize. iMednet Trial Supply Management makes it easy to manage research product inventory, including auto assignments, auto resupply, manual requests, shipments, tracking, and reporting.
Adjudication	With iMednet Clinical Adjudication, the Clinical Events Committee (CEC) can access and record critical safety data, while managing the process online with glance reporting tool and dashboards that allow complete visibility to individual Adverse Events (AEs), adjudication results, and summary metrics.
Electronic Patient-Reported Outcomes (ePRO)	iMednet ePRO makes on-site and offsite data capture easy for study participants. Optimized for mobile devices, iMednet ePRO allows subjects or coordinators to intuitively enter study-related information, and is accessible – anytime, anywhere.
Payments	iMednet Payments seamlessly allows research teams to take full control of site payments, customize triggers, automatically populate default payment values when new sites are added, streamline tracking of all site payments, and access a complete transaction history.
Application Programming Interface (API)	Mednet simplifies export or import of clinical trial data. Whether through its Data Import Manager or API, iMednet is designed to efficiently share data with other systems and effectively meet the evolving demands of today's study designs and requirements. iMednet's robust, bidirectional API allows teams to integrate with a wide range of other clinical research technologies, including CTMS, eCOA, eTMF, eConsent, and more.

Mednet | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality present via platform partners

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Mednet | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality present via platform partners | Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Mednet | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality present via platform partners | Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Mednet | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
API	Product enhancement	Launched API in connecting third-party eClinical vendor solutions in 2021
20th anniversary	Milestone	Celebrated Mednet's 20th anniversary
Star performer	Recognition	Selected by Everest Group in 2020 as Star Performer based on YoY improvement in both market impact and vision and capability
Mednet value program (MVP)	Partnership program	In 2019, announced a new partnership program to provide extra services and benefits to better support and provide additional value to CROs and other types of partners
RTSM	Product enhancement	Launched Randomization and Trial Supply Management modules in 2017
Most outstanding eClinical solution	Recognition	Received Healthcare & Life Sciences award in 2016 for Most Outstanding eClinical Solution
Silver Stevie	Recognition	Received 2015 American Business Award – Silver Stevie
Healthcare product of the year	Recognition	Recognized by Business Intelligence Group in 2014 as Healthcare Product of the Year

Merative | clinical development platforms profile (page 1 of 8)

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

- Merative enjoys good enterprise mindshare in the next-generation technology and cognitive space, allowing it to cross-leverage the expertise for the clinical trial value chain
- It provides good technical expertise and support services in terms of cloud migration and BPaaS services
- It offers a modular approach in its clinical development software, enabling clients to select (and pay for) only the modules that they want
- Clients mention that the EDC offering is user-friendly, offers lots of flexibility, and is easy for the sites and CRAs in public reviews

Limitations

- Merative has a limited focus on developing an end-to-end platform for clinical development
- Clients cite domain expertise as an area of improvement for Merative
- It has limited capabilities around regulatory, quality, and safety affairs, as well as for conducting virtual trials
- Clients mention their skepticism around using Merative for large clinical studies

Merative | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Merative aims to transform clinical research, reduce administrative burden on clinical centers, and engage with patients in their journeys toward healthy lives. Merative clinical development supports a variety of clinical study types, whether focused on a medical device or a therapeutic area in a trial during early to late phases.

Overview of the client base

Merative caters to governments, providers, health plans companies, and the top 20 pharma companies to help benefit from the data.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

Low (<10%) Medium (10-35%) High (>35%)

Biopharmaceuticals	Medical devices	Others

Revenue by buyer size[1,2]

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

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

Revenue by value chain element[1,2]

Low (<10%) Medium (10-20%) High (>20%)

Trial design and start up	Trial conduct and closeout	Quality management
Regulatory	Safety	

Revenue by geography[1,2]

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

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

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

Merative | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1: Built a database for dependable clinical studies

Business challenge

Southern Star Research wanted to build a technology platform that would allow its data managers to rapidly develop and deploy clinical studies without the help of IT staff and programmers.

Solution

Merative Health® created a brief study build program that provided Southern Star Research with a unified system for EDC and comprehensive training in building clinical studies. Also, Merative Clinical Development platform offered solutions that helped streamline clinical trial processes. From electronic patient-reported outcome (ePRO) to Randomization and Trial Supply Management (RTSM) and more, Merative helped clinical research teams launch and complete studies efficiently, bringing the needed tools to patients sooner.

Impact

- Enabled creation of case report forms, launched a study, and received the necessary resources and credentials for deploying future studies in under a week
- Provided a security-rich and intuitively rendered cloud-based EDC that supported advanced data integration, medical coding, reporting, and analytics for clients

Case study 2: Merative Health™ to design and manage complex clinical trials

Business challenge

Worldwide Clinical Trials (Worldwide) wanted to focus on its core competency and programming the databases that support clinical trial management.

Solution

Merative enabled Merative Clinical Development solution for worldwide clinical trials to capture, manage, and analyze the vast and varied data from complex, multi-site trials.

Impact

- Managed more than 300 clients using the Merative clinical development solution
- Custom reports were generated quicker than before
- Add protocols were updated and revised with ease

Merative | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Electronic Data Capture (EDC)	Merative's cloud-based EDC system is a computerized system designed for collection of clinical data in electronic format for human clinical trials. EDC replaces the traditional paper-based data collection methodology to streamline data collection and improve the time-to-market for drugs and medical devices. This solution is considered the core of the Merative Clinical Development platform.
Patient engagement (ePRO)	The technology replaces conventional reporting methods and allows patients to share important information with caregivers securely at any time. It helps provide informed decision-making through evaluation of on-demand source data.
Data integration	The data integration solution enables timely, automatic integration of data from diverse sources, which helps minimize data entry and maximize study team efficiency. Data is integrated directly into the multi-tenet SaaS solution for ease of access, stability, and security. Merative also provides an in-house training program that teaches users to build studies and control data integration.
Reporting and analytics	Merative's Smart Reports is powered by Merative Cognos Analytics, the company's business intelligence suite that helps to create single- and cross-study reports to facilitate high-level analyses and decision-making. Smart Reports enables researchers to discover new patterns and relationships from data and provide additional insights to clients.
Medical coding	It is directly integrated into Merative Clinical Development's EDC. Users performing medical coding can access electronic data capture for data review, queries, and other study tasks. It uses medical coding features that go beyond standalone services – using trial data and management workflow to give users greater power. Standard dictionary updates provide a complete and clear process for all coding procedures.

Merative | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
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Merative | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
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Merative | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
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Merative | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
iBio and Mateon	Free access	In 2020, iBio, a biotechnology company, and Mateon, a biopharmaceutical company, were selected by Merative Health to receive 18 months of free use of Merative's ICD solution. Merative Health recently began offering its ICD solution to eligible trial sponsor organizations as part of its efforts to help support the medical community to address the COVID-19 pandemic.
Merative My Clinical Diary Mobile	Product launch	In 2020, Merative launched My Clinical Diary Mobile app to provide flexibility to the participants in a clinical trial to complete electronic diaries, questionnaires, or feedback surveys during the study. The app syncs with the Merative clinical development system to allow participants to enter data from any location.
Data-driven tool	Product launch	In 2020, the company launched its data-driven tool, Merative Study Advance. The data-driven study design tool optimizes clinical trial protocol design by merging automated access to real-world patient population data, standardizing protocol template guidance, and providing a collaborative workspace designed to facilitate efficiency.

Navitas Life Sciences | clinical development platforms profile (page 1 of 8)

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

- Navitas Life Sciences has good clinical domain expertise and follows a consulting-led model for deal solutioning and enterprise engagements
- It focuses on the next-generation technologies with the OneClinical platform – an AI- and ML-based platform offering near real-time data visibility and analytics in an outcome-based engagement model
- It has a wide partnership ecosystem for implementation and support service for its solutions

Limitations

- Navitas Life Sciences is heavily focused on consulting and services as compared to products and platforms for clinical development
- It has limited focus on developing an end-to-end modular and interoperable clinical development platform suite

Navitas Life Sciences | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

The company aims to bring together the best minds in the industry to provide life sciences companies with an adaptive, innovative, and reliable partner, consistently delivering better outcomes across the value chain. The company has partnered with over 100 innovator and generics sponsors to drive outcomes for life sciences. Navitas Life Sciences has the capabilities to support the regulatory end-to-end life cycle management across the entire value chain of drug and device regulatory environment.

Overview of the client base

Navitas Life Sciences has a broad portfolio of clients for clinical trials products, ranging from small and midsize organizations to large global pharmaceutical companies. It serves global sponsors in pharma, biotech, medical device, diagnostic, and consumer health companies across the US, Europe, and Asia.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

Low (<10%) | Medium (10-35%) | High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1,2]

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

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

Revenue by value chain element[1,2]

Low (<10%) | Medium (10-20%) | High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1,2]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

Navitas Life Sciences | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1	Adaptive design for a First-in-Class therapy for critical COVID patients

Business challenge

The US-based midsize biotech company needed a partner to support end-to-end development of its first-in-class therapy for critically ill COVID-19 patients. The phase 1 study had been conducted in the US, and the company needed a partner to conduct the Phase II study in multiple countries – the US, India, and other potential countries. The client was looking to have a fast-paced program approach to reach patients faster.

Solution

Navitas Life Sciences collaborated with medical writers, medical leads, and biostatistics teams to deliver a well-designed innovative and adaptive, two-stage study protocol within a short span. Its medical and statistical leads collaborated to develop a Hybrid-adaptive study design as per the latest recommendations on innovative complex protocol designs.

Impact

Study design was accepted and appreciated by USFDA

Case study 2	Personalized study support and effective study initiation of a global Multi-center Orphan Phase 3 Imaging Trial

Business challenge

A Swedish biotechnology company wanted to seek full-service clinical trial operation and strategy support for the design and execution of their global phase 3 trial, which was to be implemented across three continents. The client wanted to create a database and study documents, manage 15 US-based sites, and wanted clinical monitoring and regulatory support.

Solution

Navitas Clinical Research, a part of Navitas Life Sciences, worked with the client to provide efficient and effective full-service clinical trial support for this pivotal study.

Impact

- Effective study support from protocol design to assisting with contract negotiations
- Enabled early identification of recruitment impediments for proactive protocol amendment
- Activated four sites in the US

Navitas Life Sciences | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
OneClinical	It is a cloud-enabled clinical analytics platform that provides real-time, high-quality data and optimizes clinical trials. The platform provides clinical and operational data capture, data aggregation, analytics monitoring, and submission capabilities. It can perform end-to-end clinical trial data management, data visualization, analytics, monitoring, and submission services.
Biologics or biological products	These products are drugs that are manufactured from living organisms using complex processes. These drugs must be handled and manufactured with care. Biologics include therapeutic proteins, cell therapies, monoclonal antibodies, and vaccines.
COVID-19 clinical trials	There are end-to-end clinical trials solutions to take COVID-19 products to successful outcomes.
Clinical data services	The company provides clinical data services across clinical data management, biostatistics & statistical programming, clinical data standardization, and medical writing.

Navitas Life Sciences | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Navitas Life Sciences | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Navitas Life Sciences | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Navitas Life Sciences | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
UL	Industry partnership	In 2022, it partnered with UL, the global safety science leader, to provide life sciences organizations with Learning Management Systems (LMS) to help optimize operational efficiency and meet regulatory compliance through learning management.
DataCeutics Inc.	Acquisition	In 2019, acquired DataCeutics Inc., a specialty Clinical Functional Service Provider (FSP), to augment global clinical data sciences services. The acquisition strengthened Navitas Life Sciences in its high-end data sciences capabilities, which include clinical data management, biostatistics and statistical programming, medical writing, data standards, and conversions. The acquisition also helped Navitas strengthen relationships with major pharma companies in North America.
KAI Research	Acquisition	In 2019, acquired KAI Research, a US-based full-service contract research organization and health research company. The acquisition strengthened Navitas' capabilities in areas such as clinical trial management, clinical research consultation, and data management & standardization. It also helped the company expand its Phase II and Phase III capabilities in North America, Europe, and APAC.
ThoughtSphere	Industry partnership	In 2019, partnered with ThoughtSphere, a cloud-based clinical data hub and analytics SaaS company, to power OneClinical Analytics, the digital clinical analytics platform of Navitas Life Sciences. The partnership helped Navitas deliver better clinical trial oversight and actionable insights for faster decision-making, leveraging capabilities such as AI and machine learning.

SAP | clinical development platforms profile (page 1 of 8)

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

- SAP has a vision toward a standardized and interoperable platform for clinical supply networks and large pharma enterprises are moving in that direction, adopting the ICSM solution
- It has deep expertise in the supply network and it cross leverages its experience from other industries into clinical development
- It enables service providers to innovate and develop capabilities on top of its platforms and solutions
- Clients appreciate SAP for its robust and sound technical architecture
- It adopts a flexible approach to client management and quick resolutions of support issues

Limitations

- Clients mention that SAP lacks life sciences domain expertise but also appreciate the fact that it is putting efforts into building that expertise; both internally as well as via partners
- Its price points have been deemed to be higher than similar solutions
- Clients cite difficulty in scaling and adding customizations to the solution

SAP | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

SAP's vision for pharmaceutical companies that run clinical trials to get their drugs approved for their target markets is to use its Intelligent Clinical Supply Management (ICSM) solution that offers a compelling way to plan clinical trials and ensure there is the right amount of medication available at sites (hospitals), ensuring that trials are executed without interruptions. Unlike other solutions, the new ICSM solution offers web-based SAP Fiori screens. It has a cloud component (study master and demand forecasting) and offers an integration into SAP S/4HANA systems (make and deliver).

Overview of the client base

SAP is an established ERP vendor for pharmaceutical, medical devices, and biopharma companies across the spectrum of procurement, supply chain, logistics, and distribution.

Clinical trial platforms revenue (excluding services)[2]

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

Low (<10%) | Medium (10-35%) | High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1,2]

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

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Revenue by value chain element[1,2]

Low (<10%) | Medium (10-20%) | High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1,2]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

SAP | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1	Optimize processes with predictive analytics and accelerate the digitalization journey

Business challenge

Roche depends on R&D finance for financial forecasts that direct the company's innovative drug development. It wanted to optimize its processes with predictive analytics and find more efficient ways to execute the manual and time-consuming finance forecasting process across the decentralized R&D business units.

Solution

Roche implemented the SAP Analytics Cloud solution to take advantage of embedded predictive planning. Native integration with the existing data foundation in the SAP Business Warehouse application powered by SAP HANA allowed the company to take advantage of years of historical data. This enabled more accurate and harmonized forecasting in a matter of hours, rather than weeks.

Impact

- Roche streamlined its financial forecast process to generate a US$4.2 billion forecast
- Roche successfully shifted the focus of the R&D finance organization from traditional bottom-up financial forecasts to an automated predictive forecasting process. This enabled the company to automate 14,000 out of 20,000 forecast data entry points

Case study 2	Strategic enterprise analytics to enhance critical decision-making

Business challenge

Parkland, a modern acute care hospital, wanted to help Emergency Room (ER) staff by making them well-informed and enable them to take timely and efficient decisions.

Solution

The company developed ER Greaseboard using SAP®Analytics Cloud solution, which is powered by SAP HANA® and SAP Cloud Platform, to efficiently manage ER volumes.

Impact

Helped clinical staff at Parkland to deliver better patient outcomes

SAP | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
SAP Business Technology Platform (BTP)	It provides users with a cloud environment to develop, manage, extend, and deliver applications.
SAP S/4HANA	It helps to downstream product development teams to collaborate and complete product definitions using a comprehensive set of applications tailored for discrete manufacturing with the SAP S/4HANA R&D/engineering solution.
SAP Intelligent Clinical Supply Management (ICSM)	It is a solution that leverages the power of SAP S/4HANA software together with the SAP Industry Cloud technology to automate and improve the clinical supplies process and gain better visibility into the status of supplies worldwide.
SAP EPD	SAP Enterprise Product Development enables clinical suppliers, CMO's exchange and collaborate on specification database
SAP PLM	SAP Product life cycle Management enables sponsor and clinical manufacturing companies record and report master recipe and other PLM functions.
SAP Fieldglass	SAP Fieldglass solution enables CROs to exchange contracts.
SAP SCC	SAP Supply Chain Collaboration aids CMOs to connect, collaborate, and exchange procurement transactions.
SAP ATTP	SAP Advance Tract and Trace for pharma enables serialization of clinical finished goods.
SAP EWM	SAP embedded and decentralized Enterprise Warehouse Management enables clinical distribution companies track and trace their warehouse movements.
SAP SAC	SAP Analytics Cloud
SAP MDG	SAP Master Data Governance enables clinical finished goods creation to align with clinical studies.

SAP | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality present via platform partners | Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
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Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	Real-time CTSM and IRT integration to study
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

SAP | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality present via platform partners

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
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SAP | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality present via platform partners

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

SAP | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Boehringer Ingelheim	Industry partnership	In 2021, partnered with Boehringer Ingelheim to create a smart app designed to track, trace, and authenticate prescription medicines in the United States.
Pharmaceutical industry pilot	Other	In 2021, SAP completed an industry-wide pilot utilizing Self-sovereign Identity (SSI) credentials to establish trust in the pharmaceutical supply chain for indirect trade relationships.
Alkem Laboratories	Collaboration	In 2020, Alkem Laboratories selected SAP Ariba solutions to accelerate procurement transformation.
Automated COVID-19 contact tracing	Other	In 2020, when COVID-19 hit the world, SAP automated and speeded up contact tracing.
BTP vendors	Collaboration	SyMetric, Aris Global, and Medable (2018)
Partner announcements	Quarterly series	Filling in whitespaces for R&D solutions while enabling potential partner ecosystem

TCS | clinical development platforms profile (page 1 of 8)

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

- TCS ADD platform is an adaptable and easy-to-deploy solution. Clients enjoy the flexibility to opt for the entire solution spectrum or pick modules and add more in the future
- Clients appreciate TCS for its solution designing, especially its expertise in data integration and management
- TCS ADD is adaptive to client requirements and brings in high-quality technical experts for designing and implementing tailor-made solutions
- Clients rank TCS high for its competitive and innovative pricing models, resulting in cost savings and benefits
- It is appreciated for its client relationship management and project management abilities

Limitations

- TCS can look to increase its domain expertise in clinical operations so that clients can consider TCS as their strategic partners along with being the implementation partners
- Clients cite difficulties in integrating (lacking APIs) solutions provided by TCS with their existing clinical development solutions
- TCS ADD can look to update its technology stack and stay up to date with the latest innovations to match client expectations
- Clients mention that the testing and delivery of solutions can become more robust and error-free

TCS | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

TCS ADD™ has a vision is to build a suite of modern & open technology platforms for life sciences that can enable digital ecosystems, simplify data complexity, and provide faster access to new and effective drugs for patients in need.

Overview of the client base

TCS ADD™ Platforms work with 9 of the Top 10 life sciences companies as customers. Since customers are global pharmaceutical companies having worldwide operations, solution implementation and application transcend geographical boundaries. Some of the key customer profiles include a global (Top 5) multinational pharma and medical devices company, a global European multinational pharma, a global top 20 based pharmaceutical conglomerate, an Indian multinational pharmaceutical company, and a US biopharmaceutical company

Clinical trial platforms revenue (excluding services)[2]

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1]

Low (<10%) Medium (10-35%) High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1,2]

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

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

Revenue by value chain element[1,2]

Low (<10%) Medium (10-20%) High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

TCS | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1: Redesigned operational analytics framework

Business challenge

- Lack of site-/study-specific clinical operations oversight
- Inefficient prediction of outcomes due to static monitoring of site/study
- Data silos and disparity impedes decision-making
- Disjointed communication between site/study teams

Solution

- Data model – single repository of harmonized data from 10+ data sources
- Key risk indicators – proactive study, site risk identification, and management
- Predictive analytics – dynamic monitoring through predictive modeling for site workload and risks
- Actionable insights – system generated intelligent actions

Impact

- Lower site monitoring cost due to dynamic approach
- Actionable insights led by data-driven decision-making
- Reduced workload due to automation
- Accelerated product submission to market

Platform is live for 300+ studies

Case study 2: Cognitive automation solution for pharmacovigilance

Business challenge

- Automate its end-to-end safety case intake and processing operations
- Reduce time and effort
- Increase accuracy and quality
- Manage blips smoothly
- Collect, manage, and analyze data through use of cognition to meet business outcomes

Solution

- Intelligent case processing – AI-enabled, automated end-to-end safety case processing for adverse events and product technical complaints
- Automated processing operations – reduce time & efforts and increase accuracy and quality
- Enhanced operational efficiencies through innovative AI technology & simplified safety processes
- Fastest ever end-to-end go-live (less 1 year)

Impact

- 96% accuracy in fields processed
- 40% efficiency gain in case processing efforts
- 30% cost savings in end-to-end case processing
- 100% compliance to regulatory timelines

TCS | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
TCS ADD™ Platforms	A suite of modern and open technology platforms for life sciences organizations, powered by cognitive artificial intelligence engine, data-driven smart analytics, and IoT that provides superior business value to the pharmaceutical industry
TCS ADD™ Metadata Repository Platform	A ready-to-use, interoperable metadata driven AI solution that automates study build, enables robust governance, and rapidly transforms and generates submission-ready datasets
TCS ADD™ Data Management	A one-stop, integrated, cloud-deployed, self-service platform that caters to all data management needs of the pharma industry
TCS ADD™ Analytics and Insights	A data science platform that leverages AI & ML technologies to provide predictive use cases such as adaptive monitoring and site feasibility, and enables quicker data-driven decisions, faster study start up, and targeted study interventions
TCS ADD™ Connected Clinical Trials	A decentralized trials platform that digitally harmonizes clinical trials processes using modern and embedded technologies for accelerated speed to market
TCS ADD™ Safety	An advanced operation platform that enables automated intake, processing, and reporting of high safety case volume with quality, accuracy, and consistency
TCS ADD™ Regulatory	It leverages state of art technologies (e.g., AI, mobility, and blockchain) to automate regulatory processes to enable faster and in-compliance drug registration

TCS | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
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Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

TCS | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	Study data tabulation model (SDTM) support	Real-world data (RWD) integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Identify critical data to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Inbuilt checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Document the conduct of risk review activities according to trial risk plan
Trial master file management	Plan expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	Informed consent form (ICF) distribution, tracking, and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

TCS | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	Health authority (HA) interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
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Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integrate data from different sources	

TCS | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Joint Customer Presentation	Industry conferences	TCS and J&J co-presented at SCOPE Summit Europe '22 on Redefining dynamic monitoring with an AI-based predictive analytics approach
AI-driven Smart Pharmacovigilance	Initiative	TCS hosted a panel discussion with speakers from Amgen, AstraZeneca and Moderna. The topic was Unlock the Future of AI-driven Smart Pharmacovigilance
Dynamic Monitoring in Clinical Trials Oversight	Initiative	TCS ADD™ Analytics and Insights collaborated with J&J to host a cross industry webinar on Dynamic Monitoring in Clinical Trials Oversight. Panelists included business stakeholders from AbbVie, Bristol-Myers Squibb, MSD, and Triall
Corporate Awards and Recognitions	Investment	TCS ADD™ Regulatory won the India Pharma Awards 2021 under Excellence in Ancillary Pharma Services category
Thought Leadership Advocacy	Initiative	TCS ADD™ subject matter experts have provided their unique techno-functional perspectives on various industry-mapped topics including eConsent, smart medication, regulatory chatbots, omni-channel intake in pharmacovigilance, and eTMF integrated with blockchain
Corporate Awards and Recognitions	Investment	TCS ADD™ Connected Clinical Trials Platform – won Citeline Award 2020 for best Patient-Facing Technology
Corporate Awards and Recognitions	Investment	TCS ADD Safety Platform – won 5th Annual AI awards 2021 Award for best technical implementation for AI category
Virtual Regulatory Cross Pharma	Initiative	In 2021, hosted a virtual Regulatory Cross-Pharma Event, co-hosted by Janssen. The event covered 10+ industry-mapped topics and saw a participation from 8+ pharma logos
CDISC Interchanges	Initiative	In 2021, organized a joint speak session with Boehringer Ingelheim at 2021 CDISC Europe and US Interchanges on 'implementation of Clinical Metadata Registry (MDR)

03

Enterprise sourcing considerations

- Aspirants
  - Calyx
  - CliniOps
  - Datatrak
  - Labcorp Drug Development
  - Signant Health

Calyx | clinical development platforms profile (page 1 of 8)

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

- Calyx brings in good capabilities around trial conduct with its Interactive Response Technology (IRT), EDC, and CTMS solutions
- It utilizes the CRO partnerships as a strategic channel to scale its products and expand its geographic presence

Limitations

- Calyx has limited capability around regulatory, quality, and safety value chain segments
- It can look to refine its marketing strategies, highlighting success stories covering all its solutions to gain enterprise mindshare in the clinical development landscape
- It lacks the end-to-end vision platform vision and markets its products individually

Calyx | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Calyx is helping the field of clinical research. Backed by technology, solve for the customer and their patients around the world whose lives depend on the treatments they help them develop. With a global footprint, operational infrastructure, and deep scientific knowledge, Calyx solves clinical development challenges to help customers bring new medical treatments to patients who need them, faster.

Overview of the client base

Calyx is investing in innovative technology catering to the global biopharmaceutical industry, sponsors, and CROs; delivered 650+ medical solutions, of which 70 have been recognized in the past.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

Low (<10%) | Medium (10-35%) | High (>35%)

Biopharmaceuticals	Medical devices	Others

Revenue by buyer size[1,2]

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

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

Revenue by value chain element[1,2]

Low (<10%) | Medium (10-20%) | High (>20%)

Trial design and start up	Trial conduct and closeout	Quality management
Regulatory	Safety	

Revenue by geography[1,2]

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

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

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

Calyx | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1	Adaptable EDC-enabled trial continuity during COVID-19

Business challenge

As the pandemic hit the world, patients could not get to clinics for scheduled visits, so accommodations had to be made for home visits, telephone calls, and virtual visits via video. EDC study design needed to adapt to new methods of clinical trial participation to continue capturing important trial data, so that trial sponsors and CROs could keep their studies on track.

Solution

Using Calyx's EDC Design Tool, the client created a COVID-19 Impact page, which captured the details of how COVID-19 impacted study participation. Questions were created to capture the occasions where a scheduled visit or treatment was missed or delayed due to a COVID-19-related issues. If the visit was conducted as scheduled, a data point was created to capture whether it occurred via telephone, video, or a health practitioner's visit to the patient's home.

Impact

The flexibility allowed the sponsor to adapt to a hybrid decentralized trial model, giving traceability of how data points were collected to support the validity of the data.

Case study 2	Enabled medical imaging expertise to support melanoma PD1/PDL1 breakthrough trial

Business challenge

A client approached Calyx Medical Imaging for support with a PD1/PDL1 trial aimed to treat patients with advanced or unreasonable melanoma, who were no longer responding to other drugs.

Solution

Calyx provided senior project management and scientific guidance to help meet the demands of a breakthrough therapy design. The trial was granted accelerated approval by the FDA. Calyx's medical imaging expertise helped achieve regulatory approval.

Impact

- Planned rolled patients increased by 30%
- Selected, trained, and contracted nine additional radiologists and oncologists

Calyx | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Medical Imaging	It delivers reliable data that enables sponsors and CROs to meet their clinical development objectives. The team helps in setting up clinical trial imaging effectively and efficiently from the start, providing consultation on trial design, protocol review, clinical data management, EDC design, and site/investigator training.
Interactive Response Technology (IRT)	IRT system optimizes RTSM processes to propel the development program forward. It guides sites on how and when to enter patient data in alignment with the protocol and minimizes data errors through real-time data entry validation.
Regulatory Information Management (RIM)	It is a cloud-based regulatory information system for optimizing regulatory publishing, submissions, and registrations.
Clinical Trial Management System (CTMS)	It is an industry-proven trial management system that combines trial technology innovation, drug development expertise, and business process optimization to simplify the oversight of clinical trial operations and enable proactive risk management.
Electronic Data Capture (EDC)	It streamlines the entire process from study design to the collection, management, and reporting of clinical trial data.

Calyx | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Calyx | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Calyx | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Calyx | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Partnership with one of the world's Top five CRO	Partnership	In 2021, announced an extended partnership with one of the world's Top five CROs. The arrangement enables the leading CRO to continue providing Calyx's proven Clinical Trial Management System (CTMS) and services to its global biopharmaceutical customers for an additional three years.
ProTrials	Partnership	In 2022, partnered with ProTrials Research, Inc., a midsized full-service CRO specializing in delivering clinical operations services to the pharmaceutical, biotechnology, and medical device industries
Expansion of presence	Expansion	In 2021, expanded its presence by opening headquarters in the US
Catalyst Clinical Research	Partnership	In 2021, partnered with Catalyst Clinical Research to leverage Calyx's Medical Imaging solution for customers' oncology trials
CTMS v15.0	Other	In 2021, launched Calyx CTMS v15.0, an advanced clinical trial management system for reducing risk and improving efficiencies in clinical development
Scientific consulting program	Initiative	In 2021, launched a scientific consulting program aimed at optimizing imaging processes and outcomes to accelerate the clinical development of new medical treatments
Partnership program	Initiative	In 2021, launched a new partnership program for CROs to provide close alignment between Calyx and its CRO partners

CliniOps | clinical development platforms profile (page 1 of 7)

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

- CliniOps has good focus on clinical development solutions such as eSource, CTMS, Clinical Data Management (CDM), and patient engagement solutions
- It offers capabilities for decentralized trials (eConsent, eCOA/ePRO, and remote monitoring) while engaging in partnerships, such as with Stefanini to support BPaaS solutions for DCTs
- It has a wide partnership ecosystem involving hyperscalers (Microsoft and AWS), AI-based healthcare start-ups, and academic institutes focused on R&D and implementation of clinical development solutions

Limitations

- CliniOps is perceived to be a DCT vendor rather than a CDP vendor owing to its positioning and marketing strategies, losing enterprise mindshare in the clinical development space
- It lacks an end-to-end vision for designing a flexible, modular, and interoperable platform for clinical development
- It has limited offerings in the regulatory and safety affairs space

CliniOps | clinical development platforms profile (page 2 of 7)

Overview

Company mission/vision statement for clinical development platforms

CliniOps' vision is to enable complete digitalization of clinical trials, drug safety, and patient care. It wants to provide comprehensive and global solutions for eSourcing, monitoring, and patient engagement, and improve the monitoring function through efficient and timely information exchange via mobile and collaboration technology. It also wants to improve patient engagement through better communication and collaboration and provide eSourcing of data through a multi-channel integration of several electronic sources (EMR, medical device, lab data, ICF, etc.) into a central data hub.

Overview of the client base

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

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

	Low (<10%)	Medium (10-35%)	High (>35%)
Biopharmaceuticals		Medical devices	Others

Revenue by buyer size[1,2]

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

Revenue by value chain element[1,2]

	Low (<10%)	Medium (10-20%)	High (>20%)
Trial design and start up		Trial conduct and closeout	Quality management
Regulatory		Safety	

Revenue by geography[1,2]

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

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

CliniOps | clinical development platforms profile (page 3 of 7)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Study portal	It is a single unified platform to streamline clinical data management, clinical operations, and accelerated regulatory submission processes.
Site app	It is a mobile application that helps with high-quality and real-time electronic data collection at source (eSource).
Patient app	This app makes the clinical trials more patient-centric by enabling data collection via telemedicine, with patients at their homes or at their normal care facility.

CliniOps | clinical development platforms profile (page 4 of 7)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

CliniOps | clinical development platforms profile (page 5 of 7)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

CliniOps | clinical development platforms profile (page 6 of 7)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

CliniOps | clinical development platforms profile (page 7 of 7)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
DOLF data management	Industry partnership	In 2021, it partnered with DOLF studies to enable electronic data capture on iPad and phones.
Microsoft	Industry collaboration	In 2020, it partnered with Microsoft to launch Open Data Campaign, to address the data divide and help organizations of all sizes to realize the benefits of data and the new technologies it powers.
Stefanini	Industry partnership	In 2020, partnered with Stefanini to launch TRUST platform to transform clinical trials. The platform helps digitize and automate trials from the study-building phase to support decentralized, virtual, and hybrid trial capabilities.

Datatrak | clinical development platforms profile (page 1 of 8)

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

- Datatrak has good capabilities covering the trial conduct area of the value chain
- Clients appreciate its support services and training program in public reviews
- Its price points are competitive and results in cost savings
- It has partnerships with CROs and data management organizations in China and Japan. They are enabling Datatrak to expand its geographic presence

Limitations

- Datatrak can look to partner with service providers for enhancing its implementation capabilities and change management services
- It has limited capabilities in the regulatory, safety, and quality value chain areas

Datatrak | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Datatrak's vision is to provide innovative eClinical solutions bundled with premier service offerings to optimize clinical trials. It wants to build and own a multi-lingual and multi-tenant enterprise platform with unified access to clinical applications, database, and workflows. The company delivers a portfolio of software products designed to accelerate the reporting of clinical research data from sites to sponsors to regulatory authorities.

Overview of the client base

The company serves more than 100 CROs, 10 of the top 15 pharmaceutical organizations, and three of the top 10 biotech companies globally. Few other clients are Planet Fitness, Florida Hospital, ICON Clinical Research, Philips, Adventist Health System, and CRA School of Montreal, Canada.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

Low (<10%) | Medium (10-35%) | High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1,2]

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

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

Revenue by value chain element[1,2]

Low (<10%) | Medium (10-20%) | High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1,2]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

Datatrak | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1	Helping a biotech company address randomization and clinical supply management issues

Business challenge

The biotech start up needed a cost-efficient solution to address a variety of challenges in randomization and clinical supply management. Optimizing clinical supply management, shipping procedures, and cost was a priority for the client.

Solution

The company provided Datatrak One software suite as a solution, utilizing its UX EDC & Medical Coding product to capture and clean the data, and its UX Randomization & Trial Supply Management product to manage randomization and clinical supplies.

Impact

Leveraging Datatrak software suite, the client saved over US$1.3 million on the trial as a result of a streamlined supply process and consistent data quality, delivered in real-time.

Case study 2	Providing EDC services to a global CRO

Business challenge

A leading global CRO ran a series of trials on behalf of a US-based company, among the Top 20 pharmaceutical sponsors, which was looking for an EDC provider that could anticipate study needs and provide the required services in time. The series of trials included sites in Japan.

Solution

Datatrak has experience in working with global sites such as Japan. It developed a strategic partnership in Japan, empowered with expertise in the Datatrak platform and experience with the Pharmaceuticals and Medical Devices Agency (PMDA). In collaboration with the client, Datatrak and its strategic partner anticipated the needs of the sites and successfully collaborated to provide the client with detailed eCRF completion guidelines. Upon completion of the trials, the PMDA reviewed them and found only one trial, the Datatrak trial, had translated the eCRF guidelines.

Impact

By leveraging the company's long-term strategic partnership in Japan to anticipate the needs of both the client and the PMDA, the Datatrak trial cleared regulatory approval and delivered both cost and time savings to the client.

Datatrak | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Datatrak Clinical Trial Management System (CTMS)	It transforms clinical operations and clinical data management with the suite of clinical solutions, offering EDC, coding, data management, study start up, eTMF, CTMS, and payments on a single cloud platform.
Datatrak Electronic Data Capture (EDC)	The platform is used by sponsors and CROs to build studies and capture data for clinical studies. It equips study teams with easy-to-use tools for quick and efficient data collection at the source on any device or desktop. It also provides reporting capabilities, allowing study team members to easily access, filter, and export real-time study data into clear and concise reports whenever required.
Medical imaging capture solution	It is an effective approach for managing imaging components of a clinical trial. The platform can accept any type of file, including DICOM, JPEG, audio files, text documents, and much more.
Datatrak direct	The platform uses an iOS or Android app to capture data directly from patients using their own mobile devices such as phone, PC, or tablet. All patient-entered data is stored on the Datatrak enterprise cloud. It allows users to enforce and track compliance with flexible form design for Electronic Patient-Reported Outcome (ePRO), Electronic Clinical Outcome Assessment (eCOA), and Electronic Informed Consent (eConsent) data.
Risk-based monitoring solution	The solution allows surveillance of clinical trial progress with focus on risks, delays, and inspection readiness. Portfolio oversight gives transparent reporting of progress across a portfolio of trials without vendor or CRO dependency.
Datatrak randomization & trial supply management (RTSM)	The platform supports all types of protocol requirements, while dispensing, controlling, and automating drug supply fulfillment. The robust manager tool lets users view, filter, update, and export information on drug containers, drug assignments, shipments, and randomization schedules on demand.
Medical imaging capture	The platform allows for the analysis and annotation of image data, including the versioned images, processed into Datatrak's EDC platform. Medical imaging and its embedded data play a pivotal role in new protocol development. This is becoming a critical source of big data and the demand for analytics for better decision-making.
Datatrak trial design	It streamlines the entire design-to-deployment process using a single tool. Trial designers can configure their studies using a visual or data architect in several solutions of the Datatrak cloud, including EDC and RTSM. Designs and changes can be viewed in the trial design environment before committing the files into the versioning repository. As the study continues through the deployment process, trial design offers a test environment and tracks user acceptance testing within an approval environment.

Datatrak | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
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Datatrak | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
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Datatrak | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
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Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Datatrak | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
RedMD	Industry partnership	In 2022, Datatrak International, Inc. and RadMD partnered to provide end-to-end medical imaging solution
ePRO, eCOA, and eConsent Solution	Investment	In 2021, launched ePRO, eCOA, and eConsent Solution to support the advancing of decentralized trials globally.
Renibus Therapeutics	Industry partnership	In 2020, the company partnered with Renibus Therapeutics for COVID-19 clinical trials. Renibus has been fast-tracked by the FDA to begin a Phase 2 study to evaluate the effects of their drug, RBT-9, in COVID-19 patients who are at high-risk of deteriorating health due to age or comorbid conditions such as kidney or cardiovascular diseases.
SCOPE Summit 2020	International summit	In 2020, the company took part in SCOPE Summit 2020. The Summit provided Datatrak an opportunity to connect with clinical operations and research executives to showcase the value its technology platform offers in reducing the operational costs of integrating redundant standalone systems.
NTT DATA	Partnership and geographic expansion	In 2019, partnered with NTT DATA. Under the terms of the agreement, NTT DATA will expand its sales and support beyond EDC to include the larger Datatrak enterprise cloud for Japan and the growing Asia Pacific market.
DIA Japan Annual Meeting in Tokyo, Japan	International conference	In 2019, the company exhibited its enterprise cloud capabilities at DIA Japan Annual Meeting in Tokyo, owing to the growing interest in and engagements of e-clinical platforms.

Labcorp Drug Development | clinical development platforms profile (page 1 of 8)

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

- Labcorp Drug Development leverages its CRO heritage to gain high enterprise mindshare in the clinical development landscape
- It has good capabilities around EDC, integrating external data sources, and real-world data for submission and receiving data from remote devices and platforms as part of clinical trials
- Clients appreciate the Xcellerate Risk and Issue Management solution, capable of creating a single system of record to create, view, and manage risks, actions, protocol deviations, issues, and decisions

Limitations

- Labcorp Drug Development is heavily focused on services rather than on platform capabilities for drug development
- Its CRO heritage eclipses capabilities as a solution provider or platform vendor
- Clients face challenges with the scattered tech stack, old technologies, and multiple integrations to be performed with other platforms and existing solutions

Labcorp Drug Development | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Labcorp Drug Development provides comprehensive drug development solutions for a range of industries. Its services cover the pre-clinical, clinical, and post-market phases of drug development, the product life cycles for medical device and diagnostics, and development services paired with regulatory support for the chemical testing and crop protection industries. The company is investing in and evolving the existing and new clinical trial solutions to advance healthcare practices and improve lives. It continues to build end-to-end digital solutions for clinical development services. It supports companies with their clinical trials, which involves early clinical / Phase IIa, Phase IIb / III services, clinical data management analysis and reporting, regulatory services, and Phase IV solutions.

Overview of the client base

The company engages with global life sciences clients, which include pharmaceutical, biopharmaceutical, and biotech companies and has supported the top 50 pharmaceutical drugs on the market. It has performed 100 CTA/IND – enabling integrated programs per year.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

Low (<10%) Medium (10-35%) High (>35%)

Biopharmaceuticals | Medical devices | Others

Revenue by buyer size[1,2]

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

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

Revenue by value chain element[1,2]

Low (<10%) Medium (10-20%) High (>20%)

Trial design and start up | Trial conduct and closeout | Quality management

Regulatory | Safety

Revenue by geography[1,2]

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

North America | Europe (excluding UK) | UK

Asia Pacific | Middle East & Africa | South America

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

Labcorp Drug Development | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1 — **Responded to a global crisis with urgency**

Business challenge

A biopharmaceutical company developing a novel treatment for a highly contagious disease was in urgent health crisis and needed to deliver an IND package on an aggressive timeline.

Solution

A risk-assessed, integrated development plan with studies was conducted in parallel to accelerating and meeting the challenging IND filing date. It also partnered with a Labcorp Drug Development team of scientific experts with extensive experience running similar programs to deliver on time.

Impact

- Estimated time saved by 50%
- The client was able to move swiftly in Phase I to determine safety, tolerability, and pharmacokinetics

Case study 2 — **Dedicated project management to integrate vendor activities and expedite program**

Business challenge

A biopharmaceutical company wanted to accommodate its need for an aggressive timeline vs. the prior CRO through partnering with Labcorp.

Solution

Enabled project management of parallel studies at Labcorp and management of activities at another vendor to integrate the project plan. It also escalated key risks to ensure that timelines were met.

Impact

- The IND Program was completed with 6.5 months, which earlier took 9-12 months
- The sponsor successfully progressed to the clinic

Labcorp Drug Development | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
Xcellerate® trial management	The platform includes Electronic Trial Master File (eTMF) and Clinical Trial Management System (CTMS) solutions. It empowers clients to monitor the progress of their studies and identify potential problems early, allowing the right decision-making.
Xcellerate CRA dashboard	Xcellerate CRA Dashboard improves site quality and site performance through monitoring efficiency by delivering critical site and study data to on-the-go Clinical Research Associates (CRAs) via mobile devices.
Xcellerate portfolio dashboard	The Xcellerate Portfolio Dashboard delivers a comprehensive view of the health of a portfolio of studies at any desired level of aggregation to provide increased oversight and collaboration.
Xcellerate medical review	The platform reimagines techniques for patient safety monitoring, increasing both the quality and the efficiency of the medical review process, and improving its ability to inform medical monitoring and clinical operations teams.
Xcellerate case management	It is an RPA, cognitive, and artificial intelligence solution that facilitates the touchless Individual Case Study Report (ICSR) management vision.
Xcellerate data review	The solution gives data managers the power to efficiently manage quality data to ensure database lock readiness.
Xcellerate patient intelligence	The solution helps deliver more patient-centric trials to improve patient recruitment and retention.
Xcellerate risk assessment & categorization tool	The tool facilitates detailed study risk assessment, identification of critical data and processes, and management of portfolio- and study-level risks and mitigation plans through a collaborative electronic process.
The medical review assist tool	The tool supports the medical reviewer or safety physician in reviewing safety source documents and other safety data. The tool applies Natural Language Processing (NLP) to help identify drug event pairs, while leveraging existing medical terminology classifications such as Medical Dictionary for Regulatory Activities (medDRA) and World Health Organization Drug Dictionary (WHODD).
Intake processing assist tool (I-PAT)	The tool completes all intake activities for case processing. It entails a three-level duplicate search on two systems, parsing the information and automated data entry into the database from structured fields of the source documents. The information is collected from consumer call centers, social media, and other consumer-facing platforms, and is used by the company's global case management team.
The case processing assist tool (C-PAT)	It is an RPA tool for assisted case data entry into Argus, ArisGlobal, or any custom database. It automates case data entry for structured source documents and ensures improved quality and efficiency.

Labcorp Drug Development | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

Patient recruitment & engagement	Subject recruitment campaign management	Patient screening and recruitment	Medication adherence support	Patient feedback management	Lay result disclosure
Site activation	Site start up packages	Tracking and follow-up of start up activities	Population of IRB/IEC packages	Gamification of start up activity progress	Site document exchange
Decentralized clinical trial capabilities	eConsent	Remote patient monitoring	Medication adherence	eCOA/ePRO	Televisits
Budgeting and forecasting	Budget forecasting	Ability to track cost per patient/procedure/visit	Financial reporting and statement analysis	Invoice generation and payments support	Support global accounting standards (GAAP, IFRS, etc.)
Protocol design and trial planning	Study design	KPIs to track assessment efficacy	Adverse events and contingency planning	Standardized authoring of study protocols	
Site feasibility and identification	Site assessments across geographies	Operational site feasibility	Site training and life cycle management	Investigator profile management	Site engagement and feedback management

Labcorp Drug Development | clinical development platforms profile (page 6 of 8)

Features of key offerings | trial conduct & closeout

NOT EXHAUSTIVE

Functionality available | Functionality not available

Electronic data capture	Real-time data capture and access	Data capture from different sources (EHR, eCOA, laboratories, etc.)	SDTM support	RWD integration with clinical data	Analytics, intuitive dashboards, and visualizations
Randomization and trial supply management	Demand planning	Randomization and unit allocations	Supplier tracking and responsibility management	Supplier and subcontractor relationship management	Supplier quality and risk management
Clinical data management	Intelligent automation and workflows for seamless data management	Critical data identification to support a risk-based monitoring approach	Unified view of trial data across clinical trial life cycle	Built-in checks for data compliance	Storage of high-dimensional and unstructured data
Centralized/remote and risk-based monitoring	Risk-based process oversight	Centralized, remote on-site monitoring	Site visit planning for on-site and remote site monitoring	Management of risks, issues, decisions, actions, and protocol deviation for sites and subjects	Documenting the conduct of risk review activities according to trial risk plan
Trial master file management	Planning of expected TMF documentation sets including key milestones	Automated document attribution and mapping to placeholders	Receive documents from multiple sources and users	Multi-format records online and offline	Archiving in accordance with compliance regulations
Clinical trial management system	Planning and tracking of project-, trial-, country-, and site-level milestones	Subject recruitment planning and tracking	ICF distribution, tracking and oversight	Management of study standards and types	Manage company, personnel, and study team responsibilities

Labcorp Drug Development | clinical development platforms profile (page 7 of 8)

Features of key offerings | regulatory affairs, quality, and safety

NOT EXHAUSTIVE

Functionality available | Functionality not available

Regulatory information management	Manage global regulatory strategy throughout product development life cycle	Regulatory intelligence	HA interaction management	Company Core Data Sheet (CCDS) management	Reporting and dashboarding for proactive regulatory strategy
Document management	Authoring, reviewing, importing, and exporting of documents and packages	Structured authoring capabilities	Support dossier and submission document management	Automated quality checks and country-specific validators	Archiving of dossiers and document packages
Submission management	Product registration management	Publishing and redaction management	Withdrawal management	Label management	Managing the provision of registration samples to HA
Quality management system	Non-compliance management	Audit and inspection management	Risk management	Document control (audit trail, version control, etc.)	Knowledge and learning management
Medicine supplier monitoring	Track and manage subcontractors	Conduct a supplier-service risk assessment	Oversight plan for the required suppliers	Document the activity status of the supplier	Supplier contract renewal and management
Case processing	Processing of PV information with use of automation and AI tools	Intake of electronic data and manual data entry	Translation capabilities using AI, QC steps, and routing capability	Automated query management	Due date-based workflow and deficiency tracking based on these due dates
Signal detection	Authoring, approval, and implementation of safety monitoring plans	Tracking of observations and activities	Provision of data fulfilling signaling requirements	Integration of data from different sources	

Labcorp Drug Development | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Partnered to deliver at home, self-collection of biological samples	Industry partnership	In 2021, partnered with a pharmaceutical company to advance their studies on a global Phase III program
Transformation of clinical trial experience	Expansion	In 2020, enabled new capabilities to transform clinical trial experience and streamline the drug development process
Fluidigm CyTOF Technology	Industry partnership	In 2020, partnered with Fluidigm's CyTOF Technology and Maxpar Direct Immune Profiling Assay to develop multiplexed immune profiling services
Genfit	Industry partnership	In 2019, the company and Genfit, a biotechnology company, signed a licensing agreement to expand access to a new diagnostic test for non-alcoholic steatohepatitis.

Signant Health | clinical development platforms profile (page 1 of 8)

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

- Signant Health has good capabilities around trial conduct value chain with eCOA, RTSM, telemedicine, and virtual monitoring solutions
- Clients appreciate the technical support team for their quick query resolutions
- It has good patient-centric capabilities for recruitment and engagement

Limitations

- Signant Health loses enterprise mindshare due to its positioning as an evidence generation company, rather than a platform player in the drug development landscape
- It does not serve the pharmacovigilance and quality value chain areas

Signant Health | clinical development platforms profile (page 2 of 8)

Overview

Company mission/vision statement for clinical development platforms

Signant Health focuses on generating the highest quality of clinical evidence that meets even the most complicated regulatory requirements.

Overview of the client base

Signant Health is dealing with CROs and leading life sciences companies and various other medical bodies. It has helped 677 novel drug approvals in the US and Europe since 2016.

Clinical trial platforms revenue (excluding services)

<US$50 million	US$50-150 million	US$150-300 million	US$300-450 million	>US$450 million

Revenue by line of business[1,2]

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1 All the revenue components add up to a total of 100%
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Signant Health | clinical development platforms profile (page 3 of 8)

Case studies

Case study 1 | **Achieved 91% retention rate for vaccine clinical trials**

Business challenge

A pharmaceutical sponsor was looking for a patient engagement partner that could engage with patients in order to reduce protocol deviations while increasing patient retention rates. Due to design of the study, it was crucial that patients did not experience protocol deviations, miss visits or visit windows (defined as visit-related protocol deviations), or drop from the study.

Solution

The customer chose Signant Health's patient engagement solution, Trial Guide, in order to realize the study goals. It is a consumer-grade, regulatory-compliant mobile app and reminder system for patient engagement. It helps patients stay connected and compliant with the study. Patients receive SMS messages reminding them of their upcoming visits, how to handle medications, visit instructions, and encouragement to continue.

Impact

- The study was completed by 91% of trial guide patients
- ZERO protocol deviations observed for 78%
- Visit-related protocol deviations were reduced for 50%

Case study 2 | **SmartSignals eConsent**

Business challenge

Improve patient understanding of multiple, complicated Informed Consent Forms (ICFs), monitors IRB review across a high number of sites, and manage scale across multiple countries and languages.

Solution

The solution allowed patients to access and review the ICF remotely from home before their clinic visit and provided an engaging digital experience with videos and pictures to improve patient comprehension of the study and treatment. Integrated IRB review and remote insights and reporting capabilities helped solve the problem further.

Impact

- Improved overall patient comprehension
- Simplified the IRB submission process for multiple and lengthy ICF
- Managed scale across multiple countries, sites, and languages

Signant Health | clinical development platforms profile (page 4 of 8)

Offerings

Proprietary solutions (representative list)	
Solution	**Details**
SmartSignals eConsent	It is a patient-centric approach that helps to gather informed signatures from around the world.
SmartSignals Engage	It helps in integrating study commitments into the patient's daily life.
SmartSignals RTSM	It ensures investigational products are effectively randomized, distributed, and managed. These algorithms are designed to eliminate overages, expiration, or incorrect assignments to the wrong subjects, safeguarding investments and setting up study for effective and accurate evidence generation.
SmartSignals supplies	It helps in forecasting & planning, supply accountability, and randomization and trial supply management.
SmartSignals telemedicine	It enables one to recruit and assess study participants more efficiently through high-quality, real-time video visits. This secure, virtual platform extends study's reach by giving access to a larger, more diverse population.
SmartSignals virtual monitoring	These are regulatory-compliant video solutions to minimize costs, risks, and administrative burdens of in-person site visits.
SmartSignals clinical data hub	It helps in organizing the growing volume, variety, and diversity of clinical trial data, manage structured and unstructured data, enable continuous data insights, and drive AI-assisted data management.
SmartSignals eCOA	It helps in collecting and delivering accurate data for near real-time analyses. This solution keeps data clean, mitigates potential issues, and meets complex protocols.
SmartSignals data workbench	It empowers data managers to drive clean data faster, speeding time to analysis-ready datasets. It also enables sponsors and CROs to eliminate time-consuming manual steps, as well as drive speed, efficiency, and accuracy in the data cleansing and validation process.
SmartSignals analytics	It helps in ensuring that data collected is valid and of the highest quality attainable so one can trust that analyses and decision-making will generate accurate conclusions.
SmartSignals advisory	It helps in ensuring accurate and reliable data delivery, guided by scientific and medical expertise.

Signant Health | clinical development platforms profile (page 5 of 8)

Features of key offerings | trial design & start up

NOT EXHAUSTIVE

Functionality available | Functionality not available

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Signant Health | clinical development platforms profile (page 7 of 8)

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Signant Health | clinical development platforms profile (page 8 of 8)

Recent developments

Key events (representative list)		
Event name	**Type of event**	**Details**
Investment in clinical data and analytics	Investment	In 2021, invested in ThoughtSphere, a leading provider of data aggregation and analytics software that helps clinical trial sponsors and CROs take control over the increasing volume and variety of clinical trial data.
Enhancement of SmartSignals™ RTSM Platform	Other	In 2021, launched key enhancements to its SmartSignals Randomization and Trial Supply Management (RTSM) solution. It enhanced functionalities including new dashboards, contemporary interface designs, enhanced reporting, and improvements to self-service user management.
eCOA Acceleration Program & Remote Assessment	Investment	In 2021, it launched eCOA Acceleration Program & Remote Assessment, which reduces study set-up timelines by 50% or more without compromising the quality of clinical data generated or the scientific impact of Signant's in-house therapeutic area expertise on study outcomes.
VirTrial	Partnership and geographic expansion	In 2021, Signant Health acquired Virtrial for its digital enablement of clinical research sites and evidence generation capabilities.
Expanding pioneering patient engagement app	International conference	In 2020, it expanded TrialGuide, its pioneering mobile patient engagement app, to enable integrated virtual visit capabilities.

04

Appendix

- Glossary

Glossary of key terms used in this report

Aspirants	Aspirants are the third set of platform/service providers rated by Everest Group, according to Everest Group's proprietary scoring methodology. They have moderate experience and delivery capability
CDM	Clinical Data Management is a software system to ensure collection, integration, and availability of clinical research data
CROs	Contract Research Organization provides research services support to pharmaceutical, biotechnology, and medical devices enterprises on a contract basis
CTMS	A Clinical Trial Management System is a software system to manage clinical trials. The system manages and maintains planning, performing, and reporting functions
EDC	An Electronic Data Capture is a software system that stores patient data collected in clinical trials
ePRO	Electronic Patient-Reported Outcome is a patient-reported clinical trial outcome collected by electronic methods
IP	Intellectual Property includes intangible creations of the human intellect, and primarily encompasses copyrights, patents, and trademarks
ITS	Information Technology Services is the transfer of ownership of some, or all information technology processes or functions to a service provider. This could include core, administrative, delivery, or management-related processes or functions
Leaders	Leaders are the highest rated platform/service providers, according to Everest Group's proprietary scoring methodology, with top-quartile performance across market success and capability
LS	Life Sciences – Everest Group defines the life sciences industry to include organizations in the fields of pharmaceuticals, biotechnology, and medical devices
Major Contenders	Major Contenders are the second-highest rated platform/service providers, according to Everest Group's proprietary scoring methodology, with second or third quartile performance across market success and capability
PV	Pharmacovigilance is a science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products
RBM	Risk-based Monitoring is the process of ensuring the quality of clinical trials by identifying, assessing, monitoring, and mitigating the risks that could affect the quality or safety of a drug
RTSM	Randomization and Trial Supply Management is a software system that randomizes trial subjects (to minimize biases) and manages drug supplies for all trials

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