

RDCG CASE STUDY: Real-Time Monitoring™ for early study completion: Database lock achieved one week early

Situation:

Sponsor needed 2 more studies to complete their NDA package. The completion of these 2 studies was on the critical path to filing the NDA on time. Each study had 110 subjects and from study start (1st subject recruited) to locked database was planned for a quick 3.5 months including 2.5 months of treatment. Data must be captured and monitored efficiently to ensure meeting the aggressive database lock deadline 1 month after 220 cohort patients complete 220 concurrent last patient last visits (LPLV).

Challenges:

Both studies were conducted simultaneously so resources had to be managed to complete both studies on time. Since EDC was used, data capture, monitoring, and data management processes had to be integrated to ensure the most efficient monitoring, query resolution and fastest database close. Since 220 patients were treated as a cohort, all patients went through each visit simultaneously resulting in 220 concurrent last patient last visits.

RDCG Actions:

Before the study started, RDCG's senior management and project team met with the Sponsor's team and Investigator staff to determine key data activities to develop a single integrated plan for site data collection, CRO data monitoring, and Sponsor data management plan for maximum efficiency. Integrated processes were designed, and tracking systems were implemented. Project management ensured both processes and data flow occurred as designed and on schedule.

RDCG worked closely with the Investigator site and Sponsor's data management on a daily basis to ensure accurate data collection, and rapid lock of each page. Weekly the team would track activities to ensure on time study completion.

RDCG had 6 monitors selected and trained less than 2 weeks after the plan meeting. The monitors worked as a team to ensure that daily eCRF monitoring kept up with the data generated by the site. The monitors also ensured that queries were answered as quickly as possible after generation.

The RDCG monitoring team had a Lead CRA who triaged the monitoring activities each day and ensured that the most critical activities were completed each day. Site issues regarding timely data transfer to the CRFs and query resolution were managed by the Lead CRA who was on site. Using expert logistical techniques, monitor assignments were made based on data monitoring needs "just-in-time".

RDCG worked with the sponsor and provided whatever it took to meet the deadlines. These actions included thinking "outside the box", effective communication between RDCG and the Sponsor, and RDCG's strong logistical planning and execution skills.

I am proud to announce that the study database is locked. It's one week ahead of schedule (April 12th). Thanks to the entire team who have worked diligently since the onset of the study.

Sponsor Data Management

Result:

All monitoring and query resolution for database lock were completed 1 week ahead of schedule and three (3) weeks after 220 concurrent LPLV. Not only was database lock completed early on an aggressive schedule but the study was completed significantly under budget.

There were 5 key results:

- The team of Sponsor, site and CRO planned and executed logistics together.
- Experienced monitors (avg. 11.3 yrs) monitored "just-in-time" as the data was entered in eCRF.
- Higher monitoring quality: Despite the tight deadlines, RDCG monitors had fewer queries than previous studies.
- Deadlines were completed early
- Project was completed significantly under budget

The Sponsor from Project Manager to Senior Management was pleased with our performance, quality and commitment to deadlines and budget.