CASE STUDY

A Challenging Device Study in Oncology using a complex drug delivery technique.

The Challenge

- The major challenge was patient compliance with the external device as the medication pump had to be placed on the patient at an interval of every 7 days for duration of 6 months.
- The pump also required periodic replacement of batteries and periodic refilling of the drug.
- Operational challenge as the neurosurgeons were required to be well versed with the stereotactic surgery involved and also trained on the new device and drug. Logistics challenges with regards to patients and reports were also critical to the study as the study required the histopathology blocks to be sent to Europe within a time-period of 7 days.
- There was a need of a central lab in Europe to be assigned to perform validation of tumor assessment based on MRI reports of subjects.

SIRO Solution

- The device solution was brought about by deploying a dedicated site and back up coordinator by SIRO.
- The operational challenges were overcome by selecting sites with high patient load and neurosurgeons capable of performing intrinsic IP administration procedures.
- A global Investigator meeting was conducted for Indian PI, to help build confidence in the technology and intended benefits to the patients.
- Logistics challenges were overcome by ensuring unhindered communication between Neurosurgery, Histopathology and Radiology Departments.
- It was ensured that radiologists remained till the end of the study and by selecting radiologists capable of complying to MRI protocol to prevent observer variance.
- In addition, a SIRO Medical Monitoring team was present at all times to solve any queries.

Key Takeaways

- SIRO project management team were able to successfully set up the study at 8 Indian sites and ensure that a team of dedicated Neurosurgeons, Pharmacist and Radiologist work cohesively and generate the data which was submitted to regulatory agencies across globe.
- 51 Patients were recruited in 8 Indian sites in a time period of 14 months as compared to recruitment of 90 patients in 28 European sites in a time period of 30 months which demonstrated India's capability to recruit patients at a much faster rate as compared to global counterparts without compromising on quality.
- There were no audit findings which enabled the sponsor to take this product to next stage of drug development.