

Pharmacovigilance and Complaint Management Operations – Service Provider Compendium 2021

April 2021: Complimentary Abstract / Table of Contents



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In addition to a suite of published research, a membership may include

- Accelerators™
- Analyst access
- Data cuts
- Pinnacle Model® reports
- PriceBook
- Virtual Roundtables
- Workshops

Custom research capabilities

- Benchmarking | pricing, delivery model, skill portfolio
- Peer analysis | scope, sourcing models, locations
- Locations | cost, skills, sustainability, portfolio – plus a tracking tool
- Tracking services | service providers, locations, risk
- Other | market intelligence, service provider capabilities, technologies, contract assessment

Contents

1. Introduction and overview	06
• Research methodology	07
• Key information on the report	08
• Background of the research	09
• Focus of the research	10
• Pharmacovigilance operations value chain	11
• Complaint management operations value chain	12
2. Section: Summary of key messages	13
• Summary of key messages	14
3. Section: Pharmacovigilance and Complaint Management Operations – Services PEAK Matrix® characteristics	15
• PEAK Matrix framework	16
• Services PEAK Matrix® evaluation dimensions	17
• Everest Group PEAK Matrix for pharmacovigilance and complaint management operations	18
• Characteristics of Leaders, Major Contenders, and Aspirants	19
• Service provider capability summary dashboard	20
4. Service providers' market share analysis	24
• Market share and growth	25
• New revenue and client share	26
• Market share by processes	27

For more information on this and other research published by Everest Group, please contact us:

Ankur Verma, Practice Director

Nirwan Upmanyu, Senior Analyst

Sonali Srivastava, Senior Information Specialist

Contents

5. Enterprise sourcing considerations	28
• Leaders	28
– Accenture	29
– Cognizant	34
– Covance	40
– IQVIA	45
– TCS	50
– Wipro	55
• Major Contenders	61
– APCER Life Sciences	62
– Atos	67
– Bioclinica	73
– ICON plc	78
– Indegene	83
– Navitas Life Sciences	88
– Parexel	93
– PharmaLex	98
– PPD	103
– PRA Health Sciences	108
– PrimeVigilance (Ergomed plc)	113
– Syneos Health	118

Contents

5. Enterprise sourcing considerations	123
• Aspirants	123
– HCL Technologies	124
– Medpace	129
– Quanticate (Qvigilance)	134
– Tech Mahindra	139
6. Appendix	140
• Glossary	145
• Research calendar	146

Our research methodology is based on four pillars of strength to produce actionable and insightful research for the industry

01

Robust definitions and frameworks

Pharmacovigilance and complaint management value chain, PEAK Matrix™, market maturity

02

Primary sources of information

Annual contractual and operational RFIs, service provider briefings and buyer interviews, web-based surveys

03

Diverse set of market touchpoints

Ongoing interactions across key stakeholders, input from a mix of perspectives and interests, supports both data analysis and thought leadership

04

Fact-based research

Data-driven analysis with expert perspectives, trend-analysis across market adoption, contracting, and service providers

Proprietary contractual database of over 220 Life Sciences (LS) contracts (updated annually)

Year-round tracking of 22+ drug and/or device vigilance service providers

Large repository of existing research in LS operations (including pharmacovigilance)

Over 25 years of experience advising clients on strategic IT, business services, engineering services, and sourcing

Executive-level relationships with buyers, service providers, technology providers, and industry associations

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

This study offers four distinct chapters providing a deep dive into key aspects pharmacovigilance and complaint management market; below are the charts to illustrate the depth of the report

Pharmacovigilance and Complaint Management Operations – Service Provider Compendium 2021

XYZ | pharmacovigilance and complaint management operations profile (page 1 of 4) Overview

Company overview
XXX is a global professional services company, providing a broad range of services and solutions in strategy, consulting, digital, technology, and operations. Combining unmatched experience and specialized skills across more than 30 industries and all business functions, XXX works at the intersection of business and technology to help clients improve their performance and create sustainable value for their stakeholders. With 57,000 people serving clients in more than 50 countries, XXX drives innovation to improve the way the world works and lives

Key leaders
XXX, Chief Executive Officer
XXX, Chief Financial Officer
XXX, Chief Operating Officer
XXX, Group Chief Executive

Headquarters: XX, XXX
Website: www.xxx.com

- Suite of services**
- **Pharmacovigilance** – ICSR case processing, signal detection, risk management, local affiliate activities, PV analytics and applications, literature surveillance, aggregate/regulatory reporting, clinical evaluation reports, medical safety assessment & other PV support activities
 - **Complaint Management** - Intake processing, complaint mailbox management, triaging, complaint coding, product investigation, complaint review, complaint approval and closure, customer communication, warranty claim processing, regulatory reporting, product return tracking, and CAP management

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

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XYZ | pharmacovigilance and complaint management operations profile (page 2 of 4) Key delivery locations



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XYZ | pharmacovigilance and complaint management operations profile (page 3 of 4) Capabilities



PV and complaint management operations – services split by buyer size¹



1: Buyer size is defined as mega (>US\$20 billion), very large (US\$10-20 billion), large (US\$1-10 billion in revenue).

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XYZ | pharmacovigilance and complaint management operations profile (page 4 of 4) Technology solutions/tools

Solution/tool name	Processes served	Year launched	Description	No. of BPS clients
ADD Safety platform	ADR intake, case processing, reporting, signal and risk management	2020	Safety database for case processing and line listing management. New version of ADD safety platform incorporates cognitive and Analytical AI platform Decision Fabric™	3
Literature tool	ADR intake	2020	Literature review management & Automated review	1
Advance analytic for trending	Signal and risk management	2020	Automated Trend analysis and advance prediction of medical devices product performance	1
Automation of coding	Case processing	2019	Automatic selection of harm / risk to patient based on event description.	1
Mailbox management	Complaint intake	2019	Automatic sorting of email and assignment of complaints based on product family	1
Medical coding	Case processing, reporting	2018	Management MedDRa terms, Seriousness, labeling, coding linked to safety database. Helps to manage SMQs.	2
PV robotic automations	ADR intake, case processing, reporting, signal and risk management	2014	40+ point automation solutions across PV process areas leveraging combination of TCS IP, RPA as well as AI/ML technologies	12

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8

Glossary of key terms used in this report

BPS	Business Process Services refers to the purchase of one or more processes or functions from a company in the business of providing such services at large or as a third-party provider
Buyer / enterprise	The company/entity that purchases outsourcing services from a service provider of such services
FTEs	Full-Time Employees on the rolls of the company
AE intake & capture	Includes intake process from safety call center reported cases, clinical trial SAES, spontaneous reports, and literature (or other sources) search engines
Case processing	Includes triaging, medical review, medical assessment, medical writing, coding, and completion
Reporting and submission	Includes submission and regulatory reporting (within given timeframes)
Safety and risk management	Includes signal management (signal detection, validation, and assessment), risk management (data collection, evaluation, selection & plan, and implementation), benefit-risk assessment, and documentation (reports)
Product quality complaints	Includes complaint intake (multi-channel / multi-lingual), triage, field alerts reporting, evaluation, and complaint prioritization
Complaint processing and investigation	Includes complaint registration, case narrative & coding, AE identification, sample retrieval, product investigation, root cause/failure analysis, and preparing response letters
Reporting and complaint closure	Includes submission, report preparation, resolution, complaint closure, trend analysis, and signal detection

Research calendar

Life Sciences BPS

■ Published
 ■ Planned
 ■ Current release

Flagship Life Sciences BPS reports

	Release date
Life Sciences Report Card – Outlook for 2019 and Enterprise Initiatives and Service Provider Performance in 2018	April 2019
Life Sciences (LS) Operations – Services PEAK Matrix™ Assessment 2020	December 2019
Life Sciences (LS) Operations – Service Provider Compendium 2020	March 2020
Pharmacovigilance and Complaint Management Operations – Services PEAK Matrix® Assessment 2021	April 2021
Life Sciences Operations PEAK Matrix Assessment with Service Provider Landscape 2021	Q2 2021
Pharmacovigilance Operations Service Provider Profile Compendium 2021	Q2 2021
Life Sciences Operations – State of the Market Report 2021	Q2 2021
Life Sciences Operations Service Provider Profile Compendium 2021	Q2 2021

Thematic Life Sciences BPS reports

	Release date
Innovation in Pharmacovigilance (PV): How to Spend Smarter Not Higher?	June 2017
Pharma Sales & Marketing: Old Strategies Into New Methods Focus on Transmutation Rather Than Transformation	June 2018
Clinical Trials of the future	Q3 2021
The Phoenix of Genomics	Q4 2021
Real-world Evidence - 3D (pharma, payer, and provider)	Q4 2021
Viewpoint on Pharmacovigilance	Q1 2022

Note: For a list of all of our published Life Sciences BPS reports, please refer to our [website page](#)



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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

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