CASE STUDY

Unhappy with the deliverables of the global CRO, a client requested SIRO to manage the study mid-way from LPI to LPO.

The Challenge

- The study was a roll over study being handled by two global CROs with 188 patients rolled over from two previous study as a part of extension safety to this study.
- There were undetected Protocol Violations, significant SDV backlog, inadequate documentation of IP management and lack in protocol understanding of site personnel.
- Lack of cooperation from the previous CRO and missing documents in TMFs. Time was critical as well since the DBL was due within 9 months from handover.

SIRO Solution

- SIRO allocated additional resource to clean the data at site including the SDV backlog.
- Extensive training was provided to both sites and the SIRO study team to carry out multi-tasking and flexibility in monitoring visits was implemented leading to maximum on-site hours.
- Timely risk mitigation including both tactical and strategic level communications with the sponsor.
- Internal processes and time lines were realigned to achieve DBL within the required time period.

Key Takeaways

- In spite of the significant impediments, SIRO was able to complete the interim.
- Database lock on schedule with a significant improvement in the data quality. The efforts and results were both appreciated by the client.
- The study team was awarded a "Role of Honour" by SIRO's Senior Management.