

CASE STUDY

Study involving diabetes patients who were fasting for more than 12 hours per day and were not flexible with taking short meals/ medicines/ blood draw during Ramadan.

The Challenge

- The preliminary challenge was to ensure that all the study sites, as well as per site enrollment, started on same date.
- Ensuring patient retention during Ramadan.
- It was essential to bridge the gap between the protocol requirements and the traditional rituals to ensure study compliance.
- Aggressive study timelines.

SIRO Solution

- Detailed discussions with the site team to create a recruitment strategy so that enrolment can commence on a specific date.
- Pre-identified suitable patients created and distributed newsletters to motivate the site to achieve overall recruitment target within specified timelines.
- Continuous communication and connection with sites during all stages of the study.
- Comprehensive study tracking and project management to ensure availability of adequate supply of Investigational Products especially in the high recruiting sites.
- Frequent Monitoring to ensure all timelines are achieved.

Key Takeaways

- 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.
- Successful DCGI inspection at 1 site.
- Client appreciation for completion of study within the proposed timeline.