

CASE STUDY

Management of a complex oncology trial involving monoclonal antibody coupled with radioactive isotope having a half life of only 5 days, due to which the finished product had to be first manufactured in India and then immediately administered to Glioblastoma patients.

The Challenge

- Setting up the manufacturing facility for coupling the radioactive isotope with the monoclonal antibody.
- The study involved a complex stereotactic procedure to be performed by a Neurosurgeon to put the catheter inside the brain tumour and then, using an infusion pump to push the drug.
- The trial demanded proper communication and co-ordination as it required coordinating with 3 groups of investigators namely, Neurosurgeons, Nuclear Medicine and Radiologist to set up the trial.
- Time-management was essential as time was a critical factor in the study.

SIRO Solution

- SIRO team were instrumental to liaise with the government agency to develop the finished Investigational product by coupling the radio isotope with the monoclonal antibodies and then ensuring the delivery of the same to the sites via government approved aircraft carrier within 48 hrs of production.
- Overcame all logistic challenges by imparting extensive training to the site personnel so that they are able to enroll and treat the correct patients within 48 hours of IP production.
- Allocation of dedicated resources to manage the coordination between sites, sponsor, drug manufacturer and logistics vendor.
- Continuous follow-up with the site till survival of patient to obtain maximize trial outcome.

Key Takeaways

- 41 patients were recruited with zero errors in drug delivery and administration process.
- Client was satisfied considering the completion as an accomplishment of a milestone.