cisiv

Real world studies in complex treatments

Oncology real world studies: fit-for-purpose technology and process

Synopsis:

Cisiv's EDC platform, Baseline Plus, is built specifically to meet the complex needs of post-approval research. Its flexible structure is well suited to oncology studies as it can adapt to very complex patient lifecycles and offers an intelligent and engaging online tool for both physicians and patients to enter study data. It includes e-learning tools, a document library, and enables the entire study to be run in any language.

- This leading global Biopharma company needed to generate real-world evidence on its oncology drug, to meet the needs of regulatory approval as well as establish health economics outcomes.
- Meeting the evidentiary needs of multiple stakeholders can be complex and expensive but Baseline Plus supported a lean process and remote management for data collection and analysis, which made the study highly cost effective.
- Despite the complexity of the patient pathway, Baseline Plus was able to streamline data capture from both patients and physicians, reducing stakeholder burden and creating a very positive site experience.

Challenge

This leading Biopharma company had launched a novel therapeutic medicine for cancer treatment. Although it had proven effective, the drug was missing key health economics data to enable access for patients who could benefit from it. The company faced the challenge of obtaining reimbursement in numerous healthcare systems, including in the UK.

Solution

Baseline Plus was deployed to support a health economics study in 163 sites and 1583 patients across 9 countries. The study supported a complex patient lifecycle. The features and functionalities built into Baseline Plus enabled the study to achieve high quality data without high data management costs.

Outcome

The data from this study enabled the Biopharma company to successfully obtain reimbursement in many countries.

It enabled a broadening of the therapy's reimbursement case and increased access for many more cancer patients.

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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