

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

Focus on Wipro
March 2021



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

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:

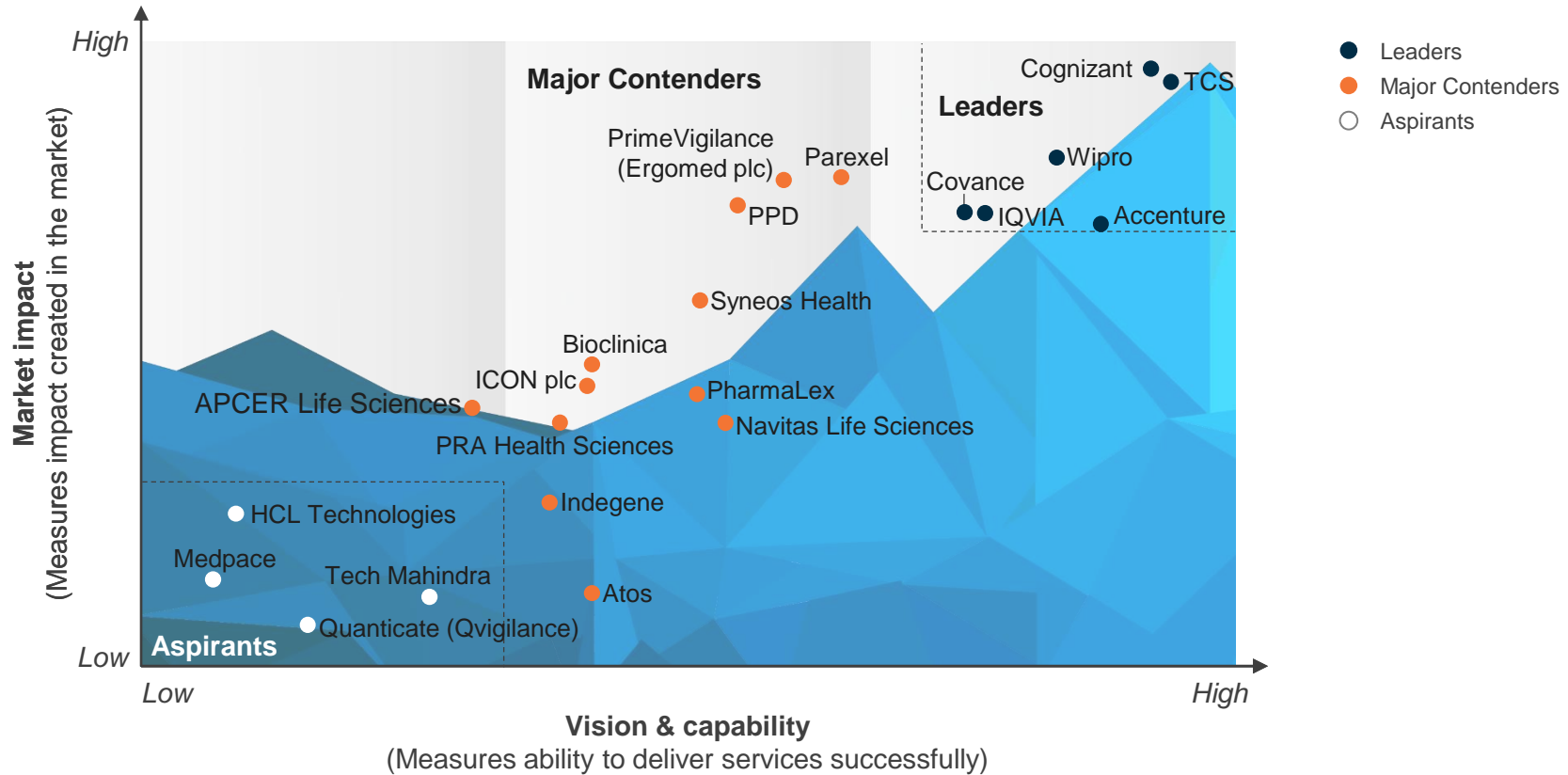
HCL Technologies, Medpace, Quanticate (Qvigilance), and Tech Mahindra are Aspirants on the PEAK Matrix®

Everest Group PEAK Matrix®

Pharmacovigilance and Complaint Management Operations – Services PEAK Matrix® Assessment 2021 | Wipro 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)

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

Overview

Company overview

Wipro Limited is a global information technology, consulting, and business process service provider. The company leverages cognitive computing, hyper-automation, robotics, cloud, analytics, and emerging technologies to help its clients adapt to the digital world. It offers end-to-end services under its Pharmacovigilance (PV) and complaint management portfolio and processed 1.3+ million complaints and one million Individual Case Study Report (ICSR) cases annually for MedTech and biopharma companies, respectively.

Headquarters: Bengaluru, India

Website: www.wipro.com

Key leaders

- **Nagendra Bandaru**, Head, iCORE
- **Krishna Nacha**, Vice President and Head, S.E.T. (Shared Services. Enterprise Services. Transformation Services)
- **Saikat Biswas**, Global Head, Medical Devices, Pharmaceuticals, Services, ENU, and Manufacturing
- **Debasis Das**, Head, Delivery, Pharmaceuticals
- **Satyabrata Haldar**, Head, Delivery, Medical Devices, APAC
- **Dr. Jagdish Babu Kotikalapudi**, Head, Pharmacovigilance and Regulatory Affairs Practice
- **Dhaval Shah**, Head, Medical Devices and In-Vitro Diagnostics Practice
- **Subhrajit Ghose**, Head, Clinical Data Services

Suite of services

- **E2E Pharmacovigilance** – Adverse Drug Reactions (ADR) intake, ICSR processing including medical review, regulatory submissions, signal detection, risk management, aggregate safety report writing, literature management, medical information call center
- **E2E Complaints management** – Complaint intake to regulatory submission, investigations including trend analysis and CAPA management, regulatory & vigilance reporting, EU MDR & in-vitro diagnostics services

Pharmacovigilance and complaint management BPS	2018	2019	2020
Revenue (US\$ million)	Not disclosed	Not disclosed	Not disclosed
Number of FTEs	1,200	1,900	2,800
Number of clients	Not disclosed	Not disclosed	Not disclosed

Recent acquisitions and partnerships

- 2020: Partnered with ComplianceQuest, an Enterprise Quality, Safety and Environment Management (QHSE) solutions platform, to develop quality management solutions for the medical devices and life sciences industries
- 2020: Partnered with Pharmalex for augmenting the current PV services offering
- 2020: Partnered with Witty Parrot, a cloud-based SaaS Company, for SOP life cycle management
- 2019: Partnered with Ontotext, a knowledge and language engineering company, for semantic search and knowledge graphs for pharma & medical devices literature management & litigation records management
- 2019: Partnered with TransPerfect, a provider of language and technology solutions, for global translation services for life sciences operations

Recent developments/announcements

- 2020: Managing COVID-19 ICSR cases for Top 5 pharmaceutical companies
- 2020: COVID-19-specific solutions in place for new and existing clients
- 2020: Launched Talosafe, an upgrade to existing Smartance platform for PV automation
- 2020: Developed customized PowerBI dashboards for complaints management projects
- 2019: Expanded capabilities in EU MDR and in-vitro diagnostics services
- 2019: Medibot chatbot deployed for medical information, complaints, and adverse events capture
- 2019: CCI agent deployment for complaints management automation
- 2018: Deployed Voice-To-Text (VTT) tool for converting calls to a structured text for case processing

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

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

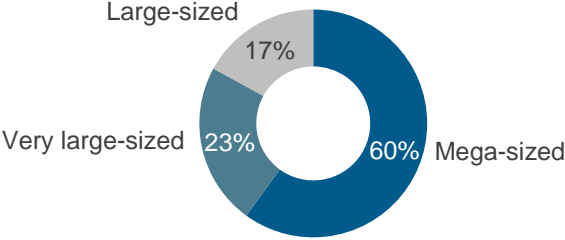
Key delivery locations



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

Capabilities

PV & complaint management operations – services FTEs mix by process	PV & complaint management operations – services FTEs mix by delivery location	PV & complaint management operations – services revenue mix by geography																						
<p>100% = Number of FTEs</p>  <table border="1"> <caption>FTEs mix by process</caption> <thead> <tr> <th>Process</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>Case processing</td> <td>68%</td> </tr> <tr> <td>Reporting</td> <td>18%</td> </tr> <tr> <td>ADR intake</td> <td>9%</td> </tr> <tr> <td>Signal and risk management</td> <td>5%</td> </tr> </tbody> </table>	Process	Percentage	Case processing	68%	Reporting	18%	ADR intake	9%	Signal and risk management	5%	<p>Number of FTEs = 2,800</p> <p>Not disclosed</p>	<p>100% = Not disclosed</p>  <table border="1"> <caption>Revenue mix by geography</caption> <thead> <tr> <th>Geography</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td>North America</td> <td>76%</td> </tr> <tr> <td>APAC</td> <td>13%</td> </tr> <tr> <td>Europe</td> <td>5%</td> </tr> <tr> <td>UK</td> <td>3%</td> </tr> <tr> <td>LATM</td> <td>3%</td> </tr> </tbody> </table>	Geography	Percentage	North America	76%	APAC	13%	Europe	5%	UK	3%	LATM	3%
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PV & complaint management operations – services split by buyer size ¹	PV & complaint management operations – services revenue mix by drug/device life cycle								
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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)

Wipro | 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
Process Manager for Complaints Management	MedTech	2020	Complaint processing platform for third-party manufactured products	1
PowerBI dashboards	BioPharma	2020	Deep analytics on quality assurance	11
TaloSafe (Advanced Version)	Both (BioPharma and MedTech)	2020	It is a pharmacovigilance platform (an advanced version of Smartance) with abilities to perform cognitive analysis by categorizing Adverse Events (AE) cases into valid or invalid. Additionally, it can perform causality analysis and auto-triggered follow-ups for duplicity, correctness, and completeness of information	2
CCI Agent	MedTech	2019	It is an automation solution for complaints management built on Integrated Automation Approach. Led by combinations of tools, technologies, and techniques such as AI/ML including Natural Language Programming, OCR, Computer Vision, and Robotic Process Automation tools	2
Wipro Medibot	Both (BioPharma and MedTech)	2019	It is used for medical information, complaints, and adverse events communication (chat) for patient, consumer, physician, or any other reporter for sharing the information/details to be captured	2
Wipro-Voice to text (VTT)	Both (BioPharma and MedTech)	2018	A solution that supports all the voice scripts coming from call centers and converts the voice to text in a structured format that can be utilized by TaloSafe or customer tools for the purpose of processing	3
Smart Scripts	MedTech	2018	Coding text analytics to capture reportable keywords for workload prioritization	2
Base Harmony	Both (BioPharma and MedTech)	2018	Web-based knowledge capture and program management tool	4
Digital training files	BioPharma	2018	Digital training files to keep a track of training files and logs of all PV/complaints associates	1

Wipro | 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
Shine Knowledge Database tool	MedTech	2018	Learning management system to track training completion and compliance	11
Tableau	BioPharma	2018	Real-time queue monitoring of productivity and adverse event	1
MDR auto-auditor tool	MedTech	2017	Aids quality audits of the MDR regulatory reports, highlights any mismatches from complaint fields vs. report fields so it can be rectified before submission to FDA	2
CMS audit tool	Both (BioPharma and MedTech)	2016	Digitized internal project audit	5
Reportum	BioPharma	2014	Digitized adverse event intake platform	1
ColossusNxtGen	Both (BioPharma and MedTech)	2014	Transactional quality audit tool	5
Auxilium	MedTech	2014	Complaint intake and processing for legal complaints	1

Wipro | 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

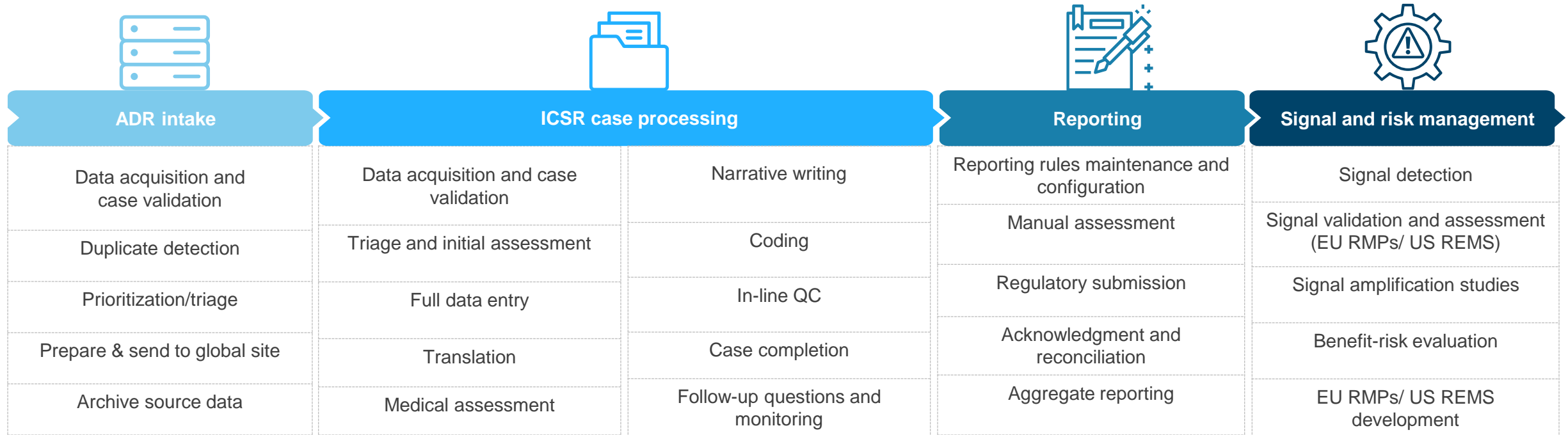
- Wipro is one of the few service providers with capability to serve both BioPharma and MedTech enterprises with its strong pharmacovigilance / complaint management services. Key services include ADR/complaint intake (multi-lingual contact center capabilities), case processing / complaints investigation, and analysis and reporting
- In addition to its growing complaint management business, the service provider has also been able to significantly increase its pharmacovigilance revenue in the last two years, growing at a CAGR of >30%
- It has a strong partnership ecosystem in place to augment its suite of services and technology within drug/device safety. Key partnerships include engagement with ComplianceQuest for quality management solution and Ontotext for literature screening
- It has made decent efforts in advancing its cognitive automation capabilities via its solutions – TaloSafe (an advanced version of its broad-based solution, Smartance) and other tools (such as Wipro-Medibot and CCI Agent) – to increase efficiencies and reduce overall operational costs
- The service provider has developed a strong network of centers and balanced delivery mix across the geographies to deliver flexible services to its clientele

Limitations

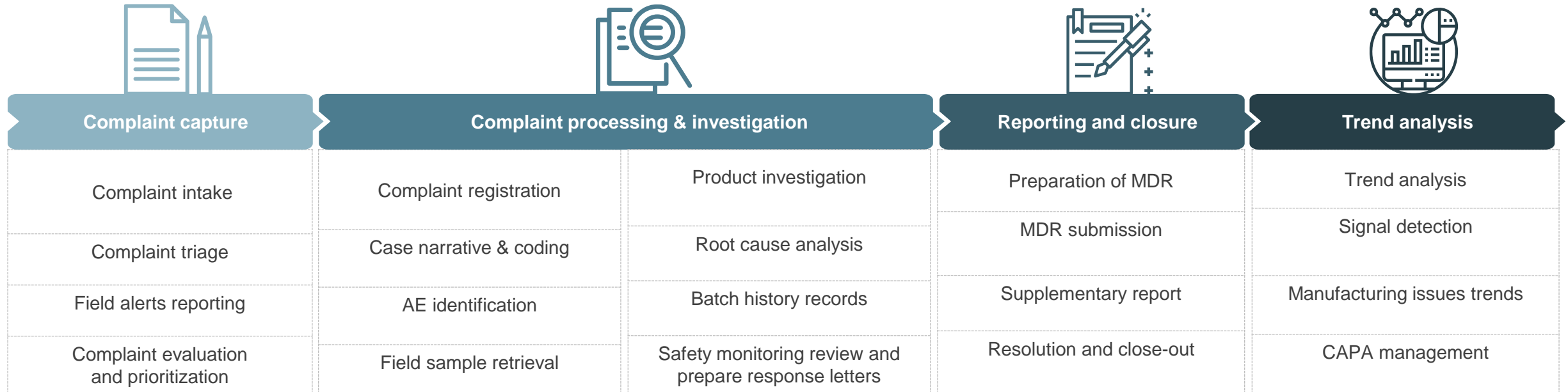
- Wipro has rich experience in serving clients based in the North American region. While the service provider has few client logos based in Europe, its capability to deliver local safety services at scale is largely untested
- Its clientele is heavily skewed toward large-sized enterprises. Small-sized buyers need to extensively evaluate its offerings, given its limited experience with the buyer segment
- Its drug safety service revenue for clinical trial drug candidate is on the lower side when compared to its peers
- While its peers are making significant investment in pharmacovigilance / complaint management platforms, the service provider is yet to make notable movement in this direction

Appendix

Everest Group's view of the pharmacovigilance operations value chain

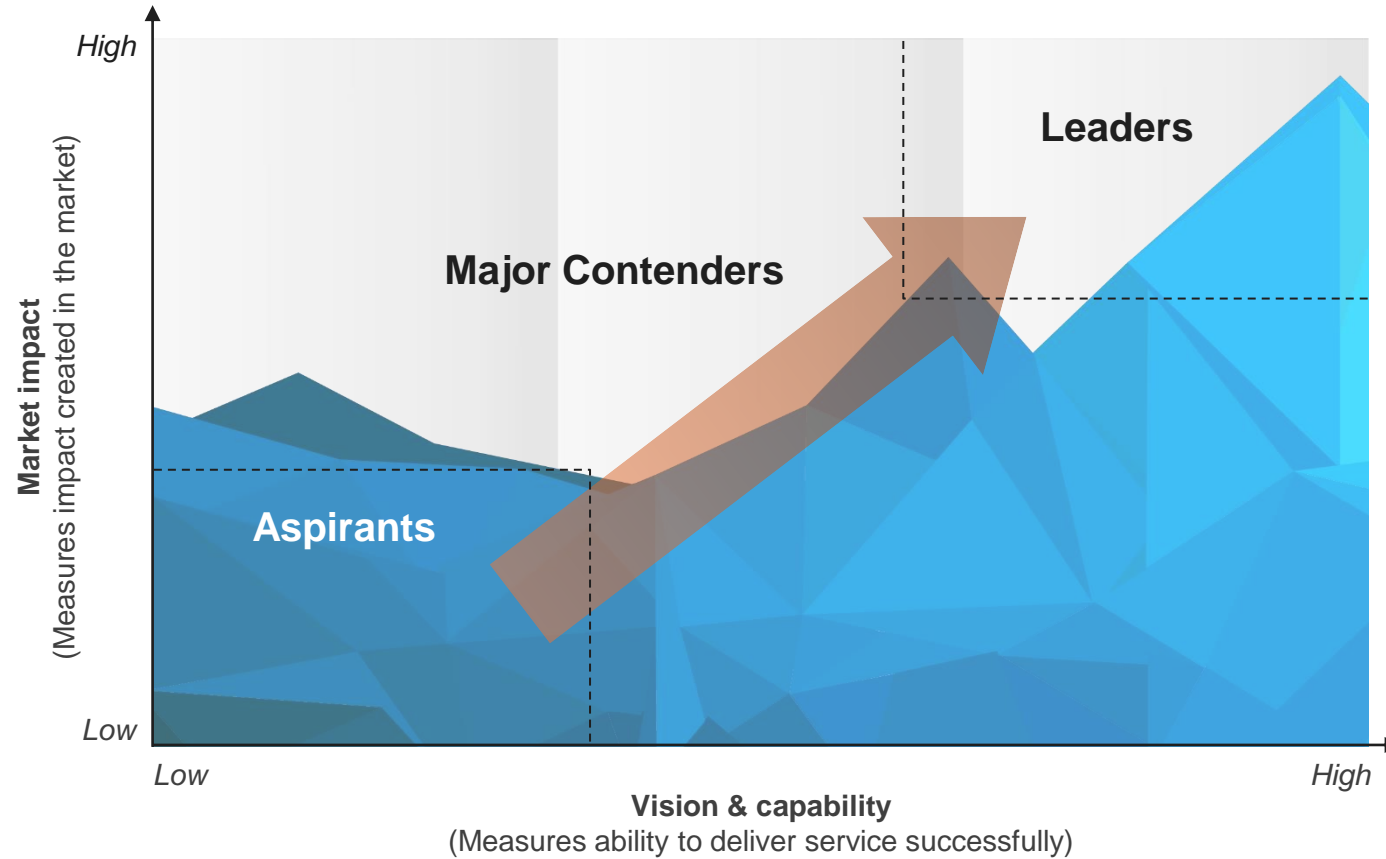


Everest Group’s view of the complaint management operations value chain



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

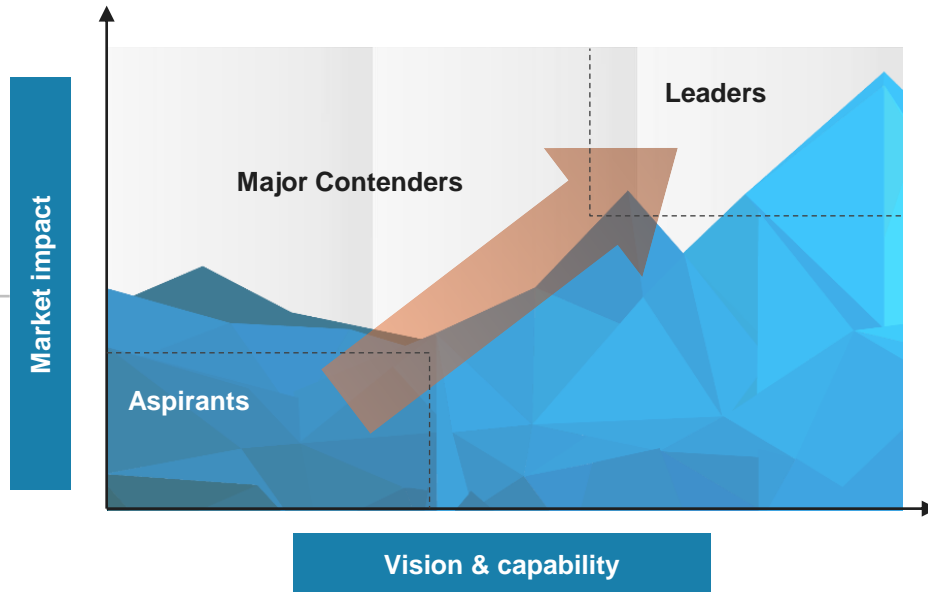
Everest Group PEAK Matrix



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

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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