Prism Ideas

Case study

Complementary Skills Combine for Safety Signal Detection

Background

A top-five pharmaceutical company selected Prism Ideas to produce two drug safety reports assessing the validity of safety signals detected for two of its marketed products.

Ongoing surveillance of the safety profile of a product ensures early detection of any potential concerns and minimisation of potentially damaging effects. The analysis of a drug safety signal should involve all sources of information available on the product, from pre-clinical data through to data from published scientific literature and all adverse events within a company safety database. Individual cases must be analysed to determine the potential association of the product with the event and should be reported in relation to the relevant patient population, taking into consideration demographics and potential confounding factors as well as the background incidence of the event in that population.

A top-five pharmaceutical company selected Prism Ideas to produce two drug safety reports assessing the validity of safety signals detected for two of its marketed products. The client company had been asked to produce cumulative analyses of the signals following submission of a Periodic Safety Update Report to the competent authorities. The safety reports were to be used internally within the client company to determine whether or not the core safety information on the products required amendment and to provide the basis for the company's response to the competent authorities.

Challenge

Safety signal detection requires a specialised approach to the analysis of available data.

The client provided Prism Ideas with the reference information from which work-up reports for each product were required within 3 weeks. Safety signal detection requires a specialised approach to the analysis of available data, necessitating the ability to review and interpret published literature, an understanding of the pathophysiology of a disease and an understanding of the medicine the mechanisms by which it may have desirable and undesirable effects. These skills must be combined with an ability to evaluate and reconcile information from a variety of sources and to provide appropriate recommendations for action.

Solution

The data were reviewed in parallel by scientists and physicians, with daily meetings to allow discussion of specific cases and the formation of a consensus opinion.

A team of physicians, scientists, data managers and editors was formed. By taking a methodical and transparent approach to organising and evaluating the available information, a large amount of data was reviewed rapidly, with a thorough quality check of the data incorporated prior to analysis. The data were reviewed in parallel by scientists and physicians, with daily meetings to allow discussion of specific cases and the formation of a consensus opinion. Emerging conclusions were communicated immediately to the sponsor so that they were kept informed of any potential impacts to the safety profiles of the two products.

Through excellent team work and the bringing together of an array of complementary skills, Prism Ideas was able to analyse all the relevant data and compile two comprehensive issue work-up reports within a short time frame.

Conclusion

The scientists and physicians at Prism Ideas are experienced in assessing drug safety information. Through excellent team work and the bringing together of an array of complementary skills, Prism Ideas was able to analyse all the relevant data and compile two comprehensive issue work-up reports within a short time frame. The analysis and conclusions and recommendations contained in the reports provided the company with a rationale for any further action regarding the safety profile of the products.