CASE STUDY

The Best Protocol Amendment Is the One You Avoid

While assisting one of our clients with changes relating to a Phase 2 protocol amendment, our regulatory writer noticed a discrepancy in the description of the extension period.

Challenges

A mid-sized pharma company's Phase 2 protocol amendment contained a discrepancy in the description of the extension period, which had thus far gone unnoticed.

Solution

Med Communications helped the client correct the discrepancy, and ensured that the study objectives in the amendment were clear and consistent.

Impact

Correcting this error during the writing of the amendment eliminated the need for a future amendment later on, saving the client time and money.

Background

Client: A mid-size pharma company was amending its Phase 2 protocol.

The current amendment was prompted by the need to address several minor questions and the desire to add a new assessment to the randomized, double-blind, placebo-controlled treatment period. In a prior amendment, the study had been revised to add an open-label extension period, which was open to all study participants who completed the first treatment period.

Challenge

As our regulatory writer was revising the schedule of activities and study schema to incorporate the new changes, she flagged a question to the team. In the study objectives, the extension period was described as providing an additional year of treatment. However, in the schedule of activities, the assessment visits were scheduled every 12 weeks. Did the team intend for the open-label extension period to end after 48 weeks of study treatment, with 4 planned visits, 12 weeks apart? Or was the study treatment to be continued through 52 weeks, which would require adding a study visit at the end of the treatment period?

Solution

Although answering that question took a surprising amount of discussion, the team agreed that it was critical to align their study objectives with the study assessments. Eventually, the team decided to end treatment at 48 weeks. With the 4-week safety

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follow-up visit after the end of treatment, participants would complete the open-label extension period after 52 weeks. Our writer revised the study objectives to be clear and consistent with the schedule of activities and the total duration of study treatment.

Business Impact

At the time of this new amendment, few participants had started the open-label extension period, and none had reached the end. Thus, no study sites had yet flagged this question back to the sponsor. By catching the discrepancy before it became an issue for the sites, our regulatory writer was able to prevent the need for an additional amendment resulting in both time and cost savings for the client.

- **Med Communications' writer caught and helped correct a discrepancy in a client's Phase 2 protocol, saving the client time and money.**