

Case study

Building a Harmonized Safety Trigger Reporting Model Across 25 Countries

OUTCOME



25 Countries
On-time reporting



Harmonized Model
Standardized cross-border operations



Improved Coordination
Global and local stakeholders aligned



Sustainable Compliance
Framework established for ongoing reporting

OVERVIEW | MULTIPLE COUNTRIES, LANGUAGES AND TIMELINES CREATED A COMPLEX CROSS-BORDER REPORTING ENVIRONMENT

A client required weekly cross-reporting of safety triggers across LATAM, Africa, and Asia. Multiple health authority requirements, languages, timelines, and stakeholders created a highly complex operational environment.

● **25 COUNTRIES** ● **MULTIPLE HEALTH AUTHORITIES** ● **MULTIPLE LANGUAGES** ● **DIFFERENT TIMELINES** ● **MULTIPLE STAKEHOLDERS**

WEEKLY SAFETY TRIGGER REPORTING



OUR APPROACH | A STANDARDIZED GLOBAL PROCESS CONNECTED LOCAL EXPERTISE THROUGH CENTRAL GOVERNANCE

PrimeVigilance developed a standardized global process supported by Local QPPVs, signal management experts, Regulatory Intelligence, and project management teams. Strong governance and communication ensured consistent implementation across all countries.



WHAT MADE IT SUCCESSFUL

- Standardized Global Process
- Strong Local Expertise
- Clear Communication
- Central Governance

Effective safety communication depends on the ability to transform global signal information into timely local regulatory action.



**Ready to Partner?
Contact Us Today!**

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