CASE STUDY

Rescue of two Post-Authorisation Safety Studies

Background

Global Pharmaceutical Company, 2 PASS studies:

- **PASS I: Cardiovascular NIS** in **~ 500 sites** in **Germany**
- **PASS II: Haematological NIS** in **~ 160 sites** in **Germany**

Engagement

Clinical Monitoring Services, Regulatory Services, Feasibility, Investigators grants' Management, Project Management

Challenges

Handover from international CRO after persistent complaints from the sites.

Re-start of studies with **50 new sites**.

Optimapharm solutions

- **Maximization of center satisfaction**: intensive support to sites - especially with a not user-friendly eCRF, provision of Flying Nurse, site contacts outside regular office hours which improved site engagement, optimized payment runs (invoice proposals)
- **Optimized coordination of both studies**: unique PM as primary contact for sponsor, single CRA team involved in both studies, efficient TCs covering both studies, fast provision of data extraction (reports) requested by client, pro-active management

Outcomes

5400

PASS I: 5400 patients enrolled (>230 patients above recruitment goal enrolled)

815

PASS II: 815 patients enrolled

100% recruitment achieved

Studies delivered within timelines