A challenging Phase III study in Dermatology

SIRO successfully handled unexpected surge in a large study without compromising database quality and study timelines

Situation: A Phase III, multicenter, double blind, randomized, vehicle controlled parallel group study comparing two topical gels for the treatment of mild to moderate acne vulgaris.

Challenges:

- CRF was missing critical variables required for judging efficacy & compliance of the study drug.
- Clinical monitoring was conducted by another clinical research organization. Sluggish turnaround of query resolutions by Clinical operations team leaving lesser time for data management activities.
- Infrequent monitoring visits resulted in a data deluge at the end of study over 30,000 CRF pages were databased and cleaned in 3 months.

SIRO Strategy:

- Team went out of its way in identifying and informing errors in CRF design. The sponsor agreed to modify CRF and include additional variables in CRF. It appreciated SIRO's meticulousness.
- SIRO detected trends in CRF data early in the study and did regular trend analysis of queries and communicated trends to sponsor and clinical operations. This allowed clinical monitors to focus in right areas for monitoring as well re-training sites on relevant aspects. This, eventually reduced repetition of errors. SIRO, when identified unavailability of CRF Completion Guidelines (CCG) at site, convinced the sponsor to have CCG in order to improve the quality of data from the sites. Sponsor eventually recognized significance of the document.
- Sponsor was requested to approve additional self evident corrections and provide few file notes to reduce queries. SIRO provided report on turnaround time for resolutions and requested to reduce the turnaround time.

- SIRO Project Manager anticipated spike in CRF flow during the end and mobilized more resources for the project.

- The process of data entry was expedited without sacrificing on quality by quickly scaling up the data entry team and also including a QC resource.

Result:

- CRF Completion Guideline document was prepared by SIRO which helped to reduce the discrepancies in incoming data.

- More than 45,000 pages were reviewed during the course of the study 4000 DCFs were sent out in 6 months & over 2500 resolutions were received and actioned in 1 month.

- **There was no major audit finding and database was locked within the stipulated timelines.**

- Modifications suggested to the CRF design resulted in revelation of important information pertaining to efficacy of the drug during analysis and reporting.