Prism Ideas

Case study

Working with Prism Ideas to Supplement In-house Capabilities and Manage the Extensive Components of a Clinical Trial Programme

Background

The extensive requirements of a successful clinical trial programme can lead to the outsourcing of clinical, writing and project management expertise.

Prism Ideas has a long-standing relationship with one of the world's leading pharmaceutical companies, supporting development and scientific communication projects for multiple brands. The company is the current leader within the field of oncology. The extensive requirements of a successful clinical trial programme can lead to the outsourcing of clinical, writing and project management expertise to support the success of the company's significant clinical trial investment.

Challenge

The company had developed an extensive Phase IIIb/IV clinical trial programme for this drug but did not have the in-house resource to manage several of the core elements. To complement the established team, additional expert support was required for the multiple trials, data sets, and internal and external stakeholders involved in the programme.

Solution

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Throughout the trial programme, Prism Ideas' medical writing team developed trial-related presentations for use at Data Safety Monitoring Board, Trial Steering Group and internal clinical team and training meetings. The dedicated Prism Ideas physician attended these meetings, as required, to provide an additional clinical resource. The Prism Ideas medical team was also responsible for monthly and *ad hoc* safety report monitoring and, alongside the writing team, production of safety narratives.

The Prism Ideas Account Director managing the trial programmes co-ordinated the study elements flowing between the client, logistics providers, contract research organisations (CRO) and clinical experts. Such project management included responsibility for scheduling and delivery of meeting milestones and final outputs, such as slides and minutes, through close communication with

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the logistics agency, co-ordination of receipt of data from the CRO, production of materials from the Prism Ideas writing team and internal Prism Ideas medical review. *Ad hoc* requirements in the form of protocol amendments, HA, EC and safety queries were balanced within the internal team to ensure speed of return where time to response is critical for the well-being of the patients and the continuation of the study. Throughout this extensive project, the key element to success was attention to detail across the Prism Ideas team.

Conclusions

...one of the world's leading pharmaceutical companies was able to supplement its in-house resource across the variety of disciplines necessary for successful management of its Phase IIIb/IV trial programme.

Through interaction with Prism Ideas, one of the world's leading pharmaceutical companies was able to supplement its in-house resource across the variety of disciplines necessary for successful management of its Phase IIIb/IV trial programme. Prism Ideas' in-depth knowledge of the therapeutic area – combined with experience of protocol development, drug safety, medical writing and project management – enabled its dedicated team to assist in managing the extensive workload of a major clinical trial programme, along with associated communication deliverables.

Support summary

Expert medical consultancy and medical writing for the strategic development of:

- study protocols, protocol writing and amendments
- ongoing review of study safety data as part of the client core medical team
- development of multiple study-related materials, including slides for Data Safety Monitoring Board, Trial Steering Group and internal clinical team meetings.

Project management of:

- multiple agencies supporting the trials and subsequent data
- stakeholder interaction within client company (medical affairs, statistical analysis and research operations, commercial) and externally, with international key opinion leaders and the CRO for each trial.