



# How to successfully conduct a multinational non-interventional study to analyze the RWE performance of a recently launched drug



## The Situation

A multinational biopharmaceutical company initiated a multinational non-interventional prospective study for a recently launched analgesic treatment to obtain preliminary quality of life and safety results in order to boost the sales of their product in those countries where it was marketed. The global recruitment goal was **400 patients**.

The Sponsor required a CRO with the following capabilities: in house full services, focused on fast recruitment, agile, flexible, experience in different European countries with local expertise and global reach.

Meeting the Sponsor's requirements, APICES was retained as CRO of choice for this challenging non-interventional study.

## The Challenge

Firstly, the participating countries are Germany, Spain, Italy, France, UK, Denmark, Finland, Netherlands, Sweden, and Greece. Of critical importance is having in-depth knowledge of the regulatory environment of each of the **10 participating countries** (and **40 sites**), with the objective to carry out a start-up strategy that would allow APICES to rapidly activate the sites and start recruiting as soon as possible.

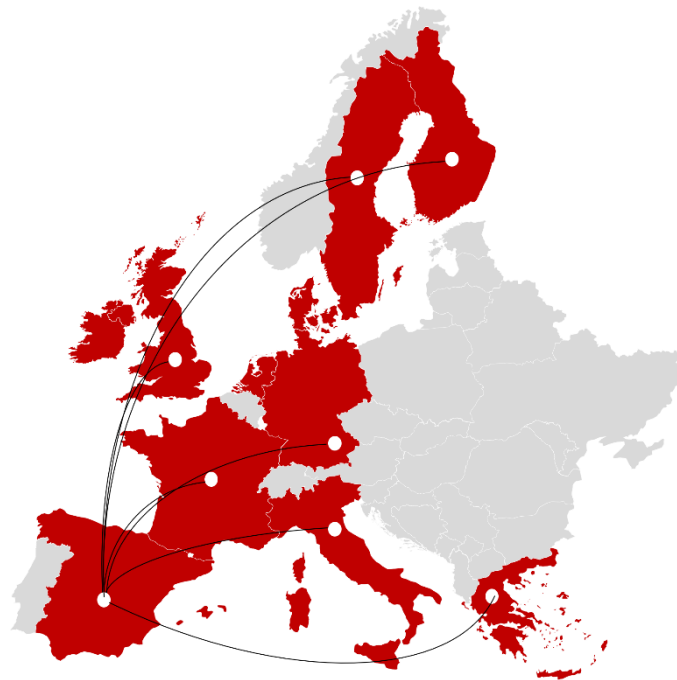
Secondly, since the drug is used in the treatment of refractory pain, it was necessary to make a solid and thorough feasibility study, which required knowing the key investigator networks, the specialized hospitals and their referral networks across the whole of Europe including any local characteristics regarding specific patient care needs.

Thirdly, it was indispensable to work as an integrated team with the Sponsor to identify across Europe the patient populations with refractory pain that are receiving treatment with the Sponsor's drug.

### The Solution

The first part of the solution was to create a regulatory strategy to optimize the activation of the sites based on the recruitment objective, approval times, strategic importance of the country, etc.

The second part of the solution was to **centralize the monitoring activities** at APICES headquarters in Spain with the objective to have **higher quality, more control, better performance, further optimization, and balanced costs**.



Finally, the key part of the solution and critical for its overall success was APICES ability to rapidly mobilize its influential networks with KOLs in the key therapeutic area to maximize recruitment and be able to meet the tight deadlines required by the Sponsor.

### The Results

Operational agility and efficiency along with deep local industry knowledge of “Know How and Know Who” across Europe, high expertise in pain area, and strong relationships with sites, enabled APICES to meet the deadlines and achieve the recruitment objectives. In addition, the study resulted in different publications in journals, conferences, and marketing materials.

The sponsor was impressed with APICES' contribution and has also publicly praised the valuable contribution by the highly dedicated APICES team and the investigators resulting in acknowledgements of APICES' work and its team in different well recognized scientific journals and publications.