Qinecsa Case Study

Compliant drug safety framework for early phase clinical trials

Challenge

A biotech had successfully completed Phase I clinical trials and was rapidly progressing into Phase II.

Serious adverse event (SAE) volume was expected to significantly increase and therefore associated workload could not be managed in-house.

A partner with in-depth drug safety expertise was required to proactively manage all aspects of drug safety with minimal client oversight due to their resource constraints.

Approach

An appropriate safety database was selected in collaboration with the client, driven by expectations associated with compounds in scope.

Relevant regulatory intelligence was proactively gathered for markets where clinical trials were expected to start.

A strong knowledge pool associated with all compounds was developed and maintained as the SAE volume increased.

Outcome

The client established a compliant and robust framework in line with budget and quality expectations to manage increased case volumes.

The regulatory intelligence gathered for active markets enabled the client to proactively establish global partners to support submissions and follow-up.

Product knowledge was consistently reviewed and evaluated in a robust manner with clearly documented decisions and outcomes.

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