

VEEDA ONCOLOGY CAN PROVIDE GLOBAL PATIENT ACCESS WHILE MINIMIZING STUDY COSTS

Problem: The Sponsor of a global supportive care study for patients with non-small cell lung cancer was frustrated at the lack of progress in India. The CRO that had been entrusted with the study had been unable to identify appropriate investigative sites and the required regulatory documents had not been submitted to the Indian Health Authorities.

Solution: Initially, Veeda Oncology was approached to assist in site identification/feasibility in India. Within 3 weeks, we had queried 39 sites of which 29 successfully completed feasibility questionnaires (86% response rate!). Due to our successful site identification, the Sponsor expanded our services to include the regulatory submission, site management, project management and monitoring services for the 11 sites with a target accrual of 38 patients. Below is a summary of our performance and strategies adopted:

- **Regulatory Strategy-** The application was submitted to DCGI in October, 2008 with final approval obtained in December, 2008. With close and constant proactive followup at the DCGI office, the regulatory approval was obtained within 10 weeks despite the holiday season and queries issued by the DCGI office.
- **Site Selection Strategy-** Sites were selected based upon the availability of appropriate patients with a focus on the number of ongoing trials in lung cancer and fatigue. We were aware that there were numerous trials in lung cancer as well as two trials in cancer cachexia that were ongoing at many of our sites. Our investigators mentioned that enrollment on these studies was almost complete so that many patients from these trials who failed treatment could be potential patients for our current trial. We also focused on second tier cities since many patients treated in first tier cities return home after exhausting treatment options. Lastly, we considered proximity to palliative care/hospice centers.
- **Site Initiation-** Initially, 11 sites were to be initiated; however, due to the holidays it appeared that the reviews by several of the Ethics Committees would be delayed. As a backup plan, we submitted the documents to two additional sites to ensure approval within the timelines. Within a week of Ethics Committee approval at the sites, site initiation visits were conducted and sites were ready to screen patients. We closely followed up with the sites for patient identification, prioritized drug shipment and other activities at the site that had identified patients.
- **Enrollment Cap Raised -** Accruals far exceeded expectations with enrollment surpassing other countries such as Russia, Georgia, Romania, Serbia and Australia. Since accruals in the other countries had been disappointing, our initial target of 38 patients was increased by the Sponsor to a total of 50 - 55 patients so their corporate objectives could be attained within the required timeframe. Not only did we meet our initial accrual target of 38 patients by March, 2009, (despite the delay in getting regulatory approval) but also we were able to recruit the additional 17 patients in less than 3 weeks.
- **Cost Savings -** By shifting accruals from Australia and other countries to India, there were significant lower per patient costs, leading to substantial savings for the Sponsor.