

## Innovative data management tools led to significant operational efficiencies & process improvements

### Situation:

- This was a 2 year Phase IV osteoarthritis study, consisting of 1771 patients.
- This generated large amount of data viz. CRF, IVRS & laboratory data which had to be checked & rectified before being electronically loaded into the database.

### Challenges:

- Lack of clarity amongst the sites about the sponsor's electronic CRFs which caused large backlog of data.
- Screening of data to ensure that duplicate data was not entered into the database.
- Timely resolution of thousands of system & manually generated queries.

### SIRO Strategy:

- Unique SAS codes were developed for quick rectification of data & auto review.
- SIRO deployed its strong in-house talents to develop special macros to scan & correct the IVRS data.

### Result:

- There was 50% reduction in time required to correct one batch of data.
- Also, since manual review was reduced, overall accuracy of data increased substantially
- Macros designed by SIRO reduced the IVRS data rectification time by 1 month.
- SIRO successfully resolved more than 800 queries per month.

- Overall, due to the significant process improvements, the daunting task was completed within the set deadline. Also, the tools developed for rectification were deployed in other data management studies.

## **Sponsor Feedback:**

“SIRO – I was so proud to represent the efforts of the DM team. Their commitment, availability and flexibility were superior and recognized without question by the clinical team”.

-Sponsor PM

“This is great team work and just shows that TEAMS get things done, not individuals. I am very proud of you all... Nice job all”

-Sponsor Executive Directive