

### Why choose PrimeVigilance PV Network:

- Market leader in the provision of local contact persons for Pharmacovigilance, Regulatory, and Quality Assurance
- Best in class management and oversight with simple and elegant solutions to manage the nuances of local markets
- Enhanced services leveraging in-house QPPVs, strategic advisors, and subject matter experts
- Audit-ready systems to guarantee compliance with local and global requirements at all times

**140+**  
countries

**300+**  
LCPPVs

**13+**  
years of  
experience

### What is a PV network?

Whether you refer to them as Local PV Contact Person, LQPPV, Local Safety Officer, or Stufenplanbeauftragter, we have them all!

Our enhanced network is bolstered by a team of local Pharmacovigilance, Regulatory Affairs, Quality Assurance and Local Literature Screening specialists ready to be deployed. They work seamlessly with our clients, affiliates, and partners in achieving complete PV and regulatory compliance.

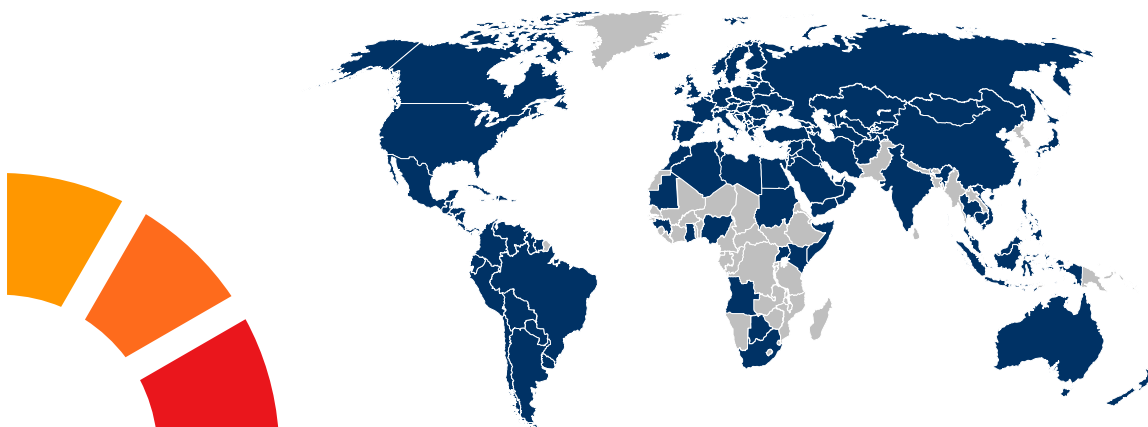
Our PV Network enables flexible ‘on demand’ resource allocation and management, delivering at the right time, right cost, and with the right experience. We offer a comprehensive, top-quality, cost-effective, and innovative safety solution.

Our flexible and fit-to-size approach facilitates tailor-made solutions that enable us to provide you with customized solutions for post-marketing PV Network services. We can provide preinspection and audit support of your Local PV system, identify and fill gaps, advise on corrective actions as well as support communication and liaison with local regulatory authorities to ensure compliance.

Our extensive and reliable network of local contact persons, robust systems, and dedicated Project Leads achieve rapid project setup to meet the tightest timelines for implementing PV/RA/QA services to align with new product launch or licence transfer schedules.

### Key Differentiators

- Global capabilities in 140+ countries
- Regulatory expertise to advise on country-specific requirements and timing for appointment of local contact person
- Controlled quality procedures developed and tested to withstand audit/inspection scrutiny
- Client/Product specific training and automated follow-up via our e-learning system to ensure compliance
- Centralized management and oversight driving consistent quality across all territories
- Customized reports and KPIs



**60+**  
clients  
globally

**300+**  
local PV  
experts

## Integrated Local Regulatory Affairs and PV Network Solutions



Clinical Development Plan/Strategy  
Pre IND and Scientific Advice meetings  
Orphan Designation applications  
Fast track and breakthrough applications (FDA), PRIME (EMA) iPSP/PIP  
CTA/IND filing



Device classification  
US Market clearance and EU CE marking  
Clinical evaluations/ investigations



Biologic and Chemical entity CMC expertise (IMPD/Module 3)



Eudravigilance product registration



Regulatory and PV Intelligence



MAA/NDA submissions  
Post marketing maintenance  
Artwork and labelling

## Case Study I Managing Multiple Stakeholders

27 countries

### Background/Project Overview:

Client requested PV Network to support change in MAH requiring compliance of LCPV services in multiple territories.

### Issues:

Previous MAH had numerous critical inspection findings. License renewal and transfer of Marketing Authorisation were at risk if findings were not addressed satisfactorily.

### PV Network Action:

- **Gap Analysis:** Reviewed CAPAs and historical information, identified issues and proposed corrective actions.
- **Communication:** Facilitated understanding between local and global MAH holder and provided liaison with Regulatory Agencies.
- **Process Development and Training:** Designed and delivered PV training to MAH personnel in alignment with local regulations to fill gaps identified. Developed local PSMF and set up local PV Systems.
- **Execution:** Mobilized in-house subject matter experts and consolidated action items to offer immediate solution whilst supporting the MAH to implement a longer term plan. Facilitated MAH transfers and avoided gaps during transfer.

### Result:

MA successfully transferred to new MA holder and license was maintained.

## Case Study II Rapid Launch

15 countries

### Background/Project Overview:

Client requested PV Network to support market launch by providing Regulatory Affairs expertise in local territories.

### Issues:

Short timeline for submission of documents to the NCA, unclear guidance regarding local requirements.

### PV Network Action:

- **Pre-Launch Meeting:** Definition of expectation, strategy and timeline, as well as cross-functional discussion.
- **Gap Analysis:** Assessment of latest approved product information for compliance with requirements, Braille certificate, artworks design, national codes, latest approved product information, prioritization with regards to business strategy, target markets, Power of Attorney, supply chain, and commercial packaging.
- **Strategy:** Development of a rapid launch plan focusing on business objectives; target markets, supply chain and commercial packaging. Development of action items and timelines to achieve milestones.
- **Execution:** Flexible approach to meet the urgent request via fully competent resources.

### Result:

Products are successfully launched on the market within agreed timeline.