

CASE STUDY

PHASE II WITH INTRA-ARTICULAR INJECTION

A biotech client approached QPS to conduct a challenging study, requiring fast recruitment at just one site, and Regulatory submission in an expedited timeframe. This case study outlines the challenges we faced and the solutions we put in place to deliver the study successfully.

CHALLENGE

The Client contacted QPS to deliver an extremely fast study and submission in one country. The Client needed a CRO with extensive experience with multiple Regulatory agencies in Eastern Europe. The Client also needed problem solving support, to ensure that the recruitment time lines were achieved.

SOLUTION – 3 FACTORS FOR SUCCESS

Flexible Team:

- ▶ QPS quickly assigned an experienced team in Eastern Europe, who had great multitasking skills and fast reaction times.
- ▶ This QPS team was able to boost recruitment by quickly adding sites in 2 additional countries and opening those new sites in a very short turnaround time.

Regulatory Expertise:

- ▶ QPS Regulatory experience in Croatia and Slovakia was key to submit the trial immediately.
- ▶ The team was able to quickly prepare and adapt all of the necessary documents required for this expedited submission.

Scientific Network:

- ▶ Due to QPS' broad and deep scientific network, the best sites for this trial were identified and brought on board very quickly.

OUTCOME

QPS delivered a very challenging Phase II study with a flexible solution to exceed the client's expectations. In addition, QPS partnered with the client to provide solutions to reach the tight recruitment targets within a very short time frame.