

C A S E S T U D Y :

NIS WITH MULTIPLE COUNTRIES WITHIN EUROPE

A pharmaceutical client approached QPS to conduct a challenging Non-Interventional Study (NIS), across 7 countries in Europe. This case study outlines the challenges we faced and the solutions we put in place to successfully deliver the study.

CHALLENGE

The client contacted QPS to deliver a large NIS, covering 500 patients across seven countries. Even though all seven countries were within Europe, each had its own specific regulatory environment.

SOLUTION - 3 Factors for Success

Local Regulatory Expertise:

- ▶ In the case of Non-Interventional Studies, many EU countries have their own specific regulatory environment. QPS tackled that challenge by opening one country after the other in a well structured cascade to ensure the smooth start of the NIS.

Effective Management:

- ▶ QPS ensured a high quality solution, delivered by a "right sized" team. This ensured that all efforts were squarely focused on efficiently conducting the optimum clinical project.

Efficient Resources:

- ▶ QPS planned the resources for this trial very carefully and provided the Sponsor with the right mixture of full time CRAs and local, freelance CRAs.

OUTCOME

QPS succeeded to provide the Sponsor with a “one shop” solution for this NIS covering 7 European countries with diverging requirements. Fulfilling all of the criteria for a successful project and ensuring the most efficient study conduct.