



Our Global Experience. Your Success.

Process Improvements Made Saving Over A Month's Time

STUDY DETAILS

This was a 2 year Phase IV Osteoarthritis Study with a large patient population with CRF data being electronically loaded into database including IVRS and lab data

CHALLENGES FACED

Sites not aware of sponsor's electronic CRFs. Many visits were not 'locked' for a long time leading to huge back logs in data being loaded to database. Therefore, data management could not process pages in a timely manner

4000+ 'visits' were 'locked' and then loaded in the database merely 3 months before DB lock date. This led to thousands of queries - both system generated and manual in bulk. SIRO's DM team resolved 800+ DCFs in 1 month before DB lock date and 7400+ DCFs in total.

In order to tackle the impending timelines and bolus of queries that got generated the team resolved 4000+ queries on a particular day.

ACCOMPLISHMENTS

To reduce manual review SAS codes were developed by the team which reduced 50% time per batch of data cleaned.

Macros were designed in-house to clean the huge amount of IVRS data. This saved over 1 month's time.

All in all there was boundless co-ordination and integrity in SIRO's DM team that helped pull off the project successfully

OUTCOME

Despite the stringent circumstances SIRO's DM team achieved the timelines as scheduled and also gained a whole lot of respect and appreciation from our client.

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...

Would you mind if I used this in a Friday note as it is indeed an excellent example of how we want teams to work. Nice job all"

-Sponsor Executive Directive