Prism Ideas

Case study

Clinical science review case study

Background

A top-five pharmaceutical company had an established oral chemotherapeutic agent already licensed in several indications. The company had performed a large randomised Phase IIIb study in Asia to evaluate the agent as adjuvant therapy for gastric cancer. In this study, the drug was added to existing standard of care with the aim of improving disease-free survival. The sponsor planned to submit the data to the regulatory authorities with the aim of obtaining an extension to the existing label.

Challenge

Due to the proximity of planned database lock, review of the completed case report forms (CRFs) for in excess of 1000 patients was required within 3 weeks.

In preparation for the submission, it was essential that the consistency and accuracy of the data was ensured. Therefore, in preparation for database closure, the company needed an expert clinical review of the information captured by the Clinical Research Organisation conducting the study. Prism Ideas had previously collaborated with the client company to provide medical monitoring and medical writing on a number of large Phase IIIb and IV studies in which a total of more than 4,000 patients had been recruited. Based on this relationship and on Prism's experience in oncology, the sponsor selected Prism Ideas to perform this task. Due to the proximity of planned database lock, review of the completed case report forms (CRFs) for in excess of 1000 patients was required within 3 weeks; this timescale included submission of queries to the investigators and subsequent review of their responses.

Solution

A percentage of the cases were reviewed by all team members to ensure consistency of the clinical review across the study.

Prism Ideas provided a bespoke medical team to organise and evaluate the information provided and to address the specialist issues arising. As approximately 25,000 data points required review, CRFs were reviewed in batches to allow query resolution to happen in parallel with the ongoing review. In addition, a percentage of the cases were reviewed by all team members to ensure consistency of the clinical review across the study. Daily meetings between the physicians were conducted to allow a consensus clinical opinion to be formed for any unusual cases.

Outcome

The rapid, but thorough, medical review of 100% of cases ensured that as complete an information picture as possible was available for the sponsor to meet its database lock goals.

Good planning and a co-ordinated expert team allowed the data review to be successfully completed within the timescale required. The rapid, but thorough, medical review of 100% of cases ensured that as complete an information picture as possible was available for the sponsor to meet its database lock goals. The study has subsequently been analysed by the sponsor for production of the study report that will enable filing for a new indication for the chemotherapeutic agent.