ACHIEVING RAPID ENROLLMENT AND STUDY STARTUP MILESTONES: AN ONCOLOGY CASE STUDY

A pharmaceutical company in China, developing an oncology product for lung cancer and other solid tumors, engaged Covance to help conduct a first-in-human (FIH) Phase I clinical trial. They were looking to conduct it first in the US and then in China. The client's initial key milestone for this FIH dose-escalation phase was rapidly enrolling the first subject into the US study. The company also partnered with Covance to develop an overall clinical development and regulatory strategy for product approval in the US, China and then the rest of the world.

Understanding the Challenge

- Achieve rapid enrollment of the first patient and study startup
- Develop and operationalize a development strategy in the US, driven by the expertise of Covance
- Educate the client—which had never conducted studies outside of China—about US trials and identify critical learnings that also should be implemented in China for its subsequent Phase I study

Study Startup Surpasses Expectations

Covance was determined to help this client achieve success outside of its home country. Our experience in running global trials and willingness to share expertise helped the client deliver against its timelines and goals. Innovation, collegiality and relentless determination to achieve the sponsor's objectives were keys to the project's success.

After reviewing the draft study protocol, Covance provided substantial feedback that significantly impacted the protocol design to enable expedited patient enrollment. The study was modified to provide a hybrid component for dose escalation: increasing the dose based on actual data observed. Covance also collaborated with the client's third-party regulatory consultant to submit an application to the FDA. The FDA had only minor comments on the recommendation and approval was received soon after their input that was provided in the 30-day review period.

Covance also worked closely with the lead site to ensure timely study startup. To save costs for the client, we negotiated with a third-party vendor, rapidly securing appropriate resources at a lower price. Less than three months after receiving FDA approval, patient screening began.

Leveraging our expertise in patient selection and efficient site startup, we enrolled the first patient less than four months after receiving FDA approval, achieving a major client milestone well ahead of deadline.

The clinical and operational expertise of Covance in conducting global clinical trials brings drug sponsors the benefit of rapid trial startup through effective strategy planning, flexibility and innovation. Consider Covance as your trusted partner to help you meet your clinical trial milestones.

Learn more about our drug development solutions at **www.covance.com**

The Americas + 1.888.COVANCE + 1.609.452.4440
Europe / Africa + 00.800.2682.2682 **Asia Pacific** + 800.6568.3000

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