

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 with QPS to recruit and enroll 90 healthy volunteers with very specific IgG levels. The Sponsor wanted the trial to be conducted at one site, but was not sure if this was possible. Finally, retaining healthy volunteers in a year long study is a significant challenge, and the Sponsor wondered if it was even possible.

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

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.