Qinecsa Case Study

Developing a robust drug safety framework

Challenge

A small biotech with a healthy development pipeline had no internal pharmacovigilance expertise. They required a compliant drug safety framework to support safety data collection, evaluation, and dissemination during clinical trials.

A drug safety framework was a mandatory prerequisite ahead of any patient exposure. Forecasted serious adverse events (SAE) volume was low based on the nature of the compounds and patient population.

The company needed an experienced pharmacovigilance partner within the EU to support all aspects of drug safety for the upcoming trials.

Approach

A simple, compliant drug safety framework was established, including a suite of policies and procedures in line with relevant legislation, to support collection, evaluation, and dissemination of SAEs.

All client employees were trained on drug safety policies in line with regulatory requirements.

The compound knowledge was managed and nurtured in a consistent and well-documented manner as the safety profile evolved throughout the development lifecycle.

Outcome

The client successfully met regulatory requirements within expected timelines to support first-in-man exposure.

A fit-for-future framework was designed for mid and long-term strategy to support budget and resource planning.

The client successfully navigated through regulatory inspections and leveraged the high-quality knowledge management to seamlessly create development RMPs.

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