Scalable end-to-end clinical PV for a resource-constrained biotech

Challenge

The client faced growing operational and regulatory complexity across a global oncology portfolio, without internal PV expertise.

Budget constraints required a cost-efficient model, while multiple studies at different lifecycle stages increased delivery demands.

They needed a single, accountable partner to manage all PV activities, ensure compliance across regions, and reduce vendor fragmentation, while also providing expert guidance typically expected from an in-house PV function.

Approach

Qinecsa implemented a single-vendor, end-to-end PV model covering all clinical studies from December 2023.

Services included SAE management, SAE reconciliation, regulatory submissions, RSI management, signal and risk management, aggregate reporting and trusted Deputy support.

Qinecsa supported all studies across global regions, and scaled delivery to include three additional studies. Acting as an embedded partner, we also provided ongoing strategic PV guidance, effectively operating as the client's PV function.

Outcome

Qinecsa achieved 100% SLA performance across all KPIs exceeding agreed thresholds.

The client benefits from seamless global PV operations, reduced internal burden, and a scalable delivery model that supports portfolio growth.

With no internal PV team, they rely on Qinecsa as trusted experts for both operational delivery and strategic input, gaining a fully functional PV capability through a single, accountable partner.

Qinecsa