

## 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.