

Pharmacovigilance (PV) Outsourcing — Emerging PV business models

Executive summary

As the pharmaceutical industry expands in size and global reach, it faces new and more complex challenges. These fall especially heavily on Pharmacovigilance groups which must keep up with product innovation, advances in technology, and changing regulatory requirements while at the same time delivering on their risk management responsibilities.

Pharmacovigilance has long been fundamental to the industry, but events of the last decade, including more thorough safety documentation and reviews for drug approvals, and increased warnings and awareness about adverse drug reactions, have made drug safety one of the top issues for consumers and regulators. Safety concerns have prompted global mandates for submitting significantly more granular product information, as well as demands for new levels of clinical and safety data transparency.

As a result, demand for robust compliance systems and experienced talent has raised the cost of maintaining the infrastructure necessary to support pharmacovigilance. Even with proper funding, an organization's ability to scale up compliance and quality operations may be limited by its ability to attract and retain qualified people to staff its in-house PV function.

Pharmaceutical companies must move to a more efficient, strategically focused PV capability in order to be less reactionary, resource-intensive, and transaction focused, and become instead a more proactive agent for patient safety. This change in role and focus for PV is driven by:

- Regulators increasing concern with timely and accurate reporting of adverse events as illustrated by the EMA Roche hearings that may result in a fine totaling 5% of Roche drug revenue in the EU (nearly one billion dollars USD)
- Regulators' increasing scrutiny of adverse events originating from sources beyond clinical trials and help lines, and which include areas like non-interventional programs, patient assistance programs, and vendor interaction with patients
- A future likely to include additional requirements and increased emphasis on safety data gleaned from social media and industry sponsored websites

As a result of these regulatory changes, new PV operating models must focus on four key components to become proactive, resource efficient, and business aligned:

- 1. Core Capabilities:** Pharmacovigilance delivers four primary capabilities to pharmaceutical companies:
 - Adverse Event Case Management including expedited reporting;
 - Aggregate Reporting;
 - Signal Intelligence; and
 - Risk Management.
- 2. Strategy:** Business strategy must take into account the benefit-risk characteristics of each product. When effectively implemented, PV can drive competitive advantage by developing a stronger benefit-risk profile and improved identification of at-risk patients.
- 3. Global Networks:** PV must achieve global coverage and meet diverse, market-specific regulatory frameworks. A network of centralized, regional, and local capabilities is required to maintain visibility and consistency while facilitating local responsiveness.
- 4. Governance:** Effective issue escalation and resolution requires clear governance. A closed loop process, tightly linked to organization-wide crisis management processes, can mitigate safety risks while maintaining compliance.

Many companies are turning to alternative delivery models to increase efficiency and capacity. These range from internal redesign to full-scale outsourcing, with many variations in between. Although elements of PV have been outsourced for a number of years, its efficiency and effectiveness has not been ideal and is only now maturing to the point where it can be considered more seriously. Regular review and assessment of fitness for purpose is an essential activity for high-performing enterprises. This paper provides an overview of the outsourcing market and examines options to use outsourcing to efficiently manage and improve the PV delivery model.

Efficiently managing the PV delivery model

There are three general lines of attack in achieving the capabilities required to meet today's challenging business needs: internal optimization, consolidation, and outsourcing. Most organizations have found that a mix of all three is required to strike the right balance of benefits and risk.

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- **Internal Optimization:** Internal optimization allows well trained (and sometimes expensive) internal employees to focus on the highest value activities. This approach includes investing in critical tools to streamline activities and increase the effectiveness of the PV organization.
- **Consolidation:** Consolidation into a single, shared services organizational unit can increase efficiency of the internal staff by easing the introduction of standardized processes that service all primary business units and product lines, while reducing redundancy and increasing centralized visibility and control.
- **Outsourcing:** Engaging a third party for some or all PV operations is the primary topic for this paper; outsourcing allows the business to target specific expertise that is difficult to develop internally. Additionally, by taking advantage of labor arbitrage and economies of scale, outsourcing can result in lower costs and increased efficiency.

Although firms have outsourced PV activities for a number of years, outsourcing this mission critical function can still be controversial. On the one hand, for those companies that consider PV a cost center whose benefits are difficult to directly monitor, outsourcing the function will seem a perfectly reasonable approach. On the other hand, since mishandling adverse events can damage a company financially and harm its reputation, great care must be taken to determine which elements of the function can be delegated to a third party provider.

Better management and planning of outsourcing strategy development, and the quality of its execution, can mitigate risks and challenges the industry has historically faced.

The decision whether to outsource work to high value

internal resources, external experts, or third party service providers is a trade-off among transparency, control, service levels, and cost-efficiency. To create and execute a long term, consistent, risk-adjusted strategy, it is essential to review each in-scope PV activity to make certain core services are retained and business risks are mitigated. Companies tend to retain functions that provide a competitive advantage in the marketplace, including areas of significant intellectual property and brand impact. Understanding how the organization delivers to business needs, and where gaps exist, is also a key dimension used to assess suitability for a third party model.

Pharmacovigilance Outsourcing: An overview

Pharmacovigilance outsourcing (PVO) transfers the execution of drug safety functions and processes to a third-party provider. These include primary PV activities like case processing, as well as governance activities like compliance management. The processes ultimately outsourced depend upon criteria which differ by organization.

Core activities include:

- Collecting adverse drug reaction (ADR) data and information
- Case processing activities
- Preparing and development of Risk Management Plans (RMPs) and Risk Evaluation Mitigation Strategy (REMS)
- Creating and submitting expedited and aggregate PV reports

Management activities include:

- Preparing standard operating procedures (SOPs) and other controlled quality documents
- Assisting with internal and external compliance

Commonly outsourced Pharmacovigilance functions (For Illustrative Purposes)

ADR Capture	Case Processing	Reporting and Submissions	Report Publishing	Quality	Risk Management	Knowledge Management	Enabling Architecture
Call Center	Case Intake	Expedited Reporting to HAs	Management Oversight	Audit Readiness	Risk Management Plan	Signal Management	Safety DB Hosting
Social Media	Case Triage	Periodic Reporting	Authoring	CAPA	Risk Evaluation	QPPV	Safety DB Hosting
Legal	Data Entry	Partner Reporting	Reviewing	QMS	Risk Minimization	SOP Development	Safety DB Management Data Warehouse
License Partner	QC	Labeling Updates	Document Management	Quality Adherence	Signal Detection	Training	Data Warehouse
Clinical Trials	Medical Review <small>Typically Core/Not Fit</small>	PSMF <small>Typically Not Fit</small>	Approval <small>Non-Core/Typically Non-Core/Fit</small>		Signal Management	SDEA Development	
Literature	Distribution	EVMPD Maintenance				Literature Screening	
Regulatory Authorities						Regulatory Intelligence	

- reporting
- Testing and monitoring business processes and systems for compliance
- Performing trend analyses and predictive modeling for compliance operations
- Preparing detailed descriptions of the Pharmacovigilance System
- Preparing or reviewing safety data exchange agreements with third parties / business partners
- Inspection readiness training
- PV system upgrades
- Audit, development of corrective action plans, and Corrective and Preventative Action (CAPA) implementation

Potential benefits of PV outsourcing

A well implemented PVO program can drive significant benefit for the organization, including:

- Converting fixed resource costs into variable, workload dependent charges
 - Reducing the number of resources to recruit, manage, and/or train
 - Improving on-demand access to unique expertise, intellectual property, and multidisciplinary knowledge
 - Increased business model and capacity flexibility
 - Improved efficiencies and Return on Investment (ROI)
- Outsourcing provides well-documented cost benefits.

The Deloitte 2012 Global Outsourcing and Insourcing Survey found 57% of respondents (from 111 companies with \$1 billion to \$5 billion median revenue, and representing 22 primary industries) achieved cost savings of more than 10%.

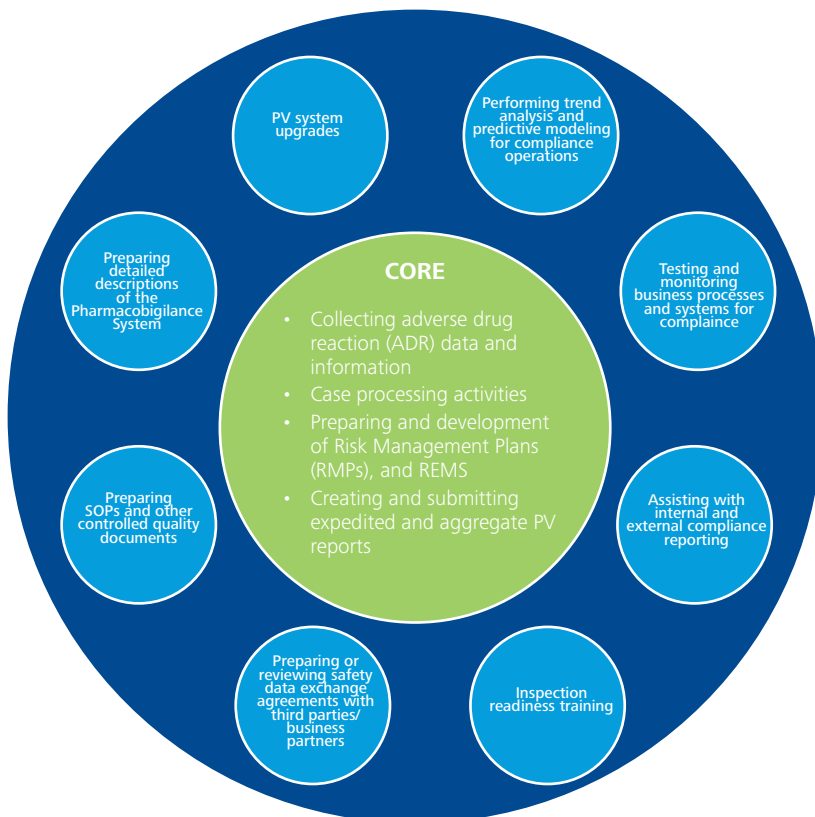
Benefits extend beyond cost savings and address three common pain points:

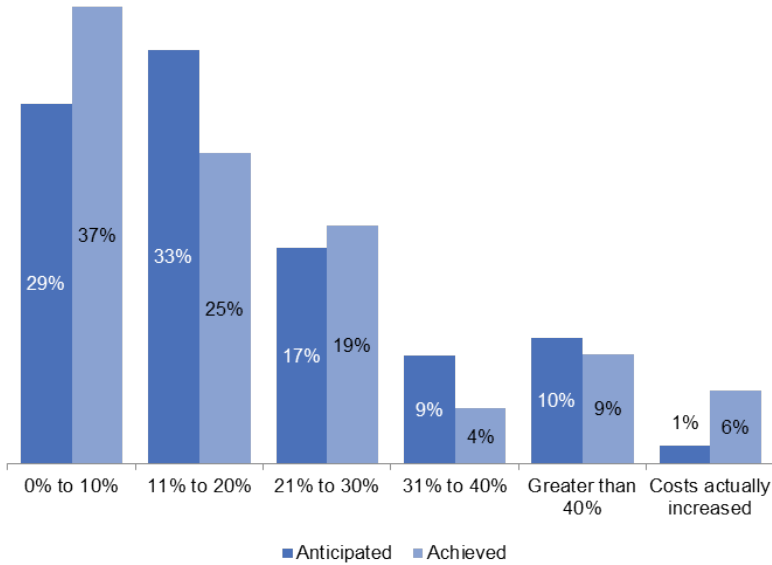
- **Talent shortages:** Maintaining compliance amidst increasing regulatory complexity, especially in a global context, requires individuals skilled in risk management and knowledgeable of regulatory and compliance operations; these professionals are in short supply and high demand. Organizations are struggling to increase operational budgets to provide training and to gain access to an extended talent pool.
- **Sub-optimal compliance processes:** Organizations want to focus on improving and streamlining their compliance processes to make them more predictable; however, continual changes in the regulatory landscape can undermine compliance process investments, leading to suboptimal and non-compliant processes. This may result in higher compliance costs (i.e., through rework) and lower quality levels.
- **Technology infrastructure investments:** Organizations are constantly investing in technology and related infrastructure to help meet compliance needs. With frequent changes to existing regulations, as well as the introduction of new regulations, frequent technology investments are needed to keep pace.

While data privacy concerns, regulatory complexity, data governance, and infrastructure challenges require a solid governance framework to realize the benefits of outsourcing, these very challenges argue in favor of PV outsourcing since many of them can be addressed more effectively by specialty third party providers. Their people come with market tested processes, technology, and expertise and can be difficult to hire internally.

Over time, organizations can foster relationships with the right outsourcing providers in partnerships that add competitive depth. These providers should be expected to deliver innovation to increase organizational competitiveness by bringing leading practices in their areas of specialization, and allowing management to focus on its strategic agenda.

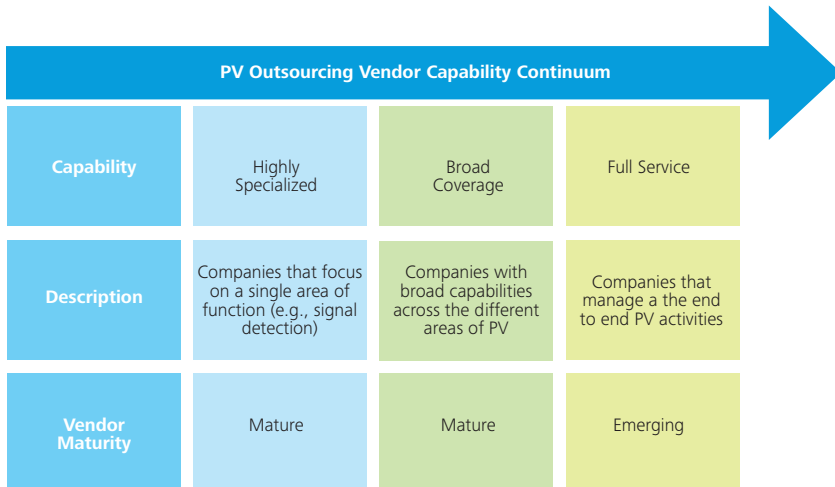
It must be noted, however, that while outsourcing PV can free management to focus its attention on core capabilities and business performance, a strong vendor management structure is necessary to meet the organization's obligation to manage and oversee the provider's performance.





The Pharmacovigilance outsourcing marketplace
 The PV outsourcing market has many participants, and their capabilities span the sourcing maturity curve.

Providers have mixed capabilities and infrastructures to support PV processes. Solutions are based on historical factors, including previous and existing relationships with life sciences companies. Despite the highly regulated nature of pharmacovigilance, the quality of service varies along technology and expertise lines, and processes are not standardized across providers. However, many PV providers have demonstrated a willingness to invest in strategic technologies and processes to deliver on specific customer requirements as they seek to expand their existing PV footprint. Since the market has not yet solidified around a particular methodology, solution



providers are often willing to invest in their customer’s preferred approach while they experiment with the optimal product package.

As we noted above, the costs to maintain the required levels of compliance infrastructure and in-house talent is growing, and this creates financial and management challenges for customer organizations. In contrast, external providers focus on developing and maintaining the

Outsourced compliance providers can offer several potential advantages over in-house compliance functions due to the specialization and systems they commonly maintain.

required knowledge as a core competency, often by hiring former regulators and experienced PV leaders from industry; this focus and specialization allows them to better control and manage costs. In addition, providers bring process frameworks, knowledge from performing similar services for other customers, and accelerators to the delivery of value-based pharmacovigilance outsourcing services. These benefits can help firms realize the benefits of cost savings and allows firms to focus on core strategic objectives.

Conclusion

Meeting pharmacovigilance requirements will increasingly include reliance on third party providers. PV outsourcing providers can help organizations address the increasing volume and complexity of regulatory requirements, add scalability to accommodate growing product portfolios, and economies of scale to help achieve aggressive cost targets. Pharmaceutical companies are pushing the envelope on how they will leverage outsourcing providers to accomplish their objectives and learn from previous missteps. This collaboration is driving further specialization and consolidation of talent within provider organizations, and is providing opportunity for internal PV organizations to adopt a more strategic role to proactively improve the safety of their products. Given the innovation that is occurring in the PV outsourcing market, life sciences firms should reexamine outsourcing as a valuable tool as they look to address future requirements and opportunities.

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