A DPP4 v/s Sulfonylurea study to compare hypoglycemia incidence during the month of Ramadan

Situation: An open label phase III diabetes study which involved recruiting 768 patients from 20 sites in 3 weeks

Challenges:

- The SIRO project team had just 3 weeks to initiate 20 sites located across India.
- All the sites had to be trained on study protocol and related procedure within this short time period.
- The Investigational Product (IP) was received just 2 days prior to patient screening. However, it was imperative that the IP reaches the sites within subsequent few days as the patients had to be screened and subsequently randomized before a particular cut-off date.
- In addition to providing adequate stock of IP at site (estimated by the sites), SIRO team also had to ensure that there was adequate buffer stock of other ancillary items like patient diary cards, glucometers, test strips, lancet, CRF binders etc.

SIRO Strategy:

Project Management Strategy:

- SIRO Project Manager developed unique study trackers which enabled monitoring and having control over all activities of the study with high degree of granularity.
- Special templates were designed for each visit so that all the study required information was captured accurately.
- The naïve sites were given additional assistance on all study related activities.
- SIRO project team requested all the sites to pre-screen and identify suitable patients from their database as well as within their referral network.

Communications Strategy:

- SIRO project team planned individualized approach with all the PIs for conducting follow-up and ensuring protocol compliance. The project manager provided regular guidance in form of Newsletter or mail to investigators & coordinators to re-iterate study related facts.
- The sites were asked to telephonically follow-up with each patient during the month of Ramadan to ensure protocol compliance and accurate entries in the CRF.
- Close coordination between Data Management team and sites in order to minimize overall queries.

Result:

- 768 patients enrolled in just 8 days instead of 3 weeks.
- 97% patients completed the study.
- 100% CRFs retrieved from all the sites within the set deadlines.