Case Study

Type: Cardiology

Geography: Europe

Study type: Phase IV

Client: Mid-sized pharma

PROJECT TITLE:

"Real-world compliance to treatment, safety and effectiveness outcomes of a fixed dose combination pill for patients on primary cardiovascular prevention"

Objective

The Sponsor approached Excelya to perform consultation on prospective clinical study design, project management, medical writing, clinical monitoring, data management and statistical functions for a national (Greek), real-world evidence (RWE) to determine real-world treatment compliance, safety, effectiveness as well as prescription patterns by cardiologists

Project Challenges:

- Determine treatment compliance under routine clinical practice conditions in >1,000 patients
- Compliance to treatment is compromised in patients with cardiovascular disease
- Confirm safety profile and effectiveness outcomes under real-world conditions
- Determine potentially rare adverse events
- Evaluate real-world prescription patterns

Excelya Solutions:

- Multiple services (medical writing; data management; statistical analysis; clinical operations and monitoring)
- Study design and eligibility criteria that were aligned with primary objective and enabled the determination of prescription patterns
- Optimize enrolment and subject retention
- Clinical study report and preparation of presentation of study results to inform investigators

Benefits for the Client

- Excelya as a one-stop partner for all activities
- Consultation on clinical study design to address potential limitations on subject retention
- Preparation of clinical study report and presentation of results to disseminate to investigators by the same team of medical writers to ensure maximum efficiency and consistency