Prism Ideas

Case study

Working with Prism Ideas to Secure a Compliant Safety Database

Prism Ideas now reviews adverse event (AE) reports arising from company-sponsored studies, ensuring both the completeness and the medical accuracy of the information.

Background

Prism Ideas has a longstanding relationship with one of the world's leading pharmaceutical companies and, to date, has provided support for more than 20 of its clinical studies. The pharmaceutical company prides itself on the safety of its medicines, and Prism Ideas has worked with the organisation for more than 5 years, initially with its team of pharmaceutical physicians providing a medical advisory service to support clinical studies. Prism Ideas now reviews adverse event (AE) reports arising from company-sponsored studies, ensuring both the completeness and the medical accuracy of the information. Prism Ideas has also been instrumental in designing and implementing the clinical trials performed by the company, including designing entire Phase IV programmes.

Challenge

The top 10-ranking pharmaceutical company established a large Phase IV safety study of a monoclonal antibody in patients with advanced cancer. This recently completed global study was conducted primarily to assess the efficacy and safety of the company's drug in clinical practice. The study involved more than 7000 patients who had limited alternative treatment options; this large patient population was used to characterise the safety profile of the drug in an enlarged patient population and to compare this with the previously established safety profile.

To ensure the accuracy and completeness of results collected, the sponsor felt that an independent expert physician review would be necessary once the study had closed. A leading provider of drug safety services was also needed for ongoing expert physician review of serious AEs (SAEs) to ensure the safety of those patients still receiving therapy after the study had ended.

Solution

...the company needed this review to be performed in the shortest possible timeframe, requiring a drug safety services provider with an experienced team and efficient processes.

As a result of Prism Ideas' established relationship with the pharmaceutical company and recognition of its high scientific standards, Prism Ideas was asked to provide an independent physician review of all SAEs that arose during the study. A key factor in this decision was that the company needed this review to be performed in the shortest possible timeframe, requiring a drug safety services provider with an experienced team and efficient processes.

Prism Ideas provided an expert assessment of the safety information collected during the study against the known safety profile of the drug. A team of expert

physicians at Prism Ideas performed a review of the study, which focused on the coding of SAEs, assignment of causality and expectedness of SAEs according to the core data sheet and investigator brochure provided by the sponsor. Prism Ideas was also responsible for the identification of any SAEs that were hidden in the narrative and should have been reported separately. Prism Ideas was then able to write a summary report to demonstrate that there were no safety issues arising from the study that warranted a change in the established safety profile of the drug. This is of particular relevance as continuous assessment of the emerging safety pattern of AE reports arising from clinical trials is an important component of a pharmaceutical company's obligation to patients, healthcare providers and regulatory authorities.

Following completion of the study, Prism Ideas continued to provide ongoing expert physician review of all SAEs to ensure the safety of those patients from the study who were still receiving therapy.

Benefits

In just 1 month, Prism Ideas examined in excess of 4000 SAE reports and compared these with previous findings.

Due to the large quantity of SAEs requiring review, Prism Ideas established a timeframe for assessment to ensure that each SAE had an expert review within the short period of time available to meet the sponsor's objectives. In just 1 month, Prism Ideas examined in excess of 4000 SAE reports and compared these with previous findings. Prism's existing internal processes enabled all data to be inputted in 2 weeks. This was followed by an extremely rapid review stage, with a thorough review conducted and report written in only 2 weeks. This was made possible as Prism Ideas could allocate a number of people with a senior level of pharmaceutical industry experience, including background in pharmacovigilance, to perform each review. The specialised team at Prism Ideas has extensive experience of performing drug safety reviews and as each member knew exactly what to look for and how to analyse each case, no time was wasted during the review process. In addition, Prism Ideas used its knowledge to develop a rigorous plan before the review process and a robust database was created to contain all the information generated. This meant that data could simply be entered into a predefined report document at the end of the review, simplifying the review process and speeding up the time taken to confirm the safety profile of the drug.

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In addition, the leadership position of each physician at Prism Ideas meant that every person reviewing the SAEs could give an autonomous medical opinion, enabling quick decision making. However, when required, colleagues at Prism Ideas would convene to produce an expert consensus on any questions arising, enabling a thorough and consistent approach.

Prism Ideas looked at the study in terms of patient safety but also worked with an understanding of the need to justify an appropriate product label and

evaluate its safety in the most cost-effective way. As a result, the pharmaceutical company could trust that Prism Ideas would only highlight issues that demonstrated that the safety profile of the drug had potential to differ from the established profile. This meant that the examination of SAEs was focused and time efficient.

Dr Colin Hayward, Prism Ideas, comments:

"At Prism Ideas we offer a pragmatic solution, reviewing the study from an extremely thorough safety point of view but with an understanding of the pharmaceutical company's objectives. We are a drug safety services provider that has safety as an absolute priority but that also understands the use of the drug in clinical practice."

When outsourcing drug safety services the main issue is that the pharmaceutical company must trust the service provider with highly confidential information. For example, in order to ensure that the safety profile of the drug generated by the study was consistent with that previously reported for this drug, the company had to supply core data as a guide. Prism Ideas guaranteed confidentiality and ensured that no information from the study was disclosed.

The pharmaceutical company also had the security of knowing that if any new signals were found, Prism Ideas could investigate these and, if necessary, recommend how to incorporate them into the safety profile of the drug.

During the review process Prism Ideas had a very dynamic relationship with the sponsor study team in which any issues were intelligently flagged to the company who could then discuss them with Prism's expert physicians. The pharmaceutical company also had the security of knowing that if any new signals were found, Prism Ideas could investigate these and, if necessary, recommend how to incorporate them into the safety profile of the drug.

Conclusion

One of the world's leading pharmaceutical companies selected Prism Ideas to perform an accurate and thorough review of SAEs arising during a global Phase IV safety study. Through Prism's understanding of how the study was performed and examination of the data gathered, it was confirmed that the clinical experience gained from the patients was consistent with the established safety profile of the drug and therefore that the new risks and benefits associated with use of the drug for the given indication remained favourable. The expert team at Prism Ideas was able to complete this complex and extensive process in an extremely short timeframe, ensuring not only thorough assessment of the safety of the drug but also working within the timeline necessary to enable its customers to meet their objectives.