CASE STUDY

Outsourcing clinical trial safety activities to PharmaLex assures compliance and puts project on track for fast registration

Situation

A US company was dissatisfied with a large global CRO's study and drug safety management for a programme of multinational clinical trials involving a complex drug device combination therapy. These ongoing studies were pivotal to the successful registration of the treatment in the EU and US. PharmaLex was given responsibility for all the clinical trial safety activities.

Challenge

It was vital to correctly interpret any adverse events to create the correct safety profile for the treatment during clinical development. It was imperative to ensure continued safety oversight and to upgrade the quality of safety data capture and follow-up, so that safety data could be readily interrogated and made available to FDA and EMA during the development and registration processes.

PHARMALEX

Solution

Using our substantial experience in clinical trial safety procedures and data handling, PharmaLex acted swiftly to:

1. Deliver an efficient and quality-controlled transfer of the legacy case data
2. Implement a detailed Safety Management Plan to clarify responsibilities
3. Introduce a programme of routine updates and review for reconciliation with the CRO-held clinical database
4. Generate monthly safety reviews and benefit/risk assessments
5. Complete an urgent overhaul of the Investigator Brochure.

Benefits

The switch to PharmaLex' pharmacovigilance team, delivered the following benefits:

Full compliance with all safety obligations met

Provision of fast and accurate responses to regulatory agency questions

Building of a treatment safety profile to support successful clinical development and registration.

PHARMALEX