



Everest Group PEAK Matrix[®] for Clinical Development Platform Vendor 2022

Focus on Medidata
August 2022



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 dimension

Scope of this report



Geography
Global



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, 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:

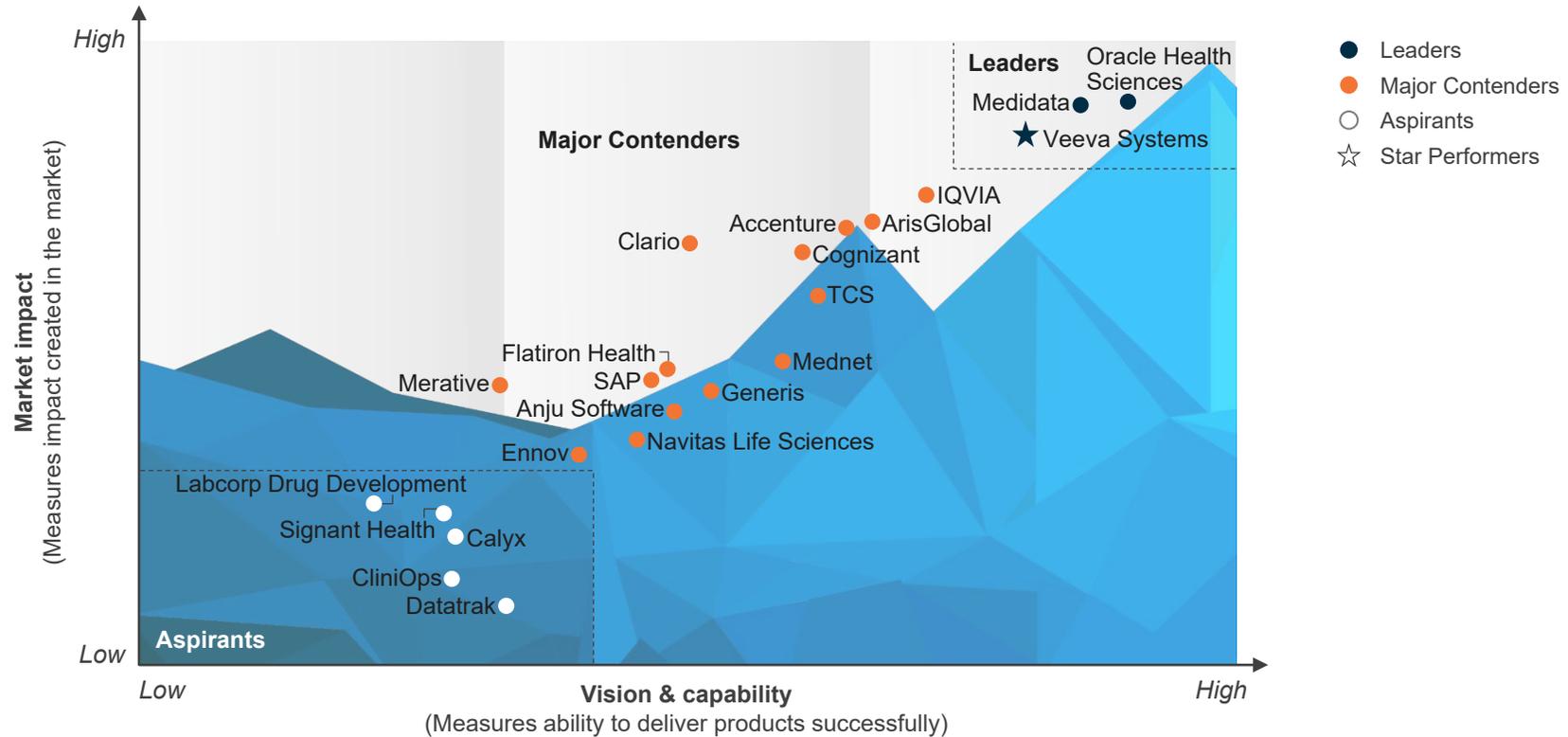
Calyx, CliniOps, Datatrak, Labcorp Drug Development, and Signant Health

- 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 PEAK Matrix®

Clinical Development Platforms Products PEAK Matrix® Assessment 2022 | Medidata positioned as Leader

Everest Group Clinical Development Platforms Products PEAK Matrix® Assessment 2022^{1,2}



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

Source: Everest Group (2022)

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

Overview

Company mission/vision statement for clinical development platforms

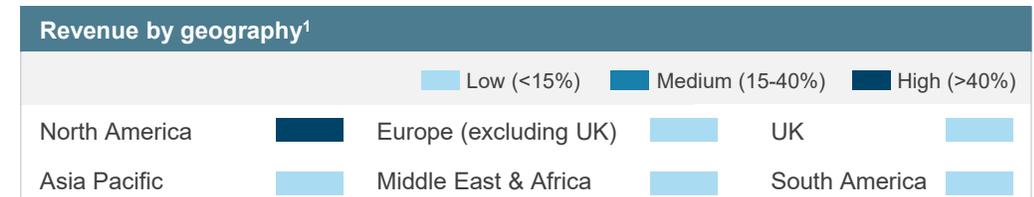
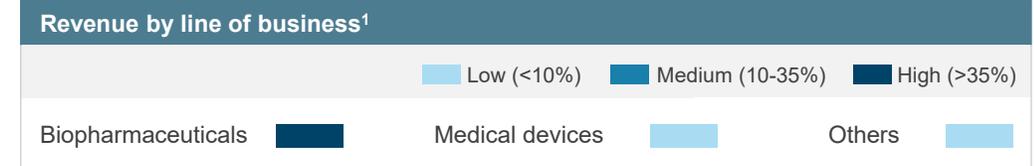
Medidata's vision is to be an end-to-end platform for clinical development in order to bring therapies to market faster and at lower cost. Their mission is to power smarter treatments and healthier people. Medidata's strategy is to remain focused on three key pillars:

- 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



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

2 Based on analyst estimates

Medidata | clinical development platforms profile (page 2 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 3 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 onsite 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 4 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 5 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 6 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 7 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 8 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

Medidata | clinical development platforms profile (page 9 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, startup, 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

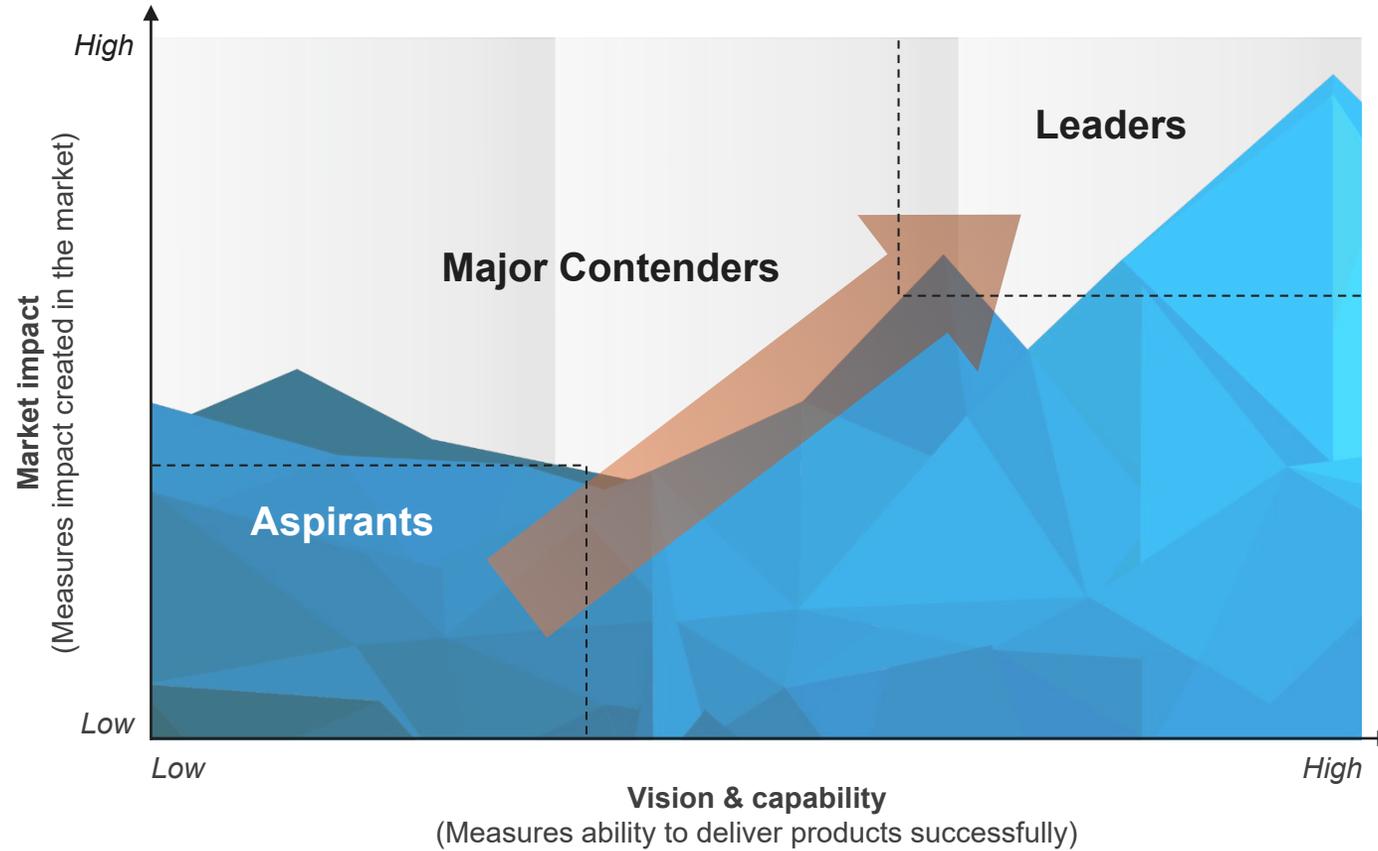
Limitations

- 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

Appendix

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

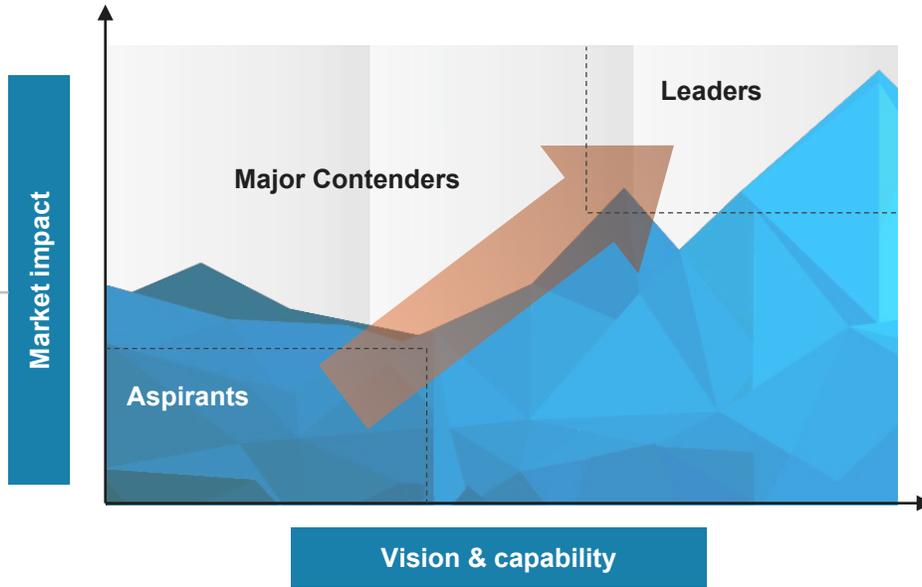
Everest Group PEAK Matrix



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



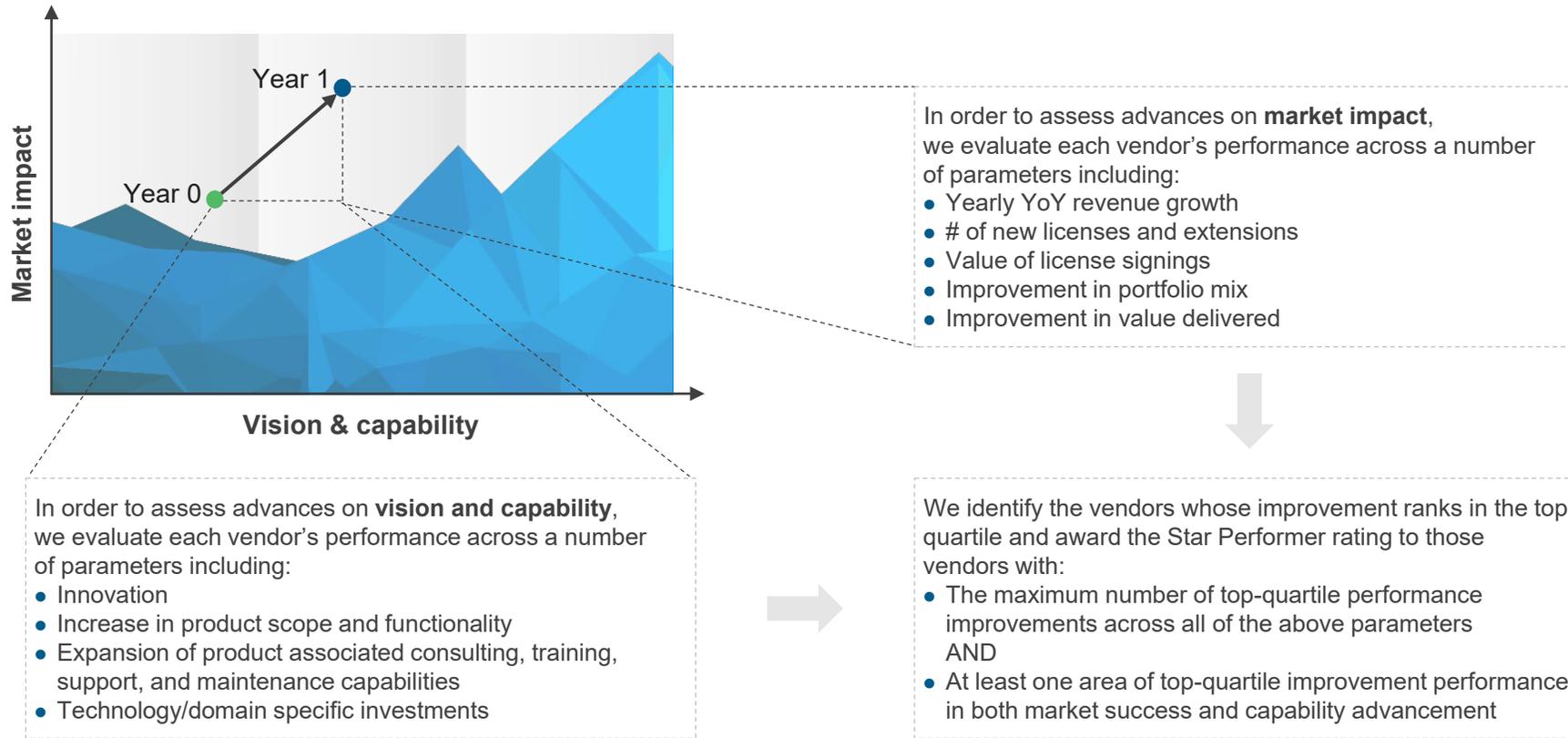
Measures ability to deliver products successfully. This is captured through five subdimensions

Vision and strategy	Technology capability	Flexibility and ease of deployment	Engagement and commercial model	Support
Vision for the client and itself; future roadmap and strategy	Technical sophistication and breadth/depth across the technology suite	Configurability/customize-ability, hosting and tenancy, integration, governance, and security and compliance	Progressiveness, effectiveness, and flexibility of engagement and commercial models	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 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 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 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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