WHITE PAPER

International pharmacovigilance: A strategic global model for compliance and patient safety

A KEY QUESTION

How can organizations simplify global and local pharmacovigilance while maintaining compliance and patient safety?

KEYWORDS International Pharmacovigilance (IPV), Global Pharmacovigilance Services, Regulatory Compliance, Patient Safety, Marketing Authorization Holders (MAHs), Qualified Person Responsible for Pharmacovigilance (QPPV), Pharmacovigilance System Master File (PSMF), Regulatory Intelligence, Literature Surveillance, Integrated Global Service Model

The globalization of pharmaceutical development and commercialization has significantly increased the complexity of Pharmacovigilance (PV) operations. Marketing Authorization Holders (MAHs), ranging from large multi-national pharmaceutical organizations to emerging biotech companies, face growing challenges in maintaining compliance with diverse and evolving global PV regulations while ensuring patient safety.

International Pharmacovigilance (IPV) requires not only centralized oversight but also local expertise, country-specific regulatory knowledge, qualified local personnel and robust operational infrastructure. As regulatory expectations continue to expand globally, outsourcing to an integrated PV service provider offering end-to-end global and local PV capabilities has become a strategic necessity rather than an operational option.

This white paper explores the challenges faced by MAHs and presents a comprehensive solution through a globally integrated PV service model.

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International pharmacovigilance: Navigating global complexity through an integrated service model

PV has evolved from a regulatory requirement into a critical component of patient safety, risk management and corporate compliance.

As pharmaceutical companies expand into multiple territories, PV activities must be managed across numerous regulatory jurisdictions, each with distinct requirements, reporting obligations, language expectations and local representation mandates.

What is international pharmacovigilance?

IPV refers to the management, oversight and execution of PV activities across multiple countries and regulatory jurisdictions while ensuring compliance with both global and local regulatory requirements.

Services included in international pharmacovigilance

A comprehensive IPV program typically includes:

- **Qualified Person Responsible for Pharmacovigilance (QPPV)**
- **Local Qualified Person Responsible for Pharmacovigilance (LQPPV)**
- **Local Contact Person Responsible for Pharmacovigilance (LCPPV)**
- **Local Safety Officer (LSO) services**
  - Health authority interactions
  - Affiliate support
- **Literature surveillance**
  - Global and local literature surveillance
  - Safety management
- **PV system management**
  - Pharmacovigilance System Master File (PSMF) authoring and maintenance
  - Local annex management
  - Inspection support
- **Business partner compliance**
  - Pharmacovigilance Agreements (PVAs) and Safety Data Exchange Agreements (SDEAs) authoring and maintenance
  - Compliance tracking
- **Regulatory intelligence**
  - Global and country-specific regulatory surveillance
  - Impact assessments
  - Regulatory implementation support

Challenges faced by marketing authorization holders

Rapidly evolving global regulatory landscape

Global PV regulations continue to evolve at an unprecedented pace. Each health authority has unique PV requirements. Some examples of differences in requirements include:

- ICSR reporting requirements
- Time of initiation of each activity (e.g., at the time of application for approval, at approval or at the time of market launch)
- Risk management
- QPPV/LQPPV/LCPPV requirements
- PSMF template

These requirements have a significant impact on MAHs, including increased compliance risk, difficulty maintaining global oversight and continuous regulatory monitoring.

Requirement for qualified local presence

Several EU and non-EU countries mandate local PV contacts with specific qualifications, language capabilities and local availability, which significantly increases operational costs for MAHs and creates challenges in maintaining local expertise, especially when supporting low-volume markets.

Limited internal resources

This challenge is particularly acute for small and mid-sized biotech companies that have lean safety teams, limited safety budgets and rapid geographic expansion plans.

While large pharmaceutical companies may have larger teams, they also have to manage complexity due to multiple products, numerous affiliates and business partner networks and extensive regulatory oversight from health authorities.

These limitations often lead to resource constraints, delayed implementation, increased compliance risk and reduced operational efficiency.

Fragmented vendor management

To minimize the challenges listed above, organizations are required to use multiple vendors for local PV activities because of limited local presence, leading to inconsistent processes, governance inefficiencies and increased oversight burden.

The solution: Integrated global pharmacovigilance services under one umbrella

A strategic solution is partnering with an experienced global PV service provider capable of delivering both global and local PV services through a single governance framework.

By consolidating services under a single provider, MAHs gain:

Operational benefits

- Simplified governance
- Centralized oversight
- Streamlined communication
- Reduced vendor management burden

Compliance benefits

- Regulatory compliance support through real-time updates in weekly or monthly governance calls
- Improved audit and inspection readiness

Financial benefits

- Lower operational costs
- Reduced infrastructure investment
- Scalable support model
- Flexible resource allocation

Strategic benefits

- Faster market expansion
- Improved business continuity
- Greater operational agility
- Focus on core business activities

Conclusion

The increasing complexity of global PV requirements presents significant operational and compliance challenges for both large pharmaceutical organizations and emerging biotech companies. Evolving regulations, local representation mandates, language barriers and limited internal resources create a compelling need for an integrated global PV model.

A comprehensive service provider offering QPPV, local PV representation, literature monitoring, PSMF management, PVA/SDEA oversight and real-time regulatory intelligence under a single governance framework enables MAHs to maintain compliance, ensure patient safety and achieve operational efficiencies globally.

As regulatory expectations continue to increase worldwide, a holistic IPV strategy is becoming a critical enabler of sustainable global commercialization and long-term regulatory success.

Fortrea can be an effective IPV provider with direct presence and access through trusted and qualified local providers across Europe, North America, Latin America (LATAM), Asia-Pacific, Middle East and North Africa (MENA) and Africa. Key IPV services offered by Fortrea include QPPV, LQPPV, LCPPV and LSO services, local literature monitoring, PSMF authoring and maintenance, PVA and SDEA authoring and maintenance and regulatory intelligence with real-time updates.

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