



Our Global Experience. Your Success.

*Challenging trial involving drug administered
intra-tumorally as continuous high-flow micro-perfusion*

Scope- A Phase II multinational trial to evaluate the efficacy and safety of two doses of anti-cancer drug in adult patients with recurrent high-grade glioma.

Indication- Glioblastoma Multiforme and Anaplastic Astrocytoma

Other Details- EMEA and US IND submission

Challenges-

- Implantation of catheter in the tumor on day 1 and patient carrying the infusion device and port for 6 months
- Drug preparation for infusion
- Continuous infusion for 6 months
- Patient follows up at alternate week cycles
- Stringent inclusion/exclusion criteria

Accomplishments-

Highest number of sites assigned,
28% of global total

Highest number of patients recruited
35 % of global total

Fastest Enrollment. Completed in **14 months**.
Global enrollment period was **30 months**



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Achievements:

****In terms of Regulatory approval:**

- Protocol to submission within 3 weeks
- Submission to Approval achieved in 4 months

*(** As per regulatory guidelines for global clinical trials the regulatory approval timelines vary between 6-12 weeks depending on the status of the clinical trial in other countries)*

In terms of patient recruitments:

Fastest enrollment amongst other sites in spite of stringent inclusion and exclusion criteria and compliance to protocol in-spite of study requirements being tough.