A study handled by 2 global CROs in succession, handed over to SIRO with a mandate to improve performance & quality

Situation: A Phase III diabetes rollover study involving 188 patients and 18 sites which was transferred to SIRO due to unsatisfactory performance of previous CROs

Challenges:

- Regulatory issues:
  - Patient serum samples were being sent to global central lab in the absence of valid export license
  - Responses to the queries raised by the regulatory agency were pending
  - There were multiple safety documents which were not submitted to the regulatory agency and Ethics Committees
- Monitoring issues:
  - There were several undetected protocol violations at the sites
  - There was significant document archival backlog in the database
  - There was significant SDV backlog at the sites
  - Data from the sites was of poor quality
  - New protocol violations were identified by SIRO
  - Site personnel were not clear about the protocol, which resulted in poor quality data and protocol violations
- Study Handover issues:
  - There was lack of co-operation from the previous CRO and project handover was not done completely
  - SIRO received over 4000 unsorted study related documents

- Majority of the project team members of the previous CRO which was involved in this study had left the organization

- The sponsor was not fully aware about many of the above mentioned issues

- SIRO received the study in October ’10 and there was an interim database lock scheduled for July’11. However, due to the numerous issues involved, the sponsor had given up the hope of meeting the timelines

SIRO Strategy:

- SIRO put in place a strategy to resolve regulatory issues.
  - SIRO re-examined adverse events and concomitant medications for all subjects
  - SIRO allocated additional resources for quick issue identification and resolution
  - SIRO team conducted extensive retraining of the site personnel in order to achieve protocol adherence and improve quality of data
  - The internal processes were realigned to ensure short turn-around time for the queries raised by the sites
  - SIRO scheduled extended monitoring visits on a monthly basis. The duration of the site visit was increased to 2-4 days in order to clear the SDV data backlog. For sites with high patient load, extended monitoring visits conducted with 2 monitors on site in order to ensure timely completion of SDV

Result:

In spite of the significant impediments, SIRO was able to complete the interim database lock on schedule and with a significant improvement in the quality of the data

Sponsor Feedback:

Congratulations to you and the team for successfully achieving this important milestone!
The remarkable effort made in following through to ensure that India does not delay the DBL, is highly commendable.

Sponsor – Project Manager

"A special "Thank You" to XXX as without her this would not have been possible. After your SOS last Wednesday, I spoke with XXX and she single handedly managed to get the data entry completed by the PI because of which the timely data lock was possible."

Sponsor – Clinical Operations Head