

### Working on tight timelines for a global study on small cell lung cancer

**Overall Problem:** The sponsor of a global study had very tight timelines for accrual to their study in patients with small cell lung cancer (SCLC). SCLC accounts for only about 10% of the lung cancer patient population so there are few patients available for clinical trials. Because it is a fast growing tumor, patients cannot wait long to be treated so there is a very narrow window to capture eligible patients. Our initial involvement included only sites in the US but later our team in India was enlisted to increase accruals.

**Solution in the US:** Thirteen (13) sites in the Veeda Oncology network participated in the trial. Our sites in the US averaged approximately 3 patients per site which was higher than the non-network sites in the US. Because of our excellent performance including rapid start-up and accrual rate, the Sponsor decided to allow us to open sites in India since global accrual was still lagging.

**Challenges for India:** The Sponsor was initially concerned about opening the study to India for a variety of reasons such as the standard of care, importation of materials and supplies, time of approval by the regulatory body, etc. By the time they made the decision to move forward in India, Veeda Oncology had only three months from the time of the signed contract with the Sponsor to the time to complete enrollment.

#### **Solution in India:**

Below is a summary of our performance and the strategy that was adopted.

- Site identification and selection – We identified 13 potential sites in 5 days and site qualification visits were completed within one week for 11 sites. All documents were collected for submission to the Indian regulatory authorities and local ethics committees.
- Investigators' Meeting – Veeda Oncology quickly organized an Investigators' Meeting of which 9 of the 11 investigators attended. Initially, the investigators were not very enthusiastic because there was little time for them to accrue patients. However, by the end of the meeting, they were motivated, fully committed and six of the nine investigators signed the contract at that time.
- Regulatory Submission/Ethics Committee (EC) – After submission of the package on August 18, 2009, Veeda Oncology was in very regular communication with the DCGI, the regulatory agency of India. The study was approved in nine weeks (on October 28, 2009) despite it being a holiday/festival season. Seven of the sites received local EC approval prior to the time of DCGI approval.
- Site Initiations – Five sites were initiated after EC approval but before the DCGI approval, so sites were basically ready to enroll by the time of the DCGI approval. An additional 3 sites were initiated within 5 days of DCGI approval. The first patient was screened on October 30, 2009, two days after DCGI approval.
- Trial Supply Procurement & Cost Savings – All required supplies, including standard chemotherapy drugs, were procured using local Indian vendors using the same supplies/ brands that the Sponsor was using in the US and Europe.
- Patient Enrollment/Follow-up – At the time of DCGI approval, there was approximately 4 weeks to meet the Sponsor's timeline objective for accrual. Investigators were updated daily via e-mail on the status of the global enrollment so that they would not miss on even a single potential patient. In a period of 20 days, six patients were screened and five dosed over five sites. Because of our rapid start up and accruals in India, the Sponsor was able to complete enrollment 14 days early and beat their corporate objectives, which were previously perceived as impossible.
- Cost Savings – By shifting accruals from the US and other countries to India, there were significantly lower per patient costs, leading to substantial savings for the Sponsor. It is estimated that the costs on a per patient basis were reduced by approximately 40%.

As best summarized by the Clinical Development Team at GeminX Pharmaceuticals, Inc. "***Veeda has demonstrated a savvy ability to evaluate a project's specifications, set accurate expectations, and deliver on those expectations.***"