Prism Ideas

Case study

Prism Ideas Provides Expert Resource to Deliver Clinical Trial Authorisation Application

Background

Prism Ideas has a long-standing relationship with a mid-size pharmaceutical company, having provided clinical consultancy and medical support throughout the clinical development of two molecules. The company had recently completed a Phase II trial of one of its products and was preparing a clinical trial authorisation (CTA) application to expand the clinical programme into new indications.

Challenge

The client required expert clinical oversight to ensure data within the CTA were presented consistently and accurately.

The company had insufficient internal resource to deliver the CTA in addition to its day-to-day responsibilities and required additional expert resource to fit seamlessly into its established teams. The client needed to maintain overall control of the CTA application but required expert clinical oversight to ensure data within the CTA were presented consistently and accurately.

Solution

An experienced pharmaceutical physician was provided to oversee the updates of the associated regulatory documents and to ensure consistency across them.

Prism Ideas had knowledge of both the background of the product and the desired future direction of the clinical programme and was able to provide practical support in preparing sections of the CTA. Prism Ideas provided a team with an understanding of the therapy area and CTA submission process to provide bespoke support in preparation of the CTA. In addition, an experienced pharmaceutical physician was provided to oversee the updates of the associated regulatory documents and to ensure consistency across them. The physician was also able to assess the new information for any potential changes to the risk:benefit profile of the molecule and to discuss their conclusions with the client and provide appropriate recommendations.

Conclusion

The team at Prism Ideas was able to integrate seamlessly into the client company's working processes, providing practical support throughout.

Familiarity with the product and therapy area as well as previous experience of developing the strategy for the clinical programme, allowed Prism Ideas to respond quickly and efficiently to the needs of the sponsor. The team of physicians and scientists provided the client with the additional support required: within 4 weeks, Prism Ideas completed an update of the Investigator's Brochure, an update of the risk-benefit statement and produced almost 100 adverse event narratives for inclusion into a clinical study report, all of which were required to support the CTA. The team at Prism Ideas was able to integrate seamlessly into the client company's working processes, providing practical support throughout, and resulting in a CTA and associated support documents that were focused and thorough and were delivered within the agreed schedule.