

Flawless execution of two Phase III diabetes studies of the same sponsor conducted simultaneously at 14 common sites

Situation: Two double blind, Phase III, Type II Diabetes Mellitus studies were conducted simultaneously across 14 sites comprising of 275 enrolled patients.

Challenges:

- Maintenance of stringent quality standards since the resources were common for both studies
- 275 patients to be recruited in 6 months
- Identifying drug naive diabetes patients
- Getting EC approvals for the study protocol since there was a 6 week washout period
- Co-ordination with 2 different logistical partners for shipments of frozen & ambient biological samples, each requiring separate export licenses

SIRO Strategy:

- Tertiary centers were identified for recruitment
- Two additional sites were identified as backup to avoid delays
- Clear demarcation of both studies was done in the following manner:
 - CRA visits were structured to focus on one study at a time to avoid mix-ups.
 - Each essential document was color coded according to the study.
 - Separate communication channels with the sponsor, investigators & vendors for both studies.

Result:

- Recruitment numbers exceeded targets set by sponsor.
- SIRO recruited the highest number of patients globally.

- SIRO received a special award from the sponsor for achieving the highest recruitment globally.
- SIRO was one of the earliest to submit clean data in spite of having highest number of patients
- In spite of the complex nature of the study, there were no critical audit findings*
- SIRO achieved more than 80% roll-over rate into a long term safety study which exceeded target set by sponsor

Sponsor Feedback:

“After many weeks of hard work, with loads of queries, approvals and re-approvals, in which I sometimes wondered if we would meet our deadline. Thank you very much for helping us to achieve this. What a great team you are.”

Sponsor - Head Clinical Research

“Thank you all for this and congratulations!!! I can find two words to describe your work and that is dedication and support.”

Sponsor – Clinical Project Manager

“India is the top one recruiting country for this study. But India had the least queries during database clean stage. India eCRF pages were all cleaned prior to global timeline. All the listed are big achievements!”

Sponsor – Clinical Project Manager

*Audit conducted by sponsor & other independent agency