

CASE STUDY

MEDICAL DEVICES: A STUDY FOR A JAPANESE SPONSOR

A Medical Devices Sponsor approached QPS to conduct a challenging ophthalmology study. This case study outlines the challenges we faced and solutions we put in place to successfully deliver the study.

CHALLENGE

The Sponsor contacted QPS to deliver a Medical Device study in ophthalmology, limited to just one study site in Austria, in a very short time frame and with the goal of receiving CE mark and access the European Market.

SOLUTION – 3 FACTORS FOR SUCCESS

Global Investigator Network:

- ▶ The very strong QPS Investigator network enabled us to quickly identify one single study site that was capable of recruiting over 100 patients for surgery within a recruitment period of just 6 months.

Communication:

- ▶ QPS provided the Sponsor with the unlimited communication flexibility, setting up Teleconferences and GoTo Meetings, and always seamlessly covering the necessary time zones.

Flexible Resources:

- ▶ QPS allocated special resources to ensure that Data Management, Biostatistics, and Medical Writing would be available and on-call to complete the Final Report in the fastest possible timeframe, maintaining the highest level of Quality standards.

OUTCOME

QPS achieved the objectives outlined by the Sponsor, delivering a tricky surgical study in a highly compressed timeframe, and delivering the Final Report in a timely manner. The sponsor was able to submit for, and receive, a CE mark, gain access to the European Market and launch this new medical device in Europe.