

C A S E S T U D Y :

PHASE I STUDY WITH HYPOGONADAL MALES

A biotech client approached QPS to conduct a challenging study that required fast recruitment of a large group of study subjects, split into multiple cohorts, all of whom had very low testosterone. This case study outlines the challenges we faced and the solutions we put in place to deliver the study successfully.

CHALLENGE

The Client challenged QPS to find and recruit 60 male study subjects, all with very low testosterone levels. The nature of this disease is embarrassing, such that finding volunteers is quite difficult, and finding such a large number of volunteers within one study site in a short period of time made it a significant challenge. In addition, one cohort has to be 23 subjects or larger to ensure sufficient power in the study.

SOLUTION - 3 Factors for Success

Operational Excellence:

- ▶ QPS set up a study specific pre-screening process to quickly identify a large number of individuals who had a higher chance of being appropriate study candidates.
- ▶ QPS set the pre-screening appointments between 6 and 8 am, to ensure that study subjects would be available during the very narrow window set for drawing blood in the study.
- ▶ Over 1,184 volunteers were pre-screened during this process.

Recruiting Expertise:

- ▶ The QPS Recruiting Team, including Marketing and the Call Center jumped into action, reaching out to all of the males in our extensive database. The team focused first on those who had self identified as having Low Testosterone.

Proactive Approach:

- ▶ QPS has deep experience conducting challenging Phase I studies in wholly owned sites around the world. This extensive experience enabled the team to develop an approach that maximized the up-front screening work and ensured that the final study subjects were able to complete the study inline with the very tight protocol requirements.

OUTCOME

QPS delivered a flexible solution to a very challenging Phase I study, exceeding the clients expectations. In addition, QPS ensured that all 60 subjects were recruited quickly, including the large cohort. All 60 subjects completed the study.