Prism Ideas

Case study

Developing a Clinical Programme to Demonstrate the Effectiveness of a New Anaesthetic Product

Background

An American biopharmaceutical company commissioned Prism Ideas to evaluate the data collected in the development programme for a new anaesthetic product in terms of preparing an Marketing Authorisation Application submission in Europe and subsequent commercialisation. The company, committed to discovering and delivering innovative medicines, had developed a local anaesthetic skin patch to alleviate pain associated with a variety of common medical procedures. Prism Ideas identified aspects in the clinical programme that warranted further research and supported the client company in the design and implementation of a clinical study to compare the effectiveness of the product with a market-leading treatment.

Challenge

To ensure that the objectives were achieved in the most effective and efficient way possible, the company felt that the assistance of an independent provider with expertise in both clinical development and medical communications was needed.

The marketplace that the client company was looking to enter was dominated by simple topical cream preparations, which included the market leader. The new anaesthetic patch had the unproven potential to provide more effective and more rapid analgesia than other preparations currently used in clinical practice. To demonstrate this potential and support regulatory filings, the biopharmaceutical company needed to understand where the clinical programme required augmentation and, if necessary, conduct additional clinical research to complete the submission package.

To ensure that the objectives were achieved in the most effective and efficient way possible, the company felt that the assistance of an independent provider with expertise in both clinical development and medical communications was needed to supplement its in-house expertise and move the project forward. It was vital that the provider had experience of the therapy area, together with a background in both pharmaceutical medicine and anaesthesia.

Solution

A key factor in Prism Ideas being selected was its expertise in clinical development services and direct experience in the field of anaesthesia.

Prism Ideas was asked to evaluate existing product data and design a research programme that would be efficient and deliver results to support regulatory filing and the product's target claims. A key factor in Prism Ideas being selected was its expertise in clinical development services and direct experience in the field of anaesthesia. An advantage of working with Prism Ideas was its ability to lead the development of the clinical plans, facilitate their implementation and provide medical supervision of their delivery. Prism Ideas follows the paradigm of beginning with the end in mind which means the rationale and

objectives of the additional clinical research were both justified and consistent with the company's needs.

Regulatory guidance in force at the time required that the new product be shown to be therapeutically equivalent to the standard of care and that the need for rescue analgesia was evaluated. Neither of these aspects was addressed fully by the clinical studies that had been conducted previously. However, the size of, and costs associated with, conducting an equivalence study were unacceptable to the client.

Prism Ideas considered a variety of study concepts and established with the client those that best fit its overall objectives for the new product.

Prism Ideas reviewed the available clinical information in order to identify product attributes that could represent meaningful clinical advantages in favour of the new anaesthetic patch over the marketed product. This approach would present a more compelling reason to choose the new product over the current standard of care and a superiority study would involve less additional expenditure for the client. Prism Ideas considered a variety of study concepts and established with the client those that best fit its overall objectives for the new product. Prism Ideas then completed the design of a controlled study comparing the effectiveness of the two treatments at different times after administration.

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The company's expert team of physicians collaborated with the contract research organisation (CRO) to implement the study, which involved 80 participants and supported the clinical interpretation of the results collected by the CRO. The study volunteers were randomised to receive the anaesthetic patch on one upper forearm and the competitor product on the other at one of four different intervals before a vascular access procedure. After each procedure, the subject and investigator completed study evaluations. The primary efficacy endpoint was subject report of pain intensity using a visual analogue scale. Secondary efficacy endpoints included subject evaluation of the effectiveness of the study drugs, investigator evaluation of the subject's pain intensity using a four-point categorical scale and the investigator's overall impression of the study drugs. Safety and tolerability were assessed using standard clinical research methods for adverse events (AEs).

Prism Ideas advised on the content of the statistical analysis plan for the data collected in the study. The results of this analysis indicated that the patch provided significantly better dermal anaesthesia than did the competitor cream after 10-, 20- and 30-minute application times. Consistent with this, significantly more subjects in those three groups reported that they would use the patch again compared with the cream, and more subjects reported no pain associated with the vascular access procedure after 20- or 30-minute applications of the patch than after applications of the cream of the same duration.

The study design developed by Prism Ideas was able to efficiently and successfully demonstrate that the patch delivery system provides more rapid onset of local anaesthesia than is possible with the traditional cream

formulation. It also produced substantial evidence of improvements in the level of analgesia compared with the cream, offering the potential for a wide variety of benefits in clinical practice. In addition, the study was able to demonstrate that the new product contributed ease-of-use advantages as well as proving that the application required less time to administer by nursing staff than traditional preparations.

Benefits

Prism Ideas was able not only to identify the additional research needs required to support successful regulatory filing but also to develop data that provided a future commercial advantage.

Prism Ideas' ability to provide clinical development services across all stages of research and its expert team of physicians, including those with relevant therapeutic expertise, resulted in the provision of seamless support to the biopharmaceutical company throughout the development, delivery and reporting of the clinical study. Prism Ideas was able not only to identify the additional research needs required to support successful regulatory filing but also to develop data that provided a future commercial advantage. Prism Ideas' internal processes also allowed the team to get the research programme 'up and running' quickly and ensure each element was completed in the shortest timeframe and in the most effective way possible.

Prism Ideas worked with the client company to develop a programme that would have future clinical relevance and would enable the research findings to be presented to the scientific community. Due to the success of the collaboration, the biopharmaceutical company felt that it was important that the study data was written up and requested that Prism Ideas' staff play a lead role. The data have since been presented at a number of launch meetings for the product as well as at the American Society of Anesthesiologists (ASA) annual conference and was published in a leading journal in the therapy area, *the British Journal of Anaesthesia*[1].

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Due to Prism Ideas' ability to incorporate expert physician review into its programmes and outputs, clinical excellence and credibility were assured. The data generated has also been used in a number of successful regulatory submissions in Europe and North America.

Marc Riteco, Director of Clinical Services at Prism Ideas, comments:

"Prism Ideas' knowledge of the industry and background in anaesthesia together with a thorough understanding of the market for the product ensured that this study maintained the highest scientific quality whilst effectively demonstrating that the anaesthetic patch is superior to other preparations"

The data collected in this clinical study presented a major clinical advantage and were subsequently used as part of the launch platform for the product in both Europe and North America.

Conclusion

Prism Ideas established precise needs for the client company and identified an efficient and appropriate research programme that addressed all the challenges faced by the company. By focusing on the programme objectives, Prism Ideas helped the client company achieve marketing approval for its product in a pragmatic and efficient manner. The data collected in this clinical study presented a major clinical advantage and were subsequently used as part of the launch platform for the product in both Europe and North America. Prism Ideas saw the project through to its conclusion, completing the cycle of activities that started by beginning with the end in mind.

Reference

1. Sawyer J, et al. *Br J Anaesthesia* 2009;102:210–5.