CUSTOM-BUILT RESEARCH™

CASE STUDY:

EXPEDITED STUDY DELIVERY - PHARMACY

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 nightime 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 throughout the day and night
- Procedures (including PK) performed throughout the night

Efficient Study Conduct:

- Dosing performed over 7 days
- Subjects in-house for 12 days
- Low incidence of self-withdrawal/drop-out

Phase I Expertise:

- Expedited study resourcing and scheduling
- Formulation challenges overcome by QPS' Pharmacy

OUTCOME

QPS exceeded the Sponsor's expectations, delivering a complex study during a difficult recruitment time and meeting all study criteria. This happy client quickly became a repeat customer.