

Case Study

Delivering higher quality whilst maintaining tighter timelines

A large pharmaceutical client was conducting a Phase II clinical trial in endocrinology therapeutic area. The trial was conducted in multiple sites with 220 patients in 2 study groups. The paper CRFs ran into approximately 120 pages for each patient, totaling the number of CRF pages to almost 26,400. The client was looking to work with a CRO, who can provide the services within limited timeframe by decreasing the turn around time of delivering the final outputs at each stage of the biometrics activity without compromising on the quality of the output. Veeda Biometrics offered the CDM services from its offices in Brussels, Belgium and Mumbai, India.

Our experience in managing paper based clinical data using a standard CDMS, helped the client to complete the trial in a simpler and faster manner meeting the timelines and within the budget.

Achievements of the study include:

Timelines:

- Database (DB) was locked in 3 weeks time from last page data in-house
- Initial key results were delivered in 5 days time from DB lock
- The complete TFLs were delivered within 15 days from DB lock
- CSR was delivered in 8 weeks from DB lock

Quality:

- DB error rate was four times less than the acceptable error rate

We achieved all this through the following,

Centralized Project Management — With a centralized project manager managing the deliverables within Data Management, Statistical Analysis and Medical writing units, Veeda ensured that information is shared across its biometrics units seamlessly, which guaranteed quality outputs within the agreed timeframe. This eased the geographic and facility constraints.

Flexibility — Veeda biometrics team worked collaboratively in conjunction with all functional areas of the study team with great flexibility.

Experienced Team — Veeda ensured that a team of highly experienced Biometrics (data management, statistical analysis and medical writing) professionals are involved in the study. The experiences of Veeda Biometrics management team enabled high-level support for providing integration, guidance, and governance of the study.

Validated systems — At Veeda we used validated system and well defined centralized SOPs across our locations, which enabled the team to meet the needs of the sponsor/study with ease.