



Update of Core Clinical Safety Information

The volume of work required exceeded the pharmaceutical company's in-house resource capacity.

Background

The pharmacovigilance department of a major pharmaceutical company with an extensive portfolio of mature products needed to update the Core Clinical Safety Information (CCSI) for many of its products to meet regulatory requirements. The volume of work required exceeded the pharmaceutical company's in-house resource capacity and, furthermore, there was no established internal process for producing and reviewing the required documentation.

To optimise the use of in-house resource within the client company... development of an internal process was required as an initial step.

Challenge

Prism Ideas was contracted by the company to provide support for the update of these documents, which covered products in a range of therapy areas. To optimise the use of in-house resource within the client company and to facilitate completion of the documents within a 2-year timeframe, development of an internal process was required as an initial step. Once a process had been established, centrally validated CCSI was required for all products to ensure that once the updated documents had gained national approval, local prescribing information was consistent across markets.

Prism Ideas provided the client with a series of recommendations for setting up the necessary process that would not only allow update of all existing CCSI but would also provide a mechanism for monitoring and delivering future updates.

Solution

After an initial briefing meeting, Prism Ideas provided the client with a series of recommendations for setting up the necessary process that would not only allow update of all existing CCSI but would also provide a mechanism for monitoring and delivering future updates. In partnership, Prism Ideas and the client worked through the update of the CCSI for one product; learnings from this were then used to refine the internal management and review processes within the client company. For each CCSI update, Prism Ideas used the existing CCSI as a base and reviewed against the consolidated safety database held by the client company. Initially, all post-marketing adverse events within each body system were reviewed to identify events that had not been included within the previous CCSI. Prism Ideas then provided a medical evaluation of individual events to determine, based on an assessment of causality and/or volume of reports, whether or not they should be included in the CCSI. These recommendations were supported by statements, drafted by Prism Ideas, which were employed in the regulatory submissions to justify each revision to the CCSI.



By first working with the client company to establish its internal processes, Prism Ideas was able to efficiently deliver updated CCSI to meet regulatory standards well within in the allocated time frame.

Conclusion

Prism Ideas updated the CCSI for approximately 12 products over an 18-month period; the products allocated to Prism Ideas were those matched to the clinical team's therapy area expertise. By first working with the client company to establish its internal processes, Prism Ideas was able to efficiently deliver updated CCSI to meet regulatory standards well within in the allocated time frame. In addition, the client benefitted from the establishment of a tried and tested process that allowed them to track and manage future CCSI updates more effectively.