



Implementing a Clinical Development Strategy for a New Indication Through Outsourcing to a Specialised Provider

Background

Prism Ideas has been working with one of Europe's speciality pharmaceutical companies to implement a clinical development strategy for one of its products. The company researches, develops, produces and markets specialised pharmaceutical products for the management of chronic diseases. Prism Ideas has worked with the company to develop a strategic 5-year medical plan to support the use of an injectable formulation when preparing patients for elective surgery.

Challenge

First, there was a need to raise awareness of the importance of proactive management of the condition. Second, data needed to be produced that would support the product's activity and value in this setting.

The pharmaceutical company's injectable formulation has been available in the clinical setting for some time, and is used for the treatment of patients when oral preparations are ineffective or cannot be used. Recently the company made the decision to expand the use of the product into new indications, including the pre-operative surgical setting. However, expanding into this setting presented a number of challenges. Awareness of the therapeutic intervention to correct the medical problem prior to hospital admission is low. The issue is further complicated by the fact that pre-operative patient management falls between two specialties – anaesthesia and surgery – and is often only begun once patients have been admitted to hospital. Therefore, the company identified two specific objectives. First, there was a need to raise awareness of the importance of proactive management of the condition. Second, data needed to be produced that would support the product's activity and value in this setting.

Prism Ideas has worked in partnership with the company and its team to produce a development strategy based on the three pillars of medical affairs: scientific advocacy, clinical development and scientific communications.

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

Prism Ideas was selected based on its expertise and the recognition that it could provide a unique integrated service offering. Prism Ideas has worked in partnership with the company and its team to produce a development strategy based on the three pillars of medical affairs: scientific advocacy, clinical development and scientific communications.



Initial development of advocacy was important, with the intention being that these advocates become supporters of this specific therapeutic strategy in the future.

Scientific advocacy

To raise awareness of the injectable formulation for pre-operative patient management, Prism Ideas was able to build on the client company's extensive engagement with key opinion leaders (KOLs) in the field of anaesthesia and surgery to further develop a network of potential advocates, both for the concept of proactive patient management, and, more specifically, for the product as a therapeutic option. Initial development of advocacy was important, with the intention being that these advocates become supporters of this specific therapeutic strategy in the future.

Prism Ideas assembled a scientific advisory board that was brought together to focus on understanding current approaches to pre-operative assessment and care in different regions, in order to obtain feedback on the use of the product in this setting. The advisory board was co-chaired by an external KOL with expertise in the area to ensure that the scientific needs were married with the objectives of the company. This also enabled the company to further strengthen their already close relationship with the KOL, which will be advantageous during the later stages of development. The scientific advisory board will continue to meet twice a year throughout the implementation of the programme. Further specialist scientific advisory boards will also be formed over the course of the development programme to facilitate expansion to other surgical specialties.

Prism Ideas supported the implementation of an international clinical audit involving more than 1000 patients and the collection of epidemiological data.

Clinical development

A layered approach to clinical development, encompassing both an initial clinical audit and future interventional studies, was decided upon. Prism Ideas considered this flexible sequential approach to be the most efficient given the current stage in the product's lifecycle. To define current practice in the pre-operative management of patients prior to orthopaedic surgery, and to characterise the breadth and scope of the issues at hand, Prism Ideas supported the implementation of an international clinical audit involving more than 1000 patients and the collection of epidemiological data. This audit will help to understand how the condition is treated pre-operatively and gauge current practice in a number of key countries. The process of the audit itself will help raise awareness of the problem and support a multi-disciplinary approach to its management between surgeons and anaesthetists. The results from the study will help shape interventional studies in the future. Prism Ideas is continuing to work with the internal experts to produce an interventional study that initially will demonstrate the efficacy of the product in this setting and subsequently drive further programmes.

These data will be supported by future studies and, as expected in a new therapeutic area, there will be a large demand by investigators for their own studies. Prism Ideas can help support investigators with their own sponsored trials by giving them support in trial design as well as tracking the status of their studies.



A mix of congress abstracts, posters and oral presentations, together with articles in scientific journals, will provide the scientific base for the medical marketing plan.

Prism Ideas is able to put in place stringent programmes for the development strategies that it works on to ensure every stage is completed in the most effective way and in the shortest timeframe.

Scientific communications

Scientific advocacy and clinical trials are interlinked inherently with the communication programme. The audit and future clinical trials will drive the company's publications plan to raise awareness of the condition and its consequences, as well as build on this medical need with subsequent data from the interventional studies.

Prism Ideas' ability to address both its clients' clinical and communication needs enables it to not only provide a critical scientific eye but also a broad view of the industry and an understanding of the pharmaceutical company's objectives for the use of the therapy in clinical practice. A mix of congress abstracts, posters and oral presentations, together with articles in scientific journals, will provide the scientific base for the medical marketing plan. This will enable existing and new data to be communicated to health care professionals in a timely and proactive manner, as well as providing important reference data for brand materials.

Benefits

As a result of its unique service offering and in-house expertise, Prism Ideas was initially able to prepare an outline of a long-term clinical development strategy for the injectable formulation in the surgical setting in just 1 month. Prism Ideas is able to put in place stringent programmes for the development strategies that it works on to ensure every stage is completed in the most effective way and in the shortest timeframe. This is made possible by Prism Ideas' team of expert physicians, which includes specialists in pharmaceutical medicine and anaesthesia amongst other disciplines, who have an in-depth understanding of a therapeutic area. Prism Ideas can therefore allocate people with senior-level experience to each element of a programme to ensure efficient processes at all stages.

By partnering with Prism Ideas on the development of this clinical strategy, the pharmaceutical company is able to maximise the value of the programme whilst optimising its own financial and staff resource. Prism Ideas' expertise supplements the company's in-house capabilities across a variety of disciplines necessary for successful delivery of the programme, such as medical consultancy, protocol development, medical writing and facilitating advisory boards.

Prism Ideas is able to offer the companies it works with continued development and expert physician review throughout all phases of strategy development and implementation. The team works closely with the pharmaceutical company on a day-to-day basis overseeing tactical delivery, providing feedback and working on a number of specific projects that support the overall programme, including publication development. A thorough and consistent approach is ensured at all stages as Prism Ideas' team of experts is

able to convene on any issues or challenges that arise throughout the duration of the programme and produce an expert consensus.

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

“Prism Ideas has been able to offer the company a mix of high-level consultancy and practical delivery to complement its in-house skills. In addition to having an understanding of the therapy area, Prism Ideas is able to bring expertise in both scientific development and commercialisation to the strategy, enabling the implementation of a scientific study programme that meets commercial objectives.”

The first phase of the strategy is currently in progress whilst the preparation for the next study is underway and will be implemented when the clinical audit is in its final stages.

Conclusion

Outsourcing the formation of a clinical development strategy that will build awareness of a pharmaceutical product in a new therapeutic area is not something that should be taken lightly. Outsourcing of this type requires a partner who has the expertise and experience to bridge the gap between Research & Development and Marketing departments and ensure active continuity at all stages of the process. As a result of Prism Ideas' specialist in-house expertise and understanding of the therapy area, the client company has been able to prepare an integrated medical affairs strategy, which will focus on establishing an understanding of the current treatment area and the potential for the therapy going forward. The programme co-developed by Prism Ideas will continue to be implemented over the next 4 years with frequent dissemination of data. More formal development and expansion into further areas will follow after a successful outcome from the current programmes.

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