Challenging data management study where efficient use of resources & effective planning led to successful study execution within stipulated timelines and provided the client with comfort of communication in the local language

Situation: A Phase I pharmacokinetic program comprising 84 patients & 4 protocols which required SIRO to perform data management activities on client's system. Client desired routine communication in local language.

Challenges:

- Client wanted a cost effective data management solution for English CRFs and preferred routine communication in local language (German).

- The operations team had to work on client database. Though team was familiar with the system, it was not familiar with the client's setting on system.

- SIRO was having limited access on client system which triggered need of continuous follow up for minute changes during database development.

- Team was required to lock databases of 4 protocols within short time span of 15 days.

SIRO Strategy:

- SIRO proposed project management (primary contact for routine communications) from Germany and operations in India. Client expectations and requirements were determined by Project Manager in Europe and relevant information was percolated down to team in India. Similarly, flow of reverse communication was streamlined by Project Manager in Europe, giving client comfort of communication in local language.

- SIRO used "train the trainer" principle to familiarize its team on client's system - Client trained key SIRO resources on its system which in turn helped remaining resources to get familiar with the system.

- The same team was used across projects, which optimized effort requirement due to transfer of efficiencies gained from one project to successive projects. It also avoided duplication of effort on activities such as system training.

- SIRO determined workload curve in advance and mobilized necessary resources to meet timelines.

Result:

- This model provided the client with comfort of communication in local language as well as leveraged cost efficiencies coming from operations in India.

- Effective teamwork & proactive communication resulted in quick and effective resolution of study issues, the SIRO team managed to complete database set up in time in spite of new system and contracted timelines.

- DM team finished all activities within stipulated timelines without major database findings.

Sponsor Feedback:

"SIRO team is highly motivated, flexible and has provided seamless services. SIRO team has very good Oracle clinical skills and has met all study timelines"

Head - Data Management in a German pharmaceutical company