CASE STUDY

Rescue of Phase III study in Acute Coronary Syndrome

Background

Top 10 Global Pharma Company, phase III, randomised, double-blind, placebo controlled, **cardiovascular study** (Acute Coronary Syndrome).

Study conducted in **5 countries** for a total of **57 sites**.

Challenge

While a large CRO was managing the study, the recruitment was delayed. Sponsor decided to rescue the study by themselves while continuing regionally collaborating with Optimapharm.

In addition, the recruitment duration was reduced at global level.

Engagement

- · Clinical Monitoring
- Project Management
- Regulatory Services
- Quality Assurance (audits)
- · Safety Reporting

Optimapharm solutions

- Strong internal management, close collaboration with sites
- Optimapharm overtook recruitment and adjusted the plan
- Some centers accepted a higher number of patients than originally planned
- Changing the recruitment target between countries

Outcomes



The study was successfully delivered by recruiting 649 patients at 57 sites in 5 countries.



100% recruitment achieved



Completed 4 months early

