Prism Ideas

Case study

Assessing the Real-life Impact of an Erectile Dysfunction Treatment at the Final Stages of Development

Background

One of the world's largest pharmaceutical companies was evaluating the potential to develop its prescription-only PDE5i as an over-the-counter product.

Phosphodiesterase type 5 inhibitors (PDE5i) are prescribed as a treatment for erectile dysfunction (ED), which has increasingly been proposed as an indicator of cardiovascular disease (CVD). One of the world's largest pharmaceutical companies was evaluating the potential to develop its prescription-only PDE5i as an over-the-counter product; however, this led to the need to assess the potential for patients with an underlying diagnosis of CVD or other conditions to be missed. To address this issue the company needed to conduct a research project that would provide an estimate of the number of patients in whom a diagnosis of underlying CVD could therefore be missed, should they take a PDE5i without having first sought diagnosis and treatment advice from a physician beforehand.

Challenge

There is already significant knowledge on the link between ED and underlying conditions such as CVD, with international guidelines in place recommending that physicians conduct a clinical assessment to detect any underlying conditions when prescribing PDE5i therapy. However, to date there are no accurate, real-life data on how many individuals are actually diagnosed as having undetected CVD or other relevant underlying medical condition when prescribed with a PDE5i.

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The pharmaceutical company had limited physician resource due to organizational changes within its medical team. As a result, the company required the services of an independent provider who could offer experience and knowledge in the area of urology. In addition, to ensure that the objectives were achieved in the most effective and efficient way possible, the company felt that an independent consultancy that could also provide expertise in medical writing and the preparation of medical manuscripts was required. Prism Ideas was therefore commissioned to provide medical consultancy to the research project as well as medical writing support to allow subsequent publication of the findings within a peer-reviewed journal.

Solution

Prism Ideas used its unique knowledge in this specific therapeutic area to develop a solution to address the goal of the research.

Prism Ideas used its unique knowledge in this specific therapeutic area to develop a solution to address the goal of the research. In collaboration with an external academic and with the client company's internal stakeholders, a series of research questions were defined to address the prevalence and detection rate of underlying disease in men with ED receiving PDE5i therapy

in the UK. The questions were then developed into a research protocol for a retrospective database study that interrogated anonymous patient records from UK general practices.

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The non-interventional study used The Health Improvement Network (THIN) database to identify men who had received an index PDE5i prescription during a specified period of time and for whom there was a continuous medical history for 60 months prior to the prescription. Almost 25,000 patient records were included and these were matched against three times as many records from control patients.

Primary endpoints were the prevalence of underlying disease prior to prescription of the therapy and the detection rate as cumulative incidence of such diagnosis in the 3 months following the drug being prescribed. Assessments included comparison with age-matched controls, comparison with identical time periods immediately before and 1 year after prescription and changes during the study period. Descriptive statistics, analysis of proportions and multivariate logistic regression analysis were used.

Benefits

As a result of Prism Ideas' in-depth knowledge of the therapeutic area, combined with its experience of protocol development and medical writing, its team was able to develop a robust study design.

Prism Ideas' used its expertise to supplement the company's in-house capabilities across the variety of disciplines necessary for successful delivery of the programme. This included expert medical consultancy on the strategic development of the research project and interaction with the various stakeholders at the client company (medical affairs, statistical data analysis and research operations) and with an international key opinion leader from academia. As a result of Prism Ideas' in-depth knowledge of the therapeutic area, combined with its experience of protocol development and medical writing, its team was able to develop a robust study design, to assist the company during the data analysis and to prepare a manuscript that was accepted in a respected international medical journal.

Prism Ideas' dedicated team was able to define the scope and objectives of the programme right from the initial conception through to delivery of the final publication.

By outsourcing to Prism Ideas, the client company received access to experienced and specialised pharmaceutical physicians in the field of urology who could ensure both scientific integrity of the project and alignment to the company's needs. Prism Ideas' dedicated team was able to define the scope and objectives of the programme right from the initial conception through to delivery of the final publication. Prism Ideas developed a solution that was easy to implement and clearly addressed the objectives. The findings will enable the client company to answer key questions from regulatory agencies and to continue its commitment to providing valuable scientific information to the medical community.

Prism Ideas was selected based on its therapy area expertise and the recognition that it could provide a unique and integrated service offering encompassing medical and editorial specialties.

Conclusion

One of the world's leading pharmaceutical companies selected Prism Ideas to support a clinical development strategy for one of its key products. Prism Ideas was selected based on its therapy area expertise and the recognition that it could provide a unique and integrated service offering encompassing medical and editorial specialties. To estimate the number of patients where an underlying medical condition could be missed if no physician assessment is involved in treatment of ED with a PDE5i, the prevalence and detection rate of underlying conditions in men with ED had to be studied. The expert team at Prism Ideas was able to develop a protocol to collate and analyse clinical data, as well as to interpret and report the data in a medical manuscript, providing a robust estimate of the real-life impact of altering PDE5i access guidelines.