

Type:
Oncology

Geography:
Europe

Study Type:
Phase IV

Client:
Mid-sized
Pharma

PROJECT TITLE:

“Health Related Quality Of Life And Multidimensional Evaluations Of A Cohort Of Prostate Cancer Subjects Aged ≥ 60 Years Initiating Gonadotropin-releasing Hormone (Gnrh) Agonist Therapy Prospective, Multi-centre, Longitudinal, Non-interventional Study Conducted In France.”

Objective

The sponsor approached Excelya to perform project management, regulatory, clinical monitoring, data management and statistical functions for a national (French), multi-center, prospective, real life, observational study of **prostate cancer study**, with 250 urologists and radiation oncologists prescribing GnRH agonist therapy.

Project Challenges:

- **High patient enrolment targets** (800+ patients total)
- Management of a **large network of sites**, recruiting active investigators and patient site investigators (250, 60 and 5 planned respectively)
- **Data quality** due to the nuances of the treatment

Excelya Solutions:

Patient recruitment: We capitalized on our strong ties across French oncology sites to select sites. We launched an active outreach campaign with follow-up phone calls and by sending motivational emails to our established network of over 2,500 investigators (urologists, oncologists).

Data control/site management: Excelya maintained a strong line of communication with investigators, sending reminders for filling eCRFs, to manage inconsistencies, etc. We also conducted on-site quality control visits to supplement remote monitoring.

Key metrics

164
Specialized
sites

250
Urologists &
radiation
oncologists

831
Enrolled
patients

Benefits for the Client

Proactive strategies delivered to meet goals in challenging study, despite large enrolment targets.