Post marketing study of a CGM device (continuous glucose monitoring) in the management of type 2 diabetes

Situation:

An interventional, post marketing study for one of the world's largest medical device firm, involving 11 sites and 250 patients, aimed at exploring the use of continouos glucose monitoring device in treatment of type 2 diabetes patients

Challenges:

- The time available for planning was very short since the study was awarded to SIRO only 10 days prior to first scheduled site initiation
- Most sites involved were naive in conducting device trials
- There was lack of awareness amongst sites with regards to reporting of device deficiencies
- The device had multiple components and a separate inventory had to be maintained for each component
- Since monitoring frequency was low, there were inherent risks of data entry backlog and low SDV ratio

SIRO Strategy:

- SIRO put together a team of experienced members that were able to complete several activities within 8 days of study award resulting into successful site initiation on scheduled time. Some of the activities which were completed were:
    - Project kick-off
    - Study team training
    - Project plan finalization
    - Designing study tools, binders, site training and support material.
    - Preparing site for initiation viz. inventory arrangement, EC notification of documents etc.

- Sites were trained on conduct of device studies at the time of SIV using specifically designed training material
- A device technician from sponsor was included in site initiation team to train the sites on device application and troubleshooting
- Sites were trained on device complaint, identification, reporting process and its importance at the time of SIV and refresher training was provided on regular intervals
- Remote monitoring techniques were used in the study to avoid data entry backlogs and thus the SDV percentage remained above 80% through-out the study
- CRA specifically queried sites for device deficiency issues during regular site management call
- Device inventory for each site was tracked on weekly basis to avoid any shortages
- Sites were motivated to support remote monitoring through weekly calls by CRA and data completion status mails to PI

Result:

- Smooth study conduct with no critical findings observed during regular monitoring and sponsor visits
- High CRF completion (90 to 95%) and SDV status (80 to 85%) each week
- Prompt reporting of device deficiencies throughout study conduct

Sponsor Feedback:

"Just wanted to take a moment to tell you guys thank you for all the hard work and the late hours you put into ensuring the IDBL happens on time.

Appreciate all your efforts , lets hope that the data looks good and that we continue to strive to use the learning's from this exercise to proactively work with sites and train them better to have data correctly entered into the system in the first place."

- **Manager, Clinical Operations**

To know more about our clinical operations & clinical monitoring services, you can reach out to us at bd@siroclinpharm.com or visit us at http://www.siroclinpharm.com/clinical_monitoring.html