Prism Ideas

Case study

In-depth Product Knowledge Allows Expert Update of Investigator Brochure

Background

The Prism Ideas team had an in-depth knowledge of both the product and its clinical development history.

Prism Ideas developed a long-standing relationship with a medium-sized pharmaceutical company client and, over a period of 5 years, was involved in many aspects of the clinical development of one of the client's lead products. This involvement included evaluation of the safety data from the entire clinical programme, medical monitoring of the majority of patients in the clinical programme, writing narratives, review of CIOMS and MedWatch forms, the development of risk:benefit statements for individual clinical trials and the Investigational Medicinal Product Dossier and presentation at Drug Safety Monitoring Board meetings. As a result, the Prism Ideas team had an in-depth knowledge of both the product and its clinical development history.

Challenge

Prism Ideas was asked to update the Investigator Brochure in preparation for future clinical studies using information available from completed clinical trials. The current brochure included extensive preclinical information as well as information on multiple formulations and potential indications, much of which was no longer relevant to the development of the molecule.

Solution

Prism Ideas revised the Investigator Brochure, ensuring compliance and consistency of content and also editing the formatting and presentation to make the document more 'user friendly'.

Prism Ideas reviewed the current Investigator Brochure and all available data from completed clinical trials. Prism Ideas then provided advice on restructuring the balance of the brochure to remove preclinical information that had been superseded by current knowledge of the clinical profile of the molecule. Once the content had been agreed, Prism Ideas revised the Investigator Brochure, ensuring compliance and consistency of content and also editing the formatting and presentation to make the document more 'user friendly'.

Conclusion

Prism Ideas' expertise ensured only relevant information was included in the final version.

The updated Investigator Brochure was completed and used in the future development of the molecule. Although more data had become available, Prism Ideas' expertise ensured only relevant information was included in the final version (obsolete information was removed), resulting in a more concise document that was easily understood and convenient to use. Furthermore, by retaining Prism Ideas throughout the clinical development programme, there was consistency of the interpretation of efficacy and safety information in all regulatory documents.