cisiv

Designing and conducting a successful HEOR study

Creating a successful Healthcare Effectiveness and Outcomes Research study with benefits for both sponsor and sites

Synopsis:

A leading global pharmaceutical company was looking for a fit for purpose technology and methodology to evaluate the eff ectiveness of an anti-psychotic drug in terms of relapse, adherence to treatment and patient outcomes.

- The complexity of this study came from the fact that it had to be conducted in 19 countries around the world and be adapted to diff erent healthcare systems and languages.
- Cisiv offered a built for purpose Electronic Data Capture platform which simplified the data collection for doctors and offered a flexibility that eased study management.
- This international study proved that using the right technology makes a difference to real-world studies.

Challenge

The data was needed to support reimbursement submissions (HTA) around the globe. The company wanted to run the study using their own resources and needed software to help manage the types of site interactions appropriate to non-interventional research. Additionally, it needed to deliver high quality data and keep the doctors engaged for many years throughout the study. Prior to initiating the study, Cisiv spent 4 months visiting clinics and hospitals, to gain insights into the care settings, and conducting focus groups. The knowledge from these focus groups enabled Cisiv to design the optimum study and technology interface for the users.

Solution

The study was built with multilingual support, a clean and simple data entry process that was not based around a traditional e-clinical model but rather matched more closely the working practice of the doctors. Features were built in to support user communities and sharing of study outputs.
Over the subsequent 9 years (2003-2011), this Health Economics study was deployed to 19 countries, 9,500 patients, 1579 sites, and was run in 8 languages. The study averaged 2 protocol amendments per year across 17 protocol variations.

Outcome

The data from this study was used globally for the lifetime of the drug for ongoing submission of data for reimbursement and to help determine the value of the drug in the real world. This study was cost effective and the feedback from sites was overwhelmingly positive, helping to reinforce the relationship with the pharmaceutical sponsor.

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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