

C A S E S T U D Y :

EXPEDITED STUDY DELIVERY - LOGISTICS

A biotech Sponsor approached QPS to conduct a challenging Phase I SAD/MAD study, involving multiple IV doses over multiple days in healthy volunteers. This case study outlines the challenges we faced and the solutions we put in place to deliver the study successfully.

CHALLENGE

The Sponsor contracted QPS to quickly deliver a complex study. The design included first-in-human, safety, tolerability and PK of multiple escalating IV infusion doses. The study subjects received multiple infusions of study drug, during daytime and nighttime hours, on each study day.

SOLUTION - 3 Factors for Success

Flexible Team:

- ▶ The team worked day and night shifts to deliver 60 and 90 minute infusions
- ▶ Procedures (including PK) were performed throughout the night

Efficient Study Conduct:

- ▶ Study submitted to EC/CA end-November
- ▶ Volunteers screened mid-January
- ▶ Part 1 - first subject, first dose at the end of January
- ▶ Part 2 - first subject, first dose in mid-February
- ▶ Last subject, last visit in early April

Phase I Expertise:

- ▶ Six SAD dose levels, DDI with 2 different drugs
- ▶ SAD and DDI sections combined in a sequential design
- ▶ Three MAD dose levels (10 days) with 10 subjects per dose level

OUTCOME

QPS exceeded the Sponsor's expectations, rapidly delivering a complex, data-intensive early phase clinical trial, and collected approximately 1,000,000 data points in just 2 months.