cisiv

Baseline Plus

Ideally suited for orphan drug post-approval studies

Creating simple, intuitive and cost-effective solutions to the management of data from a large number of sites

Synopsis:

Baseline Plus provided the ideal platform to enable a specialised European Pharma company to run a post-approval safety study as a licensing requirement. However, managing data from large number of sites around the world created a major challenge.

- There is a growing number of orphan drugs, generally requiring mandated safety studies.
- Orphan drug studies are generally long term, based at multiple sites and with a small number of patients. Whilst the audience is smaller, it is more knowledgeable and ready to engage.
- Baseline Plus enables companies to gather data efficiently, facilitates collaboration with healthcare communities and ensures a stronger relationship across the care continuum.

Challenge

This specialty European Sponsor was required to run a safety study on one of its orphan drugs as a licensing requirement. However, the challenge was to manage data from a large number of centers around the world, each with only a small number of patients in a cost effective way and with low resources.

Additionally, the company wanted to build a positive relationship with the physicians and wanted to maintain engagement during the long study period.

Solution

Baseline Plus enabled the Sponsor to create a simple and intuitive design to support infrequent system access and data entry. The study was deployed in 55 countries and across 125 HCP's who were mainly research naive.

The ease of use meant reduced burden to subscribers who were delighted with the interaction with the sponsor.

Baseline Plus allowed for remote management and monitoring which meant the sponsor could easily manage the study with few staff.

Outcome

Baseline Plus enabled this Sponsor to simplify the process, reach all of their global sites and cut the costs for data management. They were able to improve data quality at source by deploying new edit checks each year to support a light touch data managevment approach. The education module also maintained physician engagement and provided regular updates on recent developments.

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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