




## CASE STUDY

# High-Volume Global Pharmacovigilance Onboarding



A global biotechnology sponsor required rapid expansion of its pharmacovigilance operations to support high-volume Individual Case Safety Report (ICSR) processing across multiple regions. Monthly case volumes exceeded 30,000 ICSRs, creating immediate pressure on resourcing, training, quality, and regulatory compliance.

The sponsor sought an experienced partner capable of rapid global onboarding, operational scalability, and sustained compliance without disrupting ongoing safety operations.

Challenge 	Solution 	Result 
<ul style="list-style-type: none"> <li>Sudden increase in global ICSR volumes exceeding 30,000 cases per month</li> <li>Limited internal capacity to support rapid scale-up</li> <li>Tight onboarding timelines for critical PV roles</li> <li>Training large, distributed teams while maintaining compliance</li> <li>Increased risk to data quality and inspection readiness during expansion</li> </ul>	<ul style="list-style-type: none"> <li>Rapid global deployment of qualified pharmacovigilance professionals</li> <li>Phased onboarding model with structured training waves</li> <li>Dedicated training team to standardize onboarding and role readiness</li> <li>Embedded QA oversight for in-line and end-to-end case review</li> <li>Safety database and automation support to reduce manual effort and errors</li> </ul>	<ul style="list-style-type: none"> <li>Onboarded 1,000+ PV professionals globally within ~12 months</li> <li>Achieved surge capacity with 400+ resources onboarded in one month</li> <li>Maintained consistent case quality during rapid scale-up</li> <li>Supported uninterrupted global ICSR processing at volume</li> <li>Sustained partnership beyond three years</li> </ul>

**Biotech Sponsor required a Global team of 1,200+ for end-to-end case processing of ~30,000 ICSRs monthly.**

## Conclusion

ProPharma enabled the sponsor to rapidly scale global pharmacovigilance operations without compromising quality or compliance. Through structured onboarding, embedded quality oversight, and operational scalability, ProPharma delivered a resilient PV model capable of supporting sustained high-volume ICSR processing.