XENDO CASE STUDY | CLINICAL TRIAL PHARMACOVIGILANCE (PV)

EXECUTIVE SUMMARY

"Drug Safety in Clinical Trials"

A proactive partner as Drug Safety Unit and Drug Safety Officer strengthens the foundations for effective pre- and post-marketing activities.

RESULT

compliant PV processes

RESULT

coordinated global activities

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CHALLENGES

- For a multi-centre clinical trial phase III with 700 subjects, the customer needed a reliable and proactive partner as Drug Safety Unit and Drug Safety Officer
- Customer expects the partner to assume responsibility for complete Global PV and aims to establish long term partnership for future trials and future marketing authorisations

PROJECT EXECUTION

- Xendo assumes role of Drug Safety Unit and Drug Safety Officer; cooperation with and training of all sites (including Europe, Australia, South Africa)
- Set-up and maintain safety database
- Generate and submit expedited safety reports to RA authorities worldwide
- Support compilation of documents, e.g. protocol, investigator's brochure, safety management plan; compiling DSURs

ADDED VALUE

- Access to Xendo's international PV experience
- Use of the existing Xendo ARGUS database
- Building a relationship with a partner that can support pre- and post-marketing PV processes