



Clinical study report

Background

...study team required an experienced writing team to produce a comprehensive CSR

A study team from the oncology division of a global pharmaceutical company had recently completed a Phase IIIb trial evaluating the safety of a combination therapy for the first line treatment of patients with advanced breast cancer. The results of the study were positive, and the study team required an experienced writing team to produce a comprehensive clinical study report (CSR) to support the use of the combination therapy in clinical practice.

Challenge

The study team had no internal resource and CSR writing was not included in the contract with the CRO

The study team needed to outsource the writing of CSR as they had no internal resource and CSR writing was not included in the contract with the Clinical Research Organization (CRO). The study team needed an experienced writing team that was familiar with the company's resources and online document management system and that could deliver a high-quality CSR within the required timelines.

Solution

Prism's prior knowledge of the study design meant the Editorial team was well-placed to produce the CSR

Prism Ideas had been asked by a global pharmaceutical company to provide medical writing support for one of their clinical research programs. Prism provided study support, including writing protocol amendments and informed consent forms as well as providing Independent Data Monitoring Committee meeting support, for six years during the conduct of a study. Once the study was complete, Prism was approached by the company once again to provide medical writing support for the CSR. Prism's prior knowledge of the study design and objectives meant the Editorial team was well-placed to produce the CSR.

Prism completed four drafts of the CSR, starting with a shell document, addressing comments from all reviewers at each draft stage, prior to finalisation. Prism oversaw all aspects of the review process including review cycle management and final publication. The final published CSR was delivered 3 months after commission.



Conclusions

*...continue to collaborate
with Prism on various
other clinical research
programs*

Prism Ideas provided editorial study support to this company for many years, supporting a clinical study program from the early stages. The company was confident that Prism had the knowledge required to take care of the CSR while the company's study team focused on other aspects of their role. Prism worked efficiently in collaboration with the study team to ensure all comments were resolved and addressed throughout the process, resulting in a high-quality final CSR. The company continues to collaborate with Prism on various other clinical research programs.