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

Focus on Cognizant
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.
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 | Cognizant positioned as Leader

Everest Group Pharmacovigilance and Complaint Management Operations – Services PEAK Matrix® Assessment 2021

1 Assessment for APCER Life Sciences, Atos, Bioclinica, Covance, HCL Technologies, Indegene, IQVIA, Medpace, Parexel, PPD, PRA Health Sciences, PrimeVigilance (Ergomed plc), Quanticale (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)
Cognizant | pharmacovigilance and complaint management operations profile (page 1 of 6)

Company overview
Cognizant provides IT, consulting, and BPO services for the banking, insurance, healthcare, life sciences, manufacturing, logistics, energy, utilities, retail, consumer goods, travel and hospitality, telecommunications, media, and technology segments. Its digital Pharmacovigilance (PV) and complaints management solutions offer 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

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue (US$ million)</td>
<td>65-75</td>
<td>80-90</td>
<td>105-115</td>
</tr>
<tr>
<td>Number of FTEs</td>
<td>2,350-2,700</td>
<td>2,900-3,400</td>
<td>3,500-4,000</td>
</tr>
<tr>
<td>Number of clients</td>
<td>10-15</td>
<td>15-20</td>
<td>20-25</td>
</tr>
</tbody>
</table>

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
Key delivery locations

- Tokyo
- Buenos Aires
- Tampa
- Budapest
- Mumbai and Pune
- Indore
- Kolkata
- Hyderbad
- Manilla
- Dalian
- Greater Toronto Area
- Berlin
- Poland
- Indore
- Delhi
- Chennai and Coimbatore
- Bangalore
- Tokyo
## Cognizant | pharmacovigilance and complaint management operations profile (page 3 of 6)

### Capabilities

<table>
<thead>
<tr>
<th>PV &amp; complaint management operations – services FTEs mix by process</th>
<th>PV &amp; complaint management operations – services FTEs mix by delivery location</th>
<th>PV &amp; complaint management operations – services revenue mix by geography</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% = US$105-115 million</td>
<td>100% = 3,500-4,000 FTEs</td>
<td>100% = US$105-115 million</td>
</tr>
<tr>
<td>Signal and risk management (&lt;5%)</td>
<td>Onshore (&lt;5%)</td>
<td>LATAM (&lt;5%)</td>
</tr>
<tr>
<td>ADR intake</td>
<td>Offshore (&lt;5%)</td>
<td>Other (&lt;5%)</td>
</tr>
<tr>
<td>Reporting</td>
<td>Case processing</td>
<td>UK (&lt;5%)</td>
</tr>
<tr>
<td>Others (&lt;5%)</td>
<td>10-20%</td>
<td>APAC (0-10%)</td>
</tr>
<tr>
<td>60-70%</td>
<td>85-90%</td>
<td>Europe</td>
</tr>
<tr>
<td>10-20%</td>
<td></td>
<td>25-30%</td>
</tr>
</tbody>
</table>

### PV & complaint management operations – services split by buyer size

| PV & complaint management operations – services revenue mix by drug/device life cycle |
|---------------------------------|---------------------------------------------------------------|
| 100% = US$105-115 million       | Clinical studies (Phase I-III)                               |
| Large-sized                     | Post-market surveillance (Phase IV)                          |
| Small- and medium-sized         | 85-90%                                                        |
| Very large-sized                | 10-15%                                                        |
| Mega-sized                      | 10-15%                                                        |
| Large-sized                     | 25-30%                                                        |
| Very large-sized                | 15-20%                                                        |
| Large-sized                     | 40-50%                                                        |
| Small- and medium-sized         | 10-15%                                                        |

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

### Technology solutions/tools

<table>
<thead>
<tr>
<th>Solution/tool name</th>
<th>Processes served</th>
<th>Year launched</th>
<th>Description</th>
<th>No. of BPS clients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive extraction AI solution</td>
<td>Pharmacovigilance</td>
<td>2020</td>
<td>It aids and amplifies cognitive journey by identifying the right extraction solution for specific types of cases and leveraging pre-configured tools and accelerators</td>
<td>1-5</td>
</tr>
<tr>
<td>Decision Tree for complaints management</td>
<td>Complaint management</td>
<td>2020</td>
<td>Utilized for complaints management, it enables assessing reportability based on regulatory requirements. Additionally, it helps in improving the accuracy of decision-making</td>
<td>1-5</td>
</tr>
<tr>
<td>QC automation tool with narrative QC and moderation</td>
<td>Pharmacovigilance and complaint management</td>
<td>2020</td>
<td>It is ML-enabled QC tool that highlights potential quality and narration errors, checks for medical cohesiveness, and provides narrative recommendation and moderation functionality</td>
<td>1-5</td>
</tr>
<tr>
<td>Smart Pharmacovigilance</td>
<td>Pharmacovigilance</td>
<td>2019</td>
<td>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</td>
<td>1-5</td>
</tr>
<tr>
<td>Digital Operations Fabric</td>
<td>Pharmacovigilance and complaint management</td>
<td>2019</td>
<td>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</td>
<td>5-10</td>
</tr>
<tr>
<td>Smart Email Management</td>
<td>Pharmacovigilance</td>
<td>2019</td>
<td>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</td>
<td>1-5</td>
</tr>
<tr>
<td>Automated Medical Coding</td>
<td>Pharmacovigilance</td>
<td>2019</td>
<td>It leverages NLP/ML for automating the medical coding process resulting in effort reduction</td>
<td>1-5</td>
</tr>
<tr>
<td>Analytics Suite of Services</td>
<td>Pharmacovigilance and complaint management</td>
<td>2019</td>
<td>Point solutions and operational dashboards built with business intelligence to monitor trends, identify bottlenecks, and improve quality and throughput</td>
<td>1-5</td>
</tr>
</tbody>
</table>
### Cognizant | pharmacovigilance and complaint management operations profile (page 5 of 6)

#### Technology solutions/tools

<table>
<thead>
<tr>
<th>Solution/tool name</th>
<th>Processes served</th>
<th>Year launched</th>
<th>Description</th>
<th>No. of BPS clients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automation solutions</td>
<td>Pharmacovigilance and complaint management</td>
<td>2018</td>
<td>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</td>
<td>1-5</td>
</tr>
<tr>
<td>Cognizant MedVantage®</td>
<td>Complaint management</td>
<td>2013</td>
<td>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</td>
<td>1-5</td>
</tr>
</tbody>
</table>
Everest Group PEAK Matrix® for Pharmacovigilance and Complaint Management Service Providers 2021

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

Everest Group assessment – Leaders

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.
Appendix
# Everest Group’s view of the pharmacovigilance operations value chain

## ADR intake
- Data acquisition and case validation
- Duplicate detection
- Prioritization/triage
- Prepare & send to global site
- Archive source data

## ICSR case processing
- Data acquisition and case validation
- Triage and initial assessment
- Full data entry
- Translation
- Medical assessment

## Reporting
- Narrative writing
- Coding
- In-line QC
- Case completion
- Follow-up questions and monitoring

## Signal and risk management
- Reporting rules maintenance and configuration
- Manual assessment
- Regulatory submission
- Acknowledgment and reconciliation
- Aggregate reporting
- Signal detection
- Signal validation and assessment (EU RMPs/US REMS)
- EU RMPs/US REMS development
- Signal amplification studies
- Benefit-risk evaluation

## Signal and risk management
- Signal detection
- Signal validation and assessment (EU RMPs/US REMS)
- EU RMPs/US REMS development
## Everest Group’s view of the complaint management operations value chain

<table>
<thead>
<tr>
<th>Complaint capture</th>
<th>Complaint processing &amp; investigation</th>
<th>Reporting and closure</th>
<th>Trend analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complaint intake</td>
<td>Complaint registration</td>
<td>Preparation of MDR</td>
<td>Trend analysis</td>
</tr>
<tr>
<td>Complaint triage</td>
<td>Case narrative &amp; coding</td>
<td>MDR submission</td>
<td>Signal detection</td>
</tr>
<tr>
<td>Field alerts reporting</td>
<td>AE identification</td>
<td>Supplementary report</td>
<td>Manufacturing issues trends</td>
</tr>
<tr>
<td>Complaint evaluation and prioritization</td>
<td>Field sample retrieval</td>
<td>Resolution and close-out</td>
<td>CAPA management</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Everest Group PEAK Matrix® is a proprietary framework for assessment of market impact and vision & capability

Everest Group PEAK Matrix

Market impact
(Measures impact created in the market)

Vision & capability
(Measures ability to deliver service successfully)

Leaders

Major Contenders

Aspirants
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.
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.

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