excelya

Case Study

Type: Medical Data Review

Geography: Europe Study Type: FSP **Client:** Top 20 Pharma

PROJECT TITLE:

"A 6-year partnership with a Large Pharma company, delivering a medical review team providing technical assistance and deliverables."

Objective

The client selected Excelya to oversee its medical data review of all phase I, II and III clinical studies in various fields (oncology, cardiology, rheumatology, etc.), from protocol review to database freeze.

Study Summary:

- The team consists of 10 PhD pharmacists/scientists focused on combining medical review and database management aimed at combining all ongoing clinical studies.
- This covers medical data coding (via MedDRA and WHODD dictionaries), a weekly appraisal of issue severity, reviews of any deviations or medical data consistency noted in the electronic notebook (eCRF).

Excelya Solutions:

- Swift integration of new team members and expansion of their skills.
- Improvement of quality and/or responsive performance.
- Ability to improve existing processes, quality and/or swift responsiveness
- Positive work environment (flexibility/training/mutual assistance).
- Excelya's ongoing flexibility in line with client needs (reorganization), plus activities (started on client premises, then at Excelya and now remote working), while maintaining initial high quality and performance.

Business Impact:

- Minimal turnover since the launch.
- Attracted and retained an exceptionally high calibre of talent for the project.
- Ongoing and expanded relationship with client.