

## White Paper

# Outsourcing Local Pharmacovigilance (PV) Operations: Pain or Gain?

As global regulations become increasingly stringent, pharmaceutical companies face challenges in maintaining effective local pharmacovigilance (PV) operations. While global PV outsourcing is widely adopted to optimize efficiency and reduce costs, local PV operations present a unique set of hurdles.

Here we explore the challenges of local PV operations, the potential benefits of outsourcing, key considerations for vendor selection, and how a comprehensive local PV model helps pharmaceutical companies achieve compliance while optimizing costs and efficiency.

## Challenges in Local PV Operations

Maintaining compliance with local PV requirements is critical, yet many pharmaceutical companies face challenges including:

- Lack of Standardized Technology and Automation
- Inconsistent and Siloed Local PV
- Duplicated Efforts in Decentralized Structures
- Varying Adverse Drug Reaction (ADR) Collection & Reporting Practices
- Regulatory Changes & Compliance Risks

Additionally, staying up to date with frequent changes at the local level, poor coordination leading to missed signals, and the costs of training and system standardization contribute to further operational difficulties.

## The Case for Outsourcing

To reduce costs and enhance efficiencies, pharmaceutical companies often outsource their global PV operations to some extent. The advantages of outsourcing global PV processes are well-recognized, as it alleviates the burden of managing resource-intensive activities across PV department and reduces operational costs.

The industry is now increasing focus on aligning local PV operations and standardizing the practices at both local and global levels. Outsourcing local PV operations can be trickier than outsourcing global PV due to complex local regulations, limited pool of adequately qualified and reliable local resources, and the difficulty maintaining a proper oversight by parent company due to language barriers.

Maintaining an in-house PV team across multiple countries is far more expensive. Despite these challenges, the responsibility for PV compliance ultimately rests with the pharmaceutical companies.

## Key Considerations in Outsourcing Local PV Operations

Selecting the right vendor is crucial for achieving operational success at the regional/local level. Since local PV requirements differ by country, outsourcing to multiple vendors can hinder effective oversight and lead to inconsistencies due to varying standards, processes, and quality levels. Pharmaceutical companies evaluating local PV outsourcing should consider:

- 1. Regulatory Expertise** – Deep knowledge of local regulatory requirements to ensure ongoing compliance.
- 2. Consistency in Processes & Quality Standards** – Outsourcing to multiple vendors leads to inconsistencies; a unified approach is key.
- 3. Technology & Automation** – Ability to integrate with existing global PV systems ensures seamless operations.
- 4. Risk Mitigation & Oversight** – Strong governance framework helps pharmaceutical companies maintain control and visibility over local PV activities.

## Key Considerations in Outsourcing Local PV Operations

Sitero offers a comprehensive local PV outsourcing model designed to overcome the challenges of regional PV. By partnering with Sitero, pharmaceutical companies can reduce operational costs, minimize compliance challenges, and enhance the efficiency of their local PV operations. At Sitero, we provide:

- **Global Coverage:** Supporting local PV operations across North America, Europe including EU and non-EU countries, Latin America, Asia Pacific, Middle East, and Northern Africa.
- **Local Regulatory Expertise:** Our PV professionals are well-versed in country-specific regulations and compliance requirements.
- **Single-Vendor Model:** Eliminating reliance on multiple vendors, ensuring standardization, and providing a Single Point of Contact (SPOC) for streamlined communication.
- **Hybrid Operating Model:** Combining centralized oversight with local execution to balance efficiency and compliance.

## Conclusions and Next Steps

Outsourcing local PV operations can be complex, but with the right strategy and vendor, pharmaceutical companies can achieve significant cost savings, regulatory compliance, and operational efficiencies. Sitero's expertise in local PV operations provides a seamless, integrated approach that ensures consistency, compliance, and cost-effectiveness.

[Contact us](#) to learn more about how Sitero can support your local pharmacovigilance needs.