Everest Group®
RESEARCH

Everest Group PEAK Matrix® for Pharmacovigilance and Complaint Management Service Providers 2021

Focus on Cognizant

March 2021

Everest Group
PEAK MATRIX®

Copyright © 2021 Everest Global, Inc.
*This document has been licensed for exclusive use and distribution by **Cognizant***

EGR-2021-54-E-4279

Background of the research

Traditionally considered as a cost-function by the life sciences enterprises, pharmacovigilance and device-vigilance / complaint management market is finally garnering the long due spotlight from all the sections of the industry – including regulatory agencies, drug safety teams, and media – stressing the need to effectively monitor drug/devices and ensuring the utmost importance of patient safety. Further, on the operational front, the market is facing myriad of challenges including significantly increasing adverse event volumes, growing regulatory stringency (such as transition from E2B (R2) to E2B (R3) submission format, implementation of Investigational Medicinal Product Dossier (IMPD) and European Medical Device Regulation (EU-MDR), and updates on safety regulations/guidelines in emerging markets), improving signal surveillance and benefit & risk management, ageing legacy safety ecosystems, and inefficiencies within key safety databases. As a result, cost and complexity of device/drug vigilance activities are increasing and it is becoming difficult for enterprise stakeholders to achieve and sustain compliance within their safety budgets. The enterprise community is pursuing strategic technology investments (such as upgrading tools/solutions and safety databases) and realigning its focus on value-added drug safety activities (such as signal detection) while outsourcing case processing to their third-party service providers.

Service providers – CROs, IT/BPOs, and product safety specialists – are supporting enterprises in their journey of tackling these hurdles by providing well-established drug/device vigilance processes/services, offering staff augmentation capabilities with access to highly trained resources, and supporting regional Qualified Person Responsible For Pharmacovigilance (QPPV) activities. Notably, the service provider community is continuously investing in technology IP across pharmacovigilance / complaint management activities to complement its services in a bid to improve efficiency, reduce costs, manage volumes, and remain compliant. The pharmacovigilance and complaint management market has reached an inflection point where these process and technology-driven investments will start paying off in the coming years as both the communities are striving toward achieving more with less.

In this research, we present an assessment and detailed profiles of 22 service providers featured on the Pharmacovigilance and Complaint Management Operations – Services PEAK Matrix®. Each service provider profile provides a comprehensive picture of its service focus, key Intellectual Property (IP) / solutions, domain investments, and case studies. The assessment is based on Everest Group's annual RFI process for calendar year 2021, interactions with leading drug safety services providers, and an ongoing analysis of the pharmacovigilance and complaint management services market.

Scope of this report:

Geography
Global

Service providers
22

Services
Pharmacovigilance and complaint management business process services

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

Everest Group Pharmacovigilance and Complaint Management Operations – Services PEAK Matrix® characteristics

Everest Group classified 22 pharmacovigilance and complaint management BPS providers on the Everest Group PEAK Matrix® into the three categories of Leaders, Major Contenders, and Aspirants.

Leaders:

There are six service providers in the Leaders category – Accenture, Cognizant, Covance, IQVIA, TCS, and Wipro

Major Contenders:

The Major Contenders category has 12 service providers – APCER Life Sciences, Atos, Bioclinica, ICON plc, Indegene, Navitas Life Sciences, Parexel, PharmaLex, PPD, PRA Health Sciences, PrimeVigilance (Ergomed plc), and Syneos Health

Aspirants:

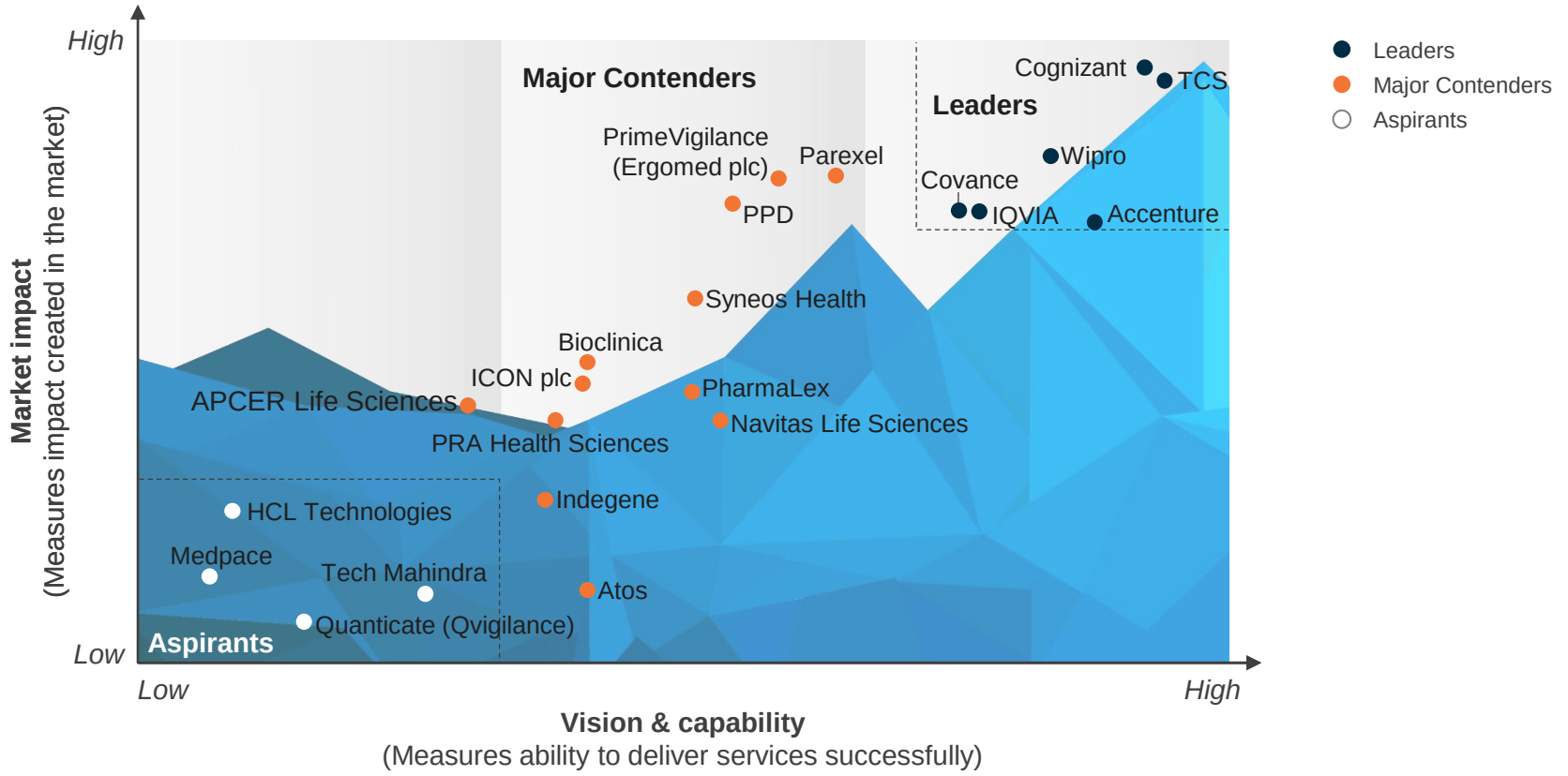
HCL Technologies, Medpace, Quanticate (Qvigilance), and Tech Mahindra are Aspirants on the PEAK Matrix®

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

Everest Group PEAK Matrix®

Pharmacovigilance and Complaint Management Operations – Services PEAK Matrix® Assessment 2021 | Cognizant positioned as Leader

Everest Group Pharmacovigilance and Complaint Management Operations – Services PEAK Matrix® Assessment 2021[1,2]



1 Assessment for APCER Life Sciences, Atos, Bioclinica, Covance, HCL Technologies, Indegene, IQVIA, Medpace, Parexel, PPD, PRA Health Sciences, PrimeVigilance (Ergomed plc), Quanticate (Qvigilance), and Syneos Health excludes service provider inputs and is based on Everest Group's proprietary Transaction Intelligence (TI) database, service provider public disclosures, and Everest Group's interactions with buyers. For these companies, Everest Group's data for assessment may be less complete

2 Analysis for PRA Health Sciences is based on capabilities before its acquisition by ICON plc

Source: Everest Group (2021)

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

Cognizant | pharmacovigilance and complaint management operations profile (page 1 of 6)

Overview

Company overview

Cognizant provides IT, consulting, and BPO services for the banking, insurance, healthcare, life sciences, manufacturing, logistics, energy, utlities, retail, consumer goods, travel and hospitality, telecommunications, media, and technology segments. Its digital Pharmacovigilance (PV) and complaints management solutions offers medical safety and human-centered design for safety management and enhanced patient experience that are augmented by leveraging AI and ML, PV tools, and solutions.

Headquarters: Teaneck, NJ, United States

Website: www.cognizant.com

Key leaders

- **Ganesh Ayyar,** Executive Vice President, Digital Business Operations
- **Krishnan Iyer,** Global Delivery Head, Digital Business Operations
- **Narsimhan PVL,** Vice President and Head, Markets, Life Sciences and Insurance Digital Business Operations
- **Sunita Lakhanpal,** Vice President and Head, Delivery, Life Sciences Digital Business Operations
- **Prashant Kandukuri,** Business Leader, Life Sciences Digital Business Operations

Suite of services

- **Pharmacovigilance** – Adverse Drug Reaction (ADR) intake, Individual Case Study Report (ICSR) case processing, reporting, signal detection, risk management, literature surveillance, and epidemiology support
- **Complaints management** – Complaints capture, complaint processing and investigation, reporting and closure, and trend analysis

Pharmacovigilance and complaint management BPS	2018	2019	2020
Revenue (US$ million)	65-75	80-90	105-115
Number of FTEs	2,350-2,700	2,900-3,400	3,500-4,000
Number of clients	10-15	15-20	20-25

Recent acquisitions and partnerships

- 2020: Partnered with Ultragenic for collaboration on Argus Data migration and implementation projects
- 2019: Formed a strategic partnership and provides advisory, implementation, and support services with automation vendors such as Indico, Xceptor, and Hyperscience
- 2018: Partnered with US-based RxLogix for Pharmacovigilance automation solutions
- 2018: Partnered with service providers for translation, literature screening, and RMP solutions
- 2018: Expanded partnerships with BluePrism, UiPath, and Automation Anywhere, for enterprise automation

Recent developments/announcements

- 2020: Launched Cognizant AI enabled extraction offering for PV and complaints
- 2020: Deployed digital operations enablers to sustain virtual operations models and transitioned over 3,000 FTEs across the practice through COVID-19
- 2019: Launched Smart PV, an end-to-end safety management service for customers bringing in technology and services to deliver optimal safety operations

1 12 months ending September 30 of any particular year, i.e., from October 1, YYYY to September 30, YYYY

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

Cognizant | pharmacovigilance and complaint management operations profile (page 2 of 6)

Key delivery locations

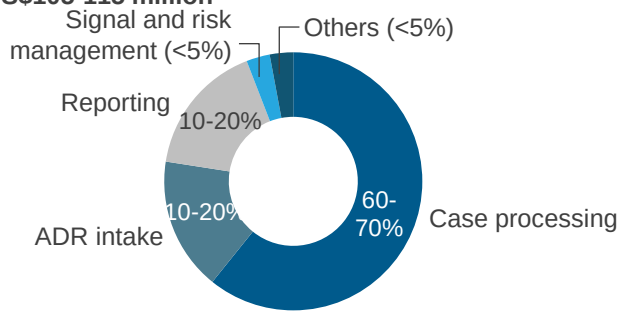
Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

Cognizant | pharmacovigilance and complaint management operations profile (page 3 of 6)

Capabilities

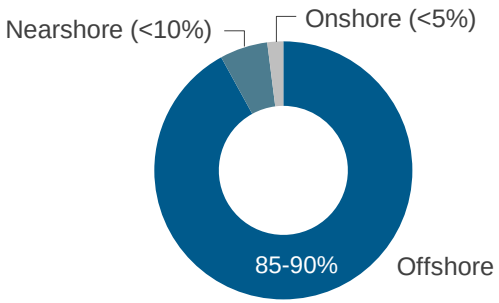
PV & complaint management operations – services FTEs mix by process

100% = US$105-115 million



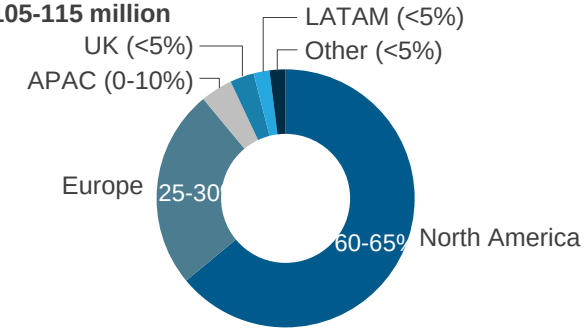
PV & complaint management operations – services FTEs mix by delivery location

100% = 3,500-4,000 FTEs



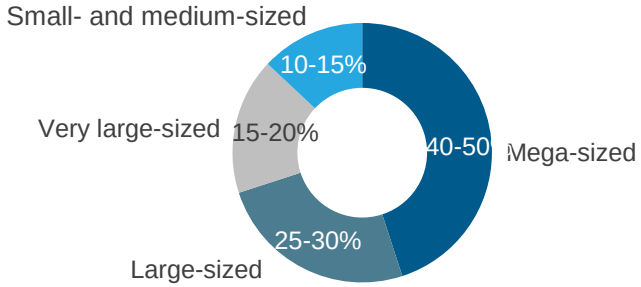
PV & complaint management operations – services revenue mix by geography

100% = US$105-115 million



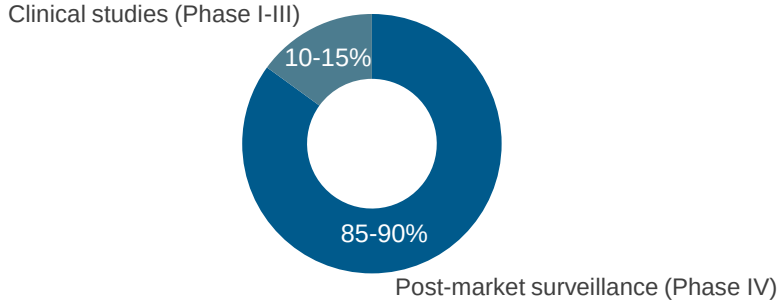
PV & complaint management operations – services split by buyer size[1]

100% = 20-25 clients



PV & complaint management operations – services revenue mix by drug/device life cycle

100% = US$105-115 million



1 Buyer size is defined as mega (>US$20 billion), very large (US$10-20 billion), large (US$1-10 billion in revenue), and small & medium (<US$1 billion in revenue)

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

Cognizant | pharmacovigilance and complaint management operations profile (page 4 of 6)

Technology solutions/tools

Solution/tool name	Processes served	Year launched	Description	No. of BPS clients
Cognitive extraction AI solution	Pharmacovigilance	2020	It aids and amplifies cognitive journey by identifying the right extraction solution for specific types of cases and leveraging pre-configured tools and accelerators	1-5
Decision Tree for complaints management	Complaint management	2020	Utilized for complaints management, it enables assessing reportability based on regulatory requirements. Additionally, it helps in improving the accuracy of decision-making	1-5
QC automation tool with narrative QC and moderation	Pharmacovigilance and complaint management	2020	It is ML-enabled QC tool that highlights potential quality and narration errors, checks for medical cohesiveness, and provides narrative recommendation and moderation functionality	1-5
Smart Pharmacovigilance	Pharmacovigilance	2019	Cognizant's Digital Pharmacovigilance solution offers an end-to-end safety management solution for its customers. It brings together the needs for a modern and modular platform, scalable operational processes, and an automation toolset that can be configured to the specific needs of the customer	1-5
Digital Operations Fabric	Pharmacovigilance and complaint management	2019	It is a configurable platform that digitizes operations management processes, optimizes workforce scheduling, and enables the team to exceed service levels. It has specific modules for work management, performance management, and quality management that can be configured for each program	5-10
Smart Email Management	Pharmacovigilance	2019	The solution leverages advanced NLP to analyze text data and email attachments for identifying new PV cases in an automated way and adds them to the daily workflow	1-5
Automated Medical Coding	Pharmacovigilance	2019	It leverages NLP/ML for automating the medical coding process resulting in effort reduction	1-5
Analytics Suite of Services	Pharmacovigilance and complaint management	2019	Point solutions and operational dashboards built with business intelligence to monitor trends, identify bottlenecks, and improve quality and throughput	1-5

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

Cognizant | pharmacovigilance and complaint management operations profile (page 5 of 6)

Technology solutions/tools

Solution/tool name	Processes served	Year launched	Description	No. of BPS clients
Automation solutions	Pharmacovigilance and complaint management	2018	It has deployed multiple automation solutions with a human in the loop to drive automation across the safety operations value chain. These include automation for electronically transmitted cases (E2B/EV) with end-to-end case processing and validation of auto-populated fields as well as an OCR-led AI/ML-enabled intake solution for non E2B cases	1-5
Cognizant MedVantage®	Complaint management	2013	An integrated field service and complaint handling business cloud solution that drives enhanced customer reach, improves customer satisfaction, and ensures regulatory compliance specifically for the MedTech industry	1-5

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

Cognizant | pharmacovigilance and complaint management operations profile (page 6 of 6)

Everest Group assessment – Leaders

Measure of capability: High Low

Market impact				Vision & capability				
Market adoption	Portfolio mix	Value delivered	Overall	Vision and strategy	Scope of services offered	Innovation and investments	Delivery footprint	Overall

Strengths

- With a massive scale of operations, strong domain expertise, and notable market presence, Cognizant is one of the leading players in pharmacovigilance market offering an end-to-end spectrum of patient safety services including ICSR case processing, aggregate reporting, and signal & risk management
- The service provider has consistently increased its portfolio, in terms of revenue, during last three years
- Additionally, its complaint management portfolio has made strong inroads in capturing the increased demand from MedTech companies. It is among the few service providers that serve both biopharma and MedTech buyers at a notable scale
- It continues to make heavy investments in strengthening its technology-enabled solutions – both via in-house (including capability expansion of its end-to-end safety management solution – Smart PV solution and Cognizant MedVantage) and partnerships ecosystem (such as engagements with Systran, Ultragenic, and RxLogix for downstream processes)
- It has a network of delivery operation centers present at strategic locations – offshore (India and the Philippines), nearshore (Argentina, China, and Hungary) and onshore (the US and Japan) – offering customized support to its clients

Limitations

- A majority of Cognizant's clients are large-sized biopharma and MedTech companies with revenue >US$1 billion. Serving smaller-sized enterprises is yet to be noted within its client base
- While the service provider has extensive experience serving the US clients, its exposure in serving clients based in Europe is relatively low when compared to its immediate peers

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

Appendix

Everest Group's view of the pharmacovigilance operations value chain

ADR intake	ICSR case processing		Reporting	Signal and risk management
Data acquisition and case validation	Data acquisition and case validation	Narrative writing	Reporting rules maintenance and configuration	Signal detection
Duplicate detection	Triage and initial assessment	Coding	Manual assessment	Signal validation and assessment (EU RMPs/ US REMS)
Prioritization/triage	Full data entry	In-line QC	Regulatory submission	Signal amplification studies
Prepare & send to global site	Translation	Case completion	Acknowledgment and reconciliation	Benefit-risk evaluation
Archive source data	Medical assessment	Follow-up questions and monitoring	Aggregate reporting	EU RMPs/ US REMS development

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

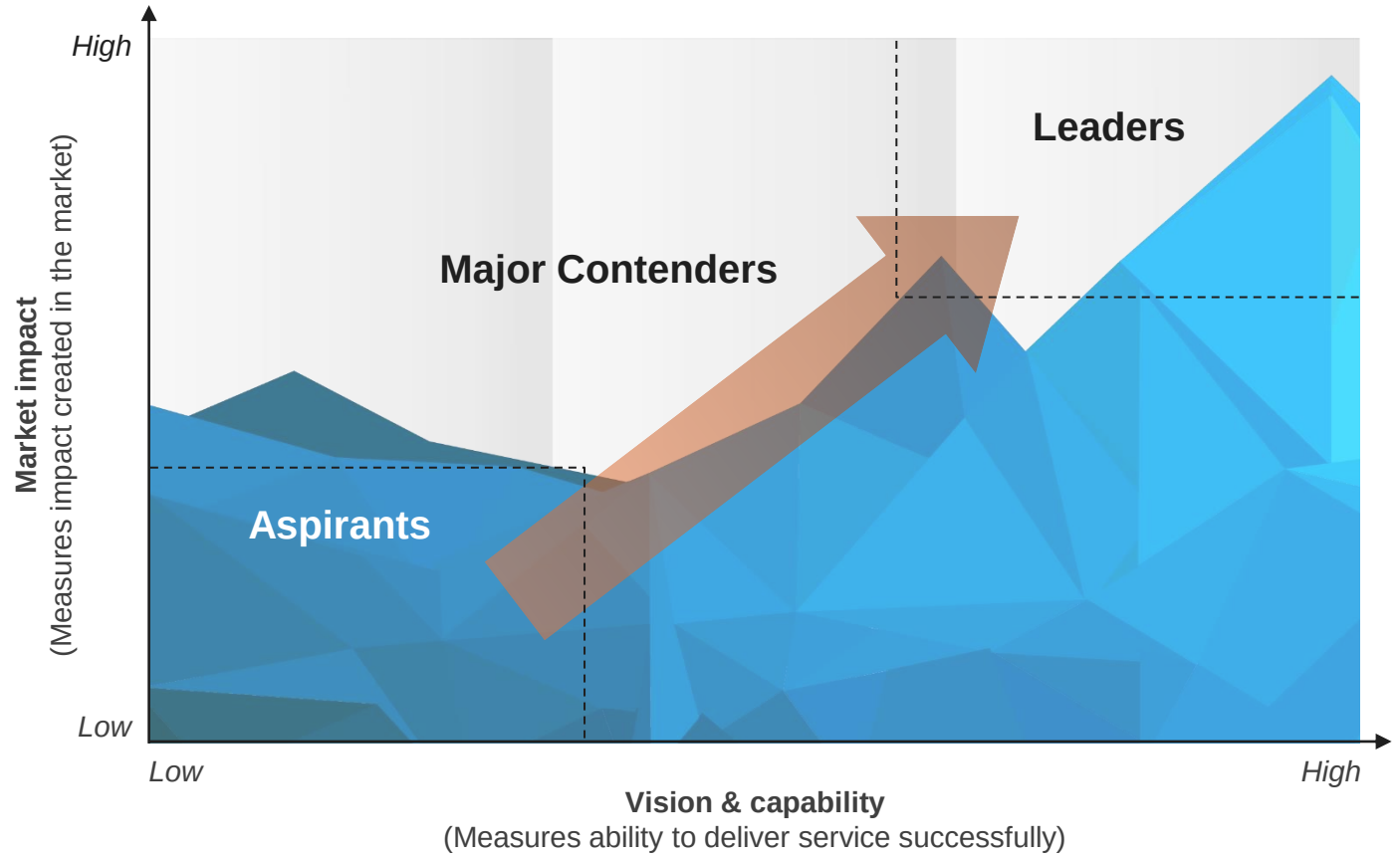
Everest Group's view of the complaint management operations value chain

Complaint capture	Complaint processing & investigation		Reporting and closure	Trend analysis
Complaint intake	Complaint registration	Product investigation	Preparation of MDR	Trend analysis
Complaint triage	Case narrative & coding	Root cause analysis	MDR submission	Signal detection
Field alerts reporting	AE identification	Batch history records	Supplementary report	Manufacturing issues trends
Complaint evaluation and prioritization	Field sample retrieval	Safety monitoring review and prepare response letters	Resolution and close-out	CAPA management

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

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

Everest Group PEAK Matrix



Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

Services PEAK Matrix® evaluation dimensions

Measures impact created in the market – captured through three subdimensions

Market adoption

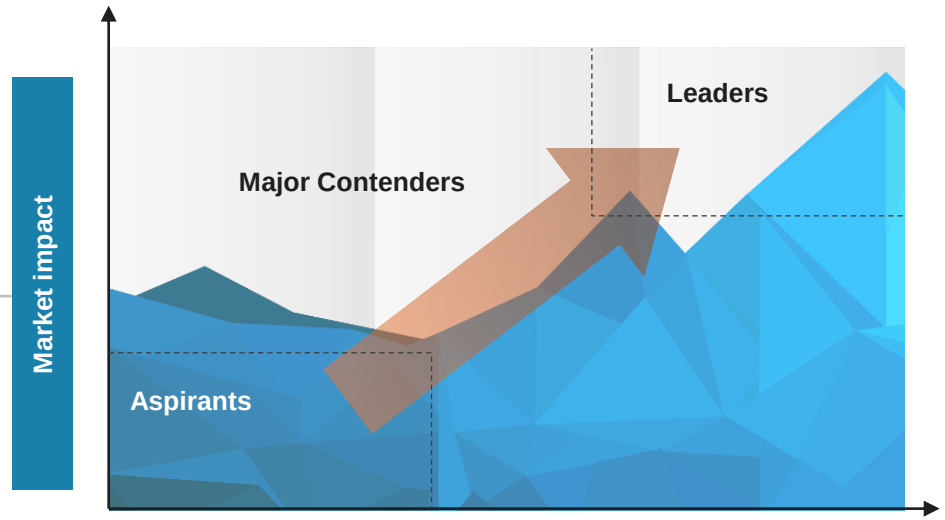
Number of clients, revenue base, YOY growth, and deal value/volume

Portfolio mix

Diversity of client/revenue base across geographies and type of engagements

Value delivered

Value delivered to the client based on customer feedback and transformational impact



Measures ability to deliver services successfully. This is captured through four subdimensions

Vision and strategy

Vision for the client and itself; future roadmap and strategy

Scope of services offered

Depth and breadth of services portfolio across service subsegments/processes

Innovation and investments

Innovation and investment in the enabling areas, e.g., technology IP, industry/domain knowledge, innovative commercial constructs, alliances, M&A, etc.

Delivery footprint

Delivery footprint and global sourcing mix

Everest Group® RESEARCH Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279

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

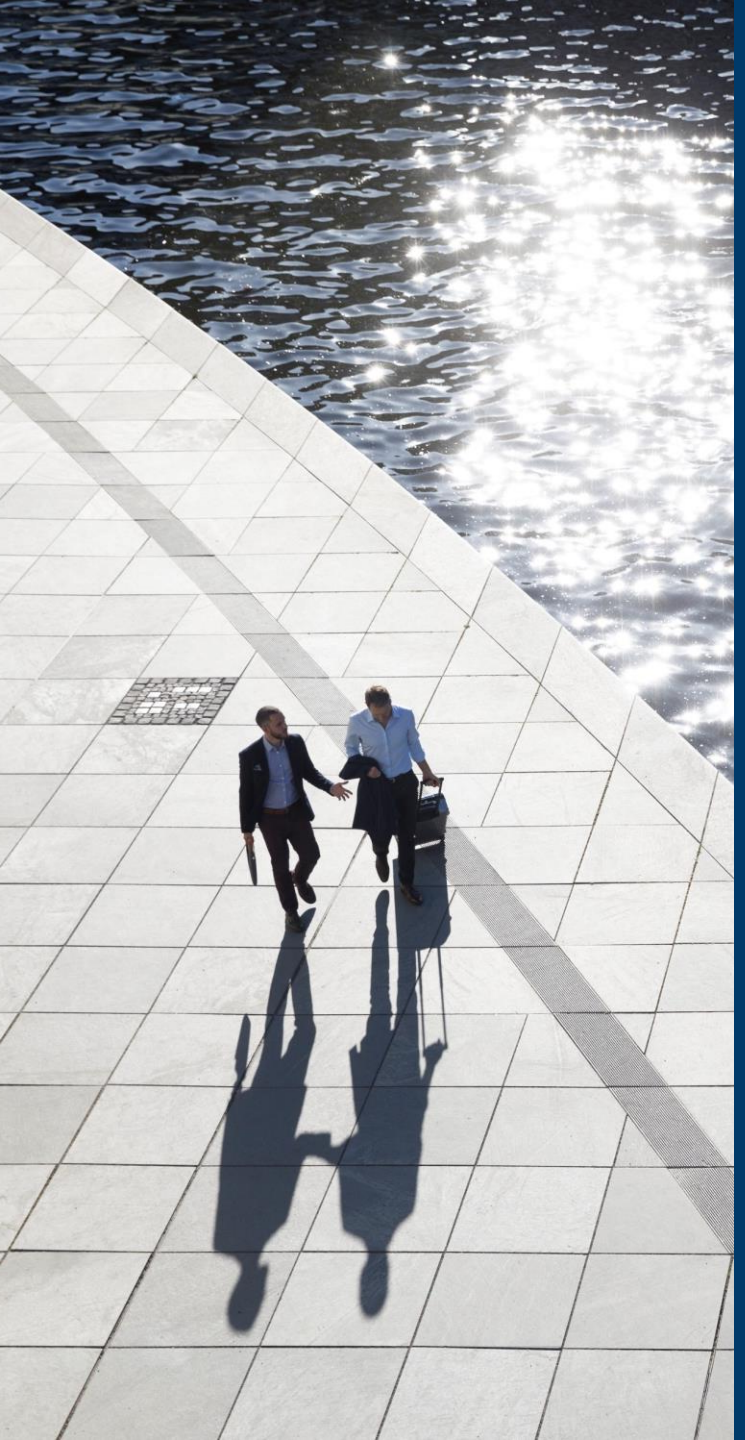
What other aspects of PEAK Matrix assessment are relevant to buyers and providers besides the "PEAK Matrix position"?
A PEAK Matrix position is only one aspect of Everest Group's overall assessment. In addition to assigning a "Leader", "Major Contender," or "Aspirant" title, Everest Group highlights 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

Proprietary & Confidential. © 2021, Everest Global, Inc. | EGR-2021-54-E-4279



Everest Group®
With you on the journey

Everest Group is a consulting and research firm focused on strategic IT, business services, engineering services, and sourcing. Our clients include leading global enterprises, service providers, and investors. Through our research-informed insights and deep experience, we guide clients in their journeys to achieve heightened operational and financial performance, accelerated value delivery, and high-impact business outcomes. Details and in-depth content are available at **everestgrp.com**.

Stay connected

Website
everestgrp.com

Social Media
@EverestGroup
@Everest Group
@Everest Group
@Everest Group

Blog
everestgrp.com/blog

Podcast
DigitalRealITy

Listen on Apple Podcasts | Google Play | STITCHER | TUNE IN

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

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

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

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

New York
info@everestgrp.com
+1-646-805-4000

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

This document is for informational purposes only, and it is being provided "as is" and "as available" without any warranty of any kind, including any warranties of completeness, adequacy, or fitness for a particular purpose. Everest Group is not a legal or investment adviser; the contents of this document should not be construed as legal, tax, or investment advice. This document should not be used as a substitute for consultation with professional advisors, and Everest Group disclaims liability for any actions or decisions not to act that are taken as a result of any material in this publication.