cisiv

Optimising post approval research

How to design and run a global post approval safety study in a cost effective and efficient way

Synopsis:

A large global Pharma company was required to run a complex global safety study by regulatory authorities. This was a crucial study to ensure that patients were not exposed to risk.

- Cisiv was able to build a study in 10 weeks and launch it across 21 countries.
- Cisiv's platform – Baseline Plus – was able to deal with complex data capture, analysis and reporting to various licensing authorities.
- As a result, the data was collected and reported faster than expected, and the study closed early, proving that patients were not at risk.
- Cisiv's technology saved the Sponsor significant costs and effort, and helped them maintain sales growth.

Challenge

This large Pharma company was facing a restriction in use of its blockbuster drug following reports of a safety problem. The company identified and addressed the source of the problem but were required to carry out a Post Approval Safety Study to prove that this low incidence, high risk problem was resolved. The study needed to be built and initiated quickly and it needed to drive a regular through put of high quality data to facilitate regular and accurate interim reports to Licensing Authorities. It had to embed safety reporting and safety follow-up forms and processes to enable a rapid response to any potential safety issue.

Solution

Cisiv built the study in 10 weeks for immediate launch across 21 countries. The study platform included Cisiv's safety reporting system, which embedded the company's safety SOPs and forms, including adverse event follow-up, and features to identify and manage suspected adverse events early in the data entry process. Baseline Plus supported a quarterly reporting to licensing authorities. The data entry workflow, designed for non-interventional research, drove a steady flow of data through the system, making it available for interim analyses with minimal data cleaning.

Outcome

The data demonstrated that, in its new formulation, the product was safe and the study was closed early in agreement with the licensing authorities, saving the sponsor significant time and effort and enabling sales growth.

About **cisiv**

Cisiv has worked closely with leading pharmaceutical companies for over 15 years developing collaborative web platforms for use in post approval activities. Baseline Plus was developed to meet the need to capture essential real world data in an international setting. The Baseline Plus platform provides a flexible, cost effective, quick to implement and easy EDC system for non-expert users.

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