

CASE STUDY

EXPEDITED CLINICAL TRIALS – FAST START UP

A large, multi-national CRO called QPS to replace a site that dropped out of a study, and required that QPS be prepared to start screening study subjects within 2 weeks of the initial conversation. This case study outlines the challenges we faced and the solutions we put in place to successfully meet their very aggressive and short timelines.

CHALLENGE

QPS sites often function as study sites for larger CROs. As such, a CRO we often work with approached QPS with a special request; to start screening healthy volunteers for trial with just a 2 week lead time.

The site that was originally contracted to do the study canceled on the screening process start date, and the CRO turned to QPS, as a trusted partner, to pick up and complete the study.

SOLUTION – 3 FACTORS FOR SUCCESS

Flexible Team:

- ▶ The Regulatory Team quickly prioritized this project to focus on the regulatory package.
- ▶ The Clinical Coordinator Team created the patient documents in 1 day.
- ▶ The Project Management Team built a tight schedule with the CRO to get approved documents to the IRB in just 2 days (typically a 2 week process).

Efficient Process:

- ▶ The Study Team led preparations to complete the Site Initiation Visit (SIV) and start screening within 2 weeks.

- ▶ The Recruitment and Marketing Teams gathered every morning to review progress and tweak plans to ensure the screening rooms remained full all day, every day.

Experienced Clinical Study Site Staff:

- ▶ The large team of experienced staff were critical in the success of this endeavor. Without the highly experienced and dedicated team that QPS has in place, it would not have been possible to jump start this study so quickly.

OUTCOME

QPS exceeded the Sponsor's expectations, getting the study started in less than 2 weeks, and screening/enrolling the 2 additional cohorts on time.