

Everest Group PEAK Matrix® for Clinical Development Platform Vendors 2020

Focus on Medidata September 2020



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Background of the research

The rising cost of drug development, coupled with increasing regulatory pressures, has led life sciences organizations to rethink the way clinical trials are conducted – the focus is increasingly on failing fast and failing cheap. However, clinical trial challenges, such as siloed data management, delayed timelines due to patient recruitment concerns, and a complex environment of multiple technology solutions, aggravate a pharma organization's woes further. Digital technologies and products have been deployed across the clinical trial landscape to solve for these challenges and bring in efficiencies and automation to reduce manual errors in the process.

Recently, product vendors have started integrating these siloed point solutions into an integrated, modular, and interoperable end-to-end clinical development platform – one platform to address the pharma organization's needs right from study start-up to study closeout. The benefits of a single-platform estate that are claimed include efficient data management, reduced total cost of ownership, and improved visibility of operations. Pharma executives, however, are yet to be convinced about a unified platform approach as they look for success stories and business casing to really move the needle from a best-of-breed approach to a consolidated approach. Everest Group's Clinical Development Platforms – Products PEAK Matrix® Assessment 2020 looks at the current vendor landscape offerings, such platforms, and presents the executive sentiment and insights for such platforms

In this report, we assess the capabilities of 21 IT vendors specific to clinical development platforms and products. These vendors are mapped on the Everest Group PEAK Matrix[®], which is a composite index of a range of distinct metrics related to a vendor's capability and market impact. We focus on:

- Market trends for clinical trials and the associated products market
- The landscape of vendors for clinical trial platforms and products
- Assessment of the vendors on several capability and market success-related dimensions

Geography

Global

Scope of this report:





Industry

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



Vendor offering Clinical development platforms

Clinical development platforms – products PEAK Matrix® characteristics

Leaders:

Medidata, Oracle Health Sciences

- Leaders have established themselves as front runners to support life sciences firms looking to achieve digital transformation within clinical trials
- These players showcase end-to-end clinical development platforms across the clinical trial value chain with highest brand recall among clients
- Leaders support a healthy mix of mid- and large-sized clientele, with accounts in many prominent life sciences firms
- Their platforms are modular and interoperable with next-gen digital technology themes such as AI and automation. Continued investments in the platforms to keep pace with market demands and broaden coverage improve their value proposition to clients
- Major Contenders are eating into the Leaders' market share through innovative and digitally-mature product launches in areas such as regulatory and virtual trials

Major Contenders:

Accenture, ArisGlobal, Bioclinica, Cognizant, Ennov, IBM, IQVIA, Mednet, Navitas Life Sciences, Parexel, PRA Health Sciences, TCS, and Veeva Systems

- Few Major Contenders showcase an integrated end-to-end platform offering. Others offer functionalities in certain parts of the clinical trial value chain, focusing on providing clients with the best-in-class solutions; for e.g., Mednet focuses primarily on the trial conduct value chain
- Most Major Contenders also focus on the small- and mid-pharma clients. Some also partner with CROs to improve the breadth and scope of coverage
- While Leaders have an extensive partner and integrator network, not all Major Contenders engage in system integrator partnerships, preferring to perform implementation and customization themselves
- To capture more market share, some Major Contenders are investing in improving their capabilities to expand their clinical trial value chain coverage or through enhancements in existing portfolio of solutions; for e.g., ArisGlobal launched the LifeSphere regulatory platform, and Veeva launched Vault Payments and a cloud-based data management tool

Aspirants:

Bio-Optronics, Castor, CliniOps, Covance, Datatrak, and eClinicalHealth

- These vendors do not support end-to-end clinical development platforms and offer point solutions focused on a narrow value chain area
- These players are limited by their scale and offer niche products addressing certain themes such as eClinicalHealth with virtual trials and Bio-Optronics with CTMS

Everest Group PEAK Matrix®



Leaders

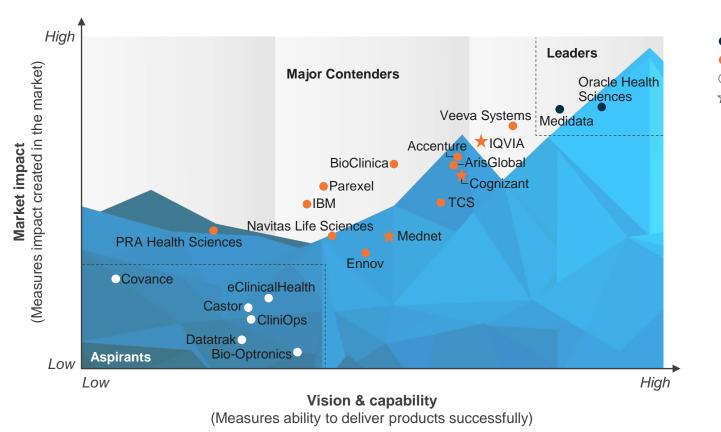
Aspirants

Major Contenders

Star Performers

Clinical Development Platforms Products PEAK Matrix® Assessment 2020 | Medidata positioned as Leader

Everest Group Clinical Development Platforms Products PEAK Matrix® Assessment 2020^{1,2}



¹ PEAK Matrix specific to clinical development platforms

² Assessments for Bioclinica, Bio-Optronics, Castor, CliniOps, Covance, Datatrak, eClinicalHealth, Ennov, IBM, Navitas Life Sciences, Parexel, PRA Health Sciences, 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 pharmaceutical firms that are buyers of clinical development platforms or products



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Medidata

Everest Group assessment – Leader

Measure of capability:





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 user experience delivered by certain products such as its EDC and supporting applications. They are very intuitive, easy to configure, and have a simple design
- Medidata solutions showcase good performance clients have cited 99% uptime and quick query redressal
- Medidata has made focused investments in industry thought leadership, which is being appreciated
 by clients and partners. For example, Medidata NEXT provides a common platform for pharma
 stakeholders and sponsors to discuss and address their challenges
- Large-sized clients have cited good customer support capabilities and limited escalations around the product
- Medidata engineers have good technical expertise and a strong overview of the platform landscape

Areas of improvement

- Medidata's price points have been deemed to be higher than the existing solutions in the market, especially its EDC and RBM solutions
- Disproportionate importance given to different accounts small-sized clients cite delays in addressing escalations or support issues
- Medidata has limited capabilities around integrating data from wearables and sensor technology to manage virtual trials
- Some clients have stated that Medidata may tend to overpromise during deal solutioning and under-deliver during execution, resulting in cost creep and overshooting of budgets
- Migrations from EDC and modifying databases can take time, often requiring custom scripting



Medidata | clinical development platforms profile (page 1 of 4)

Overview

Company mission/vision statement for clinical development platforms

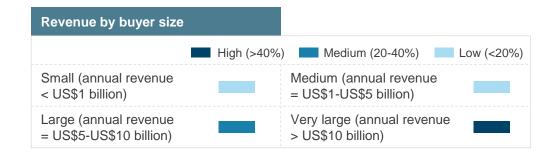
Medidata is driving business transformation across the life science industry. They bring together science, digital technologies, and data in an end-to-end platform that helps deliver innovative therapies to market faster. As part of Dassault Systèmes, Medidata spans the healthcare spectrum from basic research through medical use. Medidata's strategy to accelerate and enhance clinical trials is focused on three key pillars: accelerating, transforming, and modernizing the clinical trials process; utilizing data and analytics to turn data into insights; and ensuring that the patient is more fully able to participate in clinical trials. Their patient-centric approach to the clinical trials process is helping to realize the vision of precision medicine – delivering the right treatment to the right patient at the right time.

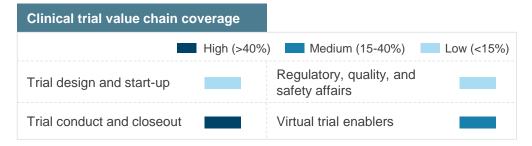
Overview of the client base

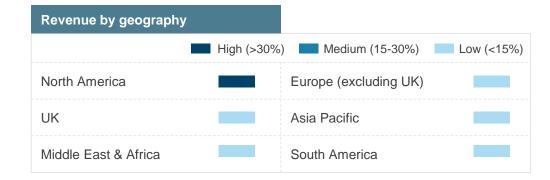
Medidata customers include global pharmaceutical companies; innovative biotech; diagnostic and device firms; leading academic medical centers; and contract research organizations. Medidata services 18 of the top 25 pharma companies, the top 10 contract research organization, 20,000+ clinical trials, and 1,500+ customers.

Clinical trial platforms revenue (excluding services)

<us\$50 million<="" th=""><th>US\$50-US\$150 million</th><th>US\$150-US\$350 million</th><th>>US\$350 million</th></us\$50>	US\$50-US\$150 million	US\$150-US\$350 million	>US\$350 million
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Medidata | clinical development platforms profile (page 2 of 4)

Case studies

Case study 1

Deployed Rave EDC and Rave RTSM to support client's clinical trials

Business challenge

Syneos wanted Randomization and Trial Supply Management (RTSM) services to support its phase I-IV clinical trials. It needed a solution to eliminate the delays associated with disparate custom systems and wanted to reduce the delays caused by custom integrations between EDC and RTSM.

Solution and impact

Medidata deployed Rave EDC and Rave RTSM that allowed Syneos to accomplish build times and manage trial complexity. With the unified platform, site staff benefited from only one point of data entry and avoided redundant processes. Over the last six years, Syneos has implemented over 130 studies in Rave RTSM

Case study 2

Deployed Rave virtual trials to remotely recruit patients and manage the informed consent process, enrollment, and randomization of participants

Business challenge

Duke Clinical Research Institute (DCRI) wanted to conduct a five-year, decentralized trial, called ADAPTABLE, to determine optimal Aspirin dosage to maximize effectiveness, while minimizing side effects. The study required a virtual interface to engage with thousands of patients in remote locations and manage the entire trial process from patient enrollment to virtual follow-up appointments

Solution and impact

Medidata's Rave virtual trials provided the platform to remotely recruit patients, manage the informed consent process, and carry out enrollment and randomization of ADAPTABLE participants between two dosage groups. Over 650,000 patients were identified as matching the inclusion criteria for the study. More than 30,000 people used their unique access codes to enter the patient-friendly Medidata portal via a browser on their desktop, laptop, smartphone, or tablet. The "golden ticket" ensured that the correct informed consent and site information was presented to the right patient. Over 15,000 patients across 40 centers enrolled in ADAPTABLE, making it the 100% virtual pragmatic clinical trial conducted

Medidata | clinical development platforms profile (page 3 of 4) Offerings

Proprietary digital solutions (representative list)				
Solution	Details			
Acorn Al platform	The platform-as-a-service offering includes industrial pipelines that link clinical, real world, and translational domains with data science tools			
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 Rave Clinical Cloud™	The Medidata Rave Clinical Cloud is a cloud-based unified platform. All Medidata's end-to-end clinical trial solutions are 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 multiple integrations between individual products. At the same time, the platform is flexible enough to work with an enterprises' existing systems, processes, and partners			
myMedidata	A patient portal that enables patients to fully participate in clinical trials that use the industry's most comprehensive patient-centric solutions, such as eCOA, eConsent, wearable and biosensors, and virtual trials for site- and remote clinical research			
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			
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 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) to an enterprises' safety system			
Rave CTMS	Clinical software that provides study teams with the ability to plan and manage all clinical 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 and milestone tracking, site monitoring, and issue management			
Rave RBQM	A suite of applications delivering the ability to define and execute a holistic, end-to-end risk-based quality management and monitoring strategy from initial protocol development to database lock			
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 | clinical development platforms profile (page 4 of 4)

Recent developments

Key events	(representative list)	
Event name	Type of event	Details
SHYFT	Acquisition	In 2018, acquired SHYFT, maker of a cloud data analytics platform specifically designed for the pharma and biotech industries, to enhance digital transformation with AI and real-world analytics to reduce risk, optimize revenue, and help patients
Mytrus	Acquisition	In 2017, acquired Mytrus, clinical trial technology company, to enhance capabilities that allow trial organizers to educate patients about the clinical trial experience with multi-media and interactive content
CHITA	Acquisition	In 2017, acquired CHITA, an IT company, to integrate its technology with cloud platform Box
Clinical Force	Acquisition	In 2011, acquired Clinical Force, provider of SaaS-based Clinical Trial Management Systems (CTMS), to leverage its CTMS solutions
Acorn Al	Investment	In 2019, designed Acorn AI to provide actionable insights to the front lines of decision-making by making data liquid across the entire life cycle, from R&D to commercialization
Syapse	Investment	In 2018, invested in Syapse, a new suite of solutions aimed at addressing precision medicine challenges and accelerating clinical research in oncology for trial sponsors
ArisGlobal	Partnership	In 2010, partnered with ArisGlobal, a suite of unified cloud solutions, to reduce risk, prevent redundant data entry, and eliminate the costly and time-sensitive burden of collecting and reconciling safety-related patient data
CRO partners	Partnership	Partnered with multiple CRO partners to provide sponsors with the planning and execution needed for long-term operational growth and efficiency
ICON	Partnership	In 2005, partnered with ICON, a global provider of outsourced development services, to migrate Patient Reported Outcome (PRO) instruments from paper to Medidata patient cloud, Medidata's mobile application for capturing patient-reported data
Almac Clinical Technologies	Partnership	Partnered with Almac Clinical Technologies, provider of computer programming services, to help the biopharmaceutical industry bring new therapies by empowering trial sponsors to proactively manage sites, patients, and clinical supplies through technology and consultancy



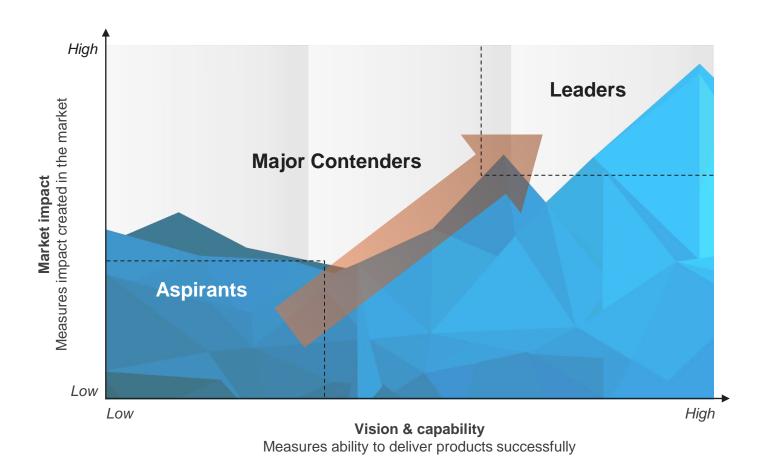
Appendix



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

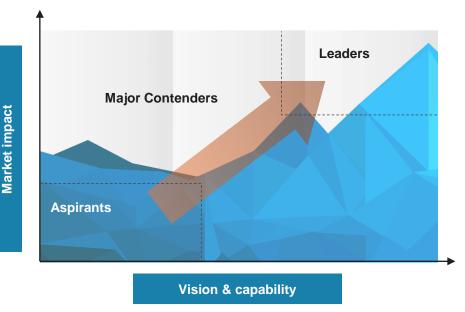
Number of clients, revenue base, and YOY growth

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

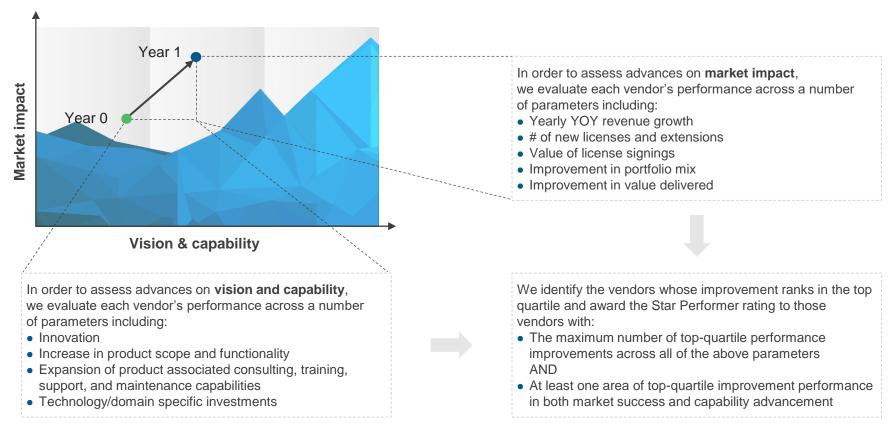


Everest Group confers the Star Performers title on providers that demonstrate the most improvement over time on the PEAK Matrix[®]



Methodology

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



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.



FAQs

Does the PEAK Matrix® assessment incorporate any subjective criteria?

Everest Group's PEAK Matrix assessment adopts an unbiased and fact-based approach (leveraging service provider / technology vendor RFIs and Everest Group's proprietary databases containing providers' deals and operational capability information). In addition, these results are validated / fine-tuned based on our market experience, buyer interaction, and provider/vendor briefings

Is being a "Major Contender" or "Aspirant" on the PEAK Matrix, an unfavorable outcome?

No. The PEAK Matrix highlights and positions only the best-in-class service providers / technology vendors in a particular space. There are a number of providers from the broader universe that are assessed and do not make it to the PEAK Matrix at all. Therefore, being represented on the PEAK Matrix is itself a favorable recognition

What other aspects of PEAK Matrix assessment are relevant to buyers and providers besides the "PEAK Matrix position"?

A PEAK Matrix position is only one aspect of Everest Group's overall assessment. In addition to assigning a "Leader", "Major Contender," or "Aspirant" title, Everest Group highlights the distinctive capabilities and unique attributes of all the PEAK Matrix providers assessed in its report. The detailed metric-level assessment and associated commentary is helpful for buyers in selecting particular providers/vendors for their specific requirements. It also helps providers/vendors showcase their strengths in specific areas

What are the incentives for buyers and providers to participate/provide input to PEAK Matrix research?

- Participation incentives for buyers include a summary of key findings from the PEAK Matrix assessment
- Participation incentives for providers/vendors include adequate representation and recognition of their capabilities/success in the market place, and a copy of their own "profile" that is published by Everest Group as part of the "compendium of PEAK Matrix providers" profiles

What is the process for a service provider / technology vendor to leverage their PEAK Matrix positioning and/or "Star Performer" status?

- Providers/vendors can use their PEAK Matrix positioning or "Star Performer" rating in multiple ways including:
- Issue a press release declaring their positioning. See citation policies
- Customized PEAK Matrix profile for circulation (with clients, prospects, etc.)
- Quotes from Everest Group analysts could be disseminated to the media
- Leverage PEAK Matrix branding across communications (e-mail signatures, marketing brochures, credential packs, client presentations, etc.)
- The provider must obtain the requisite licensing and distribution rights for the above activities through an agreement with the designated POC at Everest Group.

Does the PEAK Matrix evaluation criteria change over a period of time?

PEAK Matrix assessments are designed to serve present and future needs of the enterprises. Given the dynamic nature of the global services market and rampant disruption, the assessment criteria are realigned as and when needed to reflect the current market reality as well as serve the future expectations of enterprises







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