

Radionucleotide MAb trial in adult patients with Glioblastoma Multiforme

Situation: Open-label, Dose Confirmation Study of radionucleotide MAb for the Treatment of Glioblastoma Multiforme (GBM) at first relapse.

Challenges:

- Approvals from three different regulatory authorities due to nature of IP
- Patient recruitment & retention due to the following factors:
 - Identification of patients to conform to the stringent inclusion/exclusion criteria of the study.
 - Apprehension of the patient to the therapy since the IP was radioactive.
 - Apprehension of the patient to undergo surgery for implantation of catheter, intra-tumorally & overnight infusion of radioactive MAb.
- Identification of sites which were approved by the Atomic Energy Review Board due to unique nature of IP & study protocol.
- Sites were not equipped to use the special infusion pumps required for the study protocol.
- Drug preparation, due to the short half-life of the drug.
- Complex logistics in preparation & shipping of IP.

SIRO Strategy:

- SIRO experts conducted training of sites for use of infusion pumps & the assembly for infusion.
- Special training was imparted to site personnel for accurate IP administration.
- SIRO pre-planned the IP delivery schedule 1 year in advance to obviate the risk of non-compliance with study protocol. The deliveries were scheduled such that, the IP was shipped to site one day after production (Day-2) & the clearance certificate was provided to the site one day prior to infusion (Day-4). This enabled infusion on day-5 & day-6 from drug production date.

Result:

- The complex logistics involved in the trial, due to the nature of the IP were managed without any problems.
- Highest number of sites assigned (6 out of 9 globally) and highest number of patients recruited (34 out of 41 globally).