Efficient & accurate data processing for a Phase III heartburn study

Situation: 13,000 CRF pages to be entered in 12 days with stringent quality requirements

Challenges:

- Stringent timeline of database lock in 12 workdays of last CRF-in and quality requirement of error rate <0.05%
- Keep track of DCFs, resolutions & coding

SIRO Strategy:

- Additional resources were mobilized to the study
- Division of work across wider resource pool and adjustment of workload for efficient use of resources
- Monthly status reporting was converted to weekly status reporting to ensure clear communication with sponsor

Result:

- SIRO achieved database within planned timelines and error rate was less than 0.05%
- The database successfully underwent USFDA inspection

Sponsor Feedback:

"One of the reasons that we recommend SIRO Clinpharm is that their DM project managers have both the technical competence and the medical judgment when they handle clinical data. We cannot find this when we work with other CROs, data management companies and other ITES. This is a unique differentiator of SIRO Clinpharm".

- Principal Scientist & study Data Manager