

RDCG CASE STUDY: Rescue study to meet NDA deadlines

Situation:

Sponsor had six (6) ongoing studies that were behind schedule and critical to the upcoming NDA filing. If they reported late, the NDA filing date would be missed. The current large CRO was unable to resolve this situation. RDCG was able to provide monitoring to meet database freeze in 4 to 10 weeks depending on the study. Seven hundred (700) subjects' data needed to be monitored at all sites. RDCG's activities included completing all CRF monitoring and query resolution at all sites in time to meet database deadlines.

Challenges:

Although all 6 studies were ongoing, late case report form delivery delayed data recording, data from completed subject visits were still in the source documents and needed to be transcribed to the CRFs... hundreds of patients' CRF data had yet to be monitored at several sites, database freeze for each study ranged from 4 weeks to 10 weeks from the start of the rescue..., current large CRO did not supply the monitors to increase the monitoring at each site.

RDCG Actions:

Our senior management and project team met with the Sponsor's team to assess key activity status, prepare a plan of monitoring action and develop a team to manage the project. RDCG also needed to work well with the current large CRO as they had been the most current monitors at the sites. RDCG worked closely with each site and the Sponsor to integrate the site with the monitoring efforts. Each week the team would meet to ensure activities were completed and the project was on track.

RDCG started training the monitors within 1 week of the CDA and project discussions with the sponsors. Within 8 working days of the CDA RDCG had 7 monitors working at 3 sites. By the second week of the project RDCG had 11 monitors working at 4 sites.

RDCG prepared a SWAT team of a total of 17 experienced monitors to visit the sites to complete the monitoring and meet the data base lock deadlines. The monitoring team at each site had a team leader 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 was managed by the monitoring team leader on site. Using expert logistical techniques, monitor assignments were made based on data monitoring needs at that site at that 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.

Thanks to all who are part of the Swat Team - your team work and commitment to our monitoring requests have been fantastic - and have allowed us to meet our goals! No small feat!!

Sponsor Project Manager

Result:

All monitoring and query resolution for database freeze were completed on time and under budget so Sponsor could meet NDA deadlines.

There were 5 key results:

- The team between the sponsor, site and CRO planned and executed logistics together.
- Experienced monitors (avg. 11.3 yrs experience) met the CRF monitoring deadlines
- Higher monitoring quality: Despite the tight deadlines, RDCG monitors had fewer queries than the previous large CRO monitors (avg. 1 yr experience)
- Deadlines were met
- Project was completed under budget

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