

Global PV Oversight for China Development Programs

Early PV alignment helps protect safety data consistency, reduce operational fragmentation, and support stronger regulatory decision-making as programs progress from IIS activity to formal IND development.

SUPPORTING SAFETY CONSISTENCY FROM IIS TO IND-ENABLING STUDIES

As development programs expand across different sponsorship models, countries, and regulatory environments, consistent safety data management becomes critical. For sponsors running IIS activities in China while preparing for future IND-enabling studies, strong pharmacovigilance governance from the outset can help protect data integrity, strengthen oversight, and support better regulatory decision-making.

PrimeVigilance is well positioned to support China-related programs by working in coordination with local sponsors and stakeholders to maintain local compliance while preserving global safety consistency, oversight, and governance across the broader development program.

HOW PRIMEVIGILANCE CAN SUPPORT

For IIS activities in China, PrimeVigilance can provide centralized global PV support in coordination with local sponsor responsibilities, including:



- Global safety case intake and processing
- SAE reconciliation and oversight



- Aggregate reporting support
- Safety database management



- Signal detection and safety surveillance
- Global literature monitoring



- Medical review and PV governance
- SOP alignment and procedural oversight



- Vendor oversight and coordination with local Chinese PV stakeholders
- Safety data consistency across global and regional programs

WHY A SINGLE-VENDOR PV STRATEGY MATTERS

For IIS activities in China, PrimeVigilance can provide centralized global PV support in coordination with local sponsor responsibilities, including:

Consistent Global Safety Oversight

One PV partner helps ensure harmonized safety governance, standardized workflows, and consistent medical review across regions, including China.

Simplified Vendor Management

A centralized model reduces duplication across contracts, governance meetings, reconciliation activities, KPIs, quality management, and oversight processes.

Improved Data Quality and Inspection Readiness

A unified safety database and standardized processes improve traceability, audit readiness, and consistency across global submissions.

Stronger Integration of Global and Local Requirements

PrimeVigilance can coordinate with local Chinese partners and sponsors to ensure local obligations are addressed while maintaining alignment with the global safety strategy.

Scalability for Future China Expansion

Establishing a centralized PV governance model early creates a scalable foundation for future IND studies, multi-center trials, and commercialization activities.

Reduced Communication Gaps

A single accountable PV lead improves communication between sponsor teams, CROs, local partners, and investigators, supporting faster issue resolution and clearer safety accountability.

Strengthen Safety Governance from IIS to IND Development

As development strategies evolve toward formal IND studies in China, PrimeVigilance supports the development of tailored pharmacovigilance operating models that align local regulatory expectations with broader global development objectives. By integrating China-specific activities into a unified global PV framework, PrimeVigilance helps maintain operational continuity, support local regulatory expertise where required, and define clear oversight structures and role delineation between global PV teams, local sponsors, and regional stakeholders.

Discuss your China PV operating model with PrimeVigilance.

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