

## Case study: Global non-interventional study

This case study looks at how cisiv provided a web-based observational study run on the Baseline Plus platform to establish a large, long-term database to document clinical outcomes benefits of a newly approved anti-psychotic under real life conditions.

Used by physicians around the world to input data on the use of the drug, the solution is in use in seventeen countries. It has allowed early analysis of data and rapid route to publication. The data and the publications have been successfully used for reimbursement in several countries.

The strengths of eSTAR are web based data capture, quicker release of clean data, real-time reporting and ease of use.

### The customer's requirement

With the global launch of a new antipsychotic treatment, the customer required a scalable, flexible and cost-effective way to capture real world observational data to support applications for reimbursement at a national level.

They needed a robust data capture system which would provide them with fast access to live data and a rapid route to publication. It was important that a broad base of investigators was able to enter data quickly and easily with no training and that the local operating company staff were able to be involved in the study with the investigators to understand their responses to the study and the data it showed on their own patients. The resulting system, called e-STAR, allowed this to happen.

### cisiv's solution

Cisiv provided the customer with a secure web-based data capture system with a rules engine to validate data at the point of entry. The data capture tool allowed the customer to use variations on the protocol in each country. It also

supported local language implementation.

e-STAR includes a set of online reports which provide graphs and charts showing an instant overview of key variables. There are different levels of reporting access so that investigators only see data on their own patients whereas an operating company will see national data.

Although data is validated at entry, this will not identify some types of missing or anomalous data. Cisiv provided a rolling quality control process which is tied to the data closure process, allowing us to extract only data which is clean and ready for analysis. In most countries, 90% of data passes the quality control checks without need for further follow-up.

The modular design of the system allows us to provide different features to different countries as they are required. Some countries have a monitoring requirement and so are using the monitoring module. There is also an online adverse event reporting module and various additional features designed for the investigators, such as a

graphical summary of a patient's progress and a treatment timetable.

### How the customer is using e-STAR

e-STAR is running in seventeen countries around the world with data from nearly 9,000 patients collected so far. Over 1,000 investigators are involved in this study which will generate approximately 30,000 patient years of data.

e-STAR has allowed early release of patient data for analysis and subsequent publication early in the study. Since the start of the study in October 2003 22 publications have been made using this data.

In addition to fulfilling its primary goal it has also fostered closer relationships between the customer's in-country staff and the physicians taking part in the trial.

**Non-interventional observational studies create new opportunities for pharmaceutical companies to collect meaningful data on the real world value of their products. This data can bring a host of benefits:**

- Identify the true cost/benefit of a treatment
- Highlight particular patient groups where a product will succeed
- Support safety reporting
- Build a stronger value case to support reimbursement activities
- Obtain a new level of data around products to give greater competitive advantage

## Table of cisiv studies

	Study 1	Study 2	Study 3
<b>Sponsor</b>	Multinational pharma company		
<b>Study drug</b>	Antipsychotic		Multiple Myeloma
<b>Study type</b>	Global, multi-lingual study begun in 2003	Global, multi-lingual observational study begun in 2006	Global, multi-lingual study begun in 2006
<b>Duration</b>	2-4 year follow-up	2 year follow-up	1 year retrospective data and up to 3 years follow-up
<b>Start date</b>	2003	2006	2006
<b>End date</b>	Ongoing	2010	2013
<b>Countries</b>	19	21	8
<b>Sites</b>	1,600	2,000	125
<b>Patients</b>	9,500	10,000	850
<b>Languages</b>	4	1	3
<b>Protocol variations</b>	16 countries use a variation from the core protocol	3 countries use a variation from the core protocol	2 countries use a variation from the core protocol
<b>Study benefits</b>	Date for reimbursement	Licensing Authority Requirement	Health outcomes data

Baseline Plus is suitable for studies of all sizes. It can be scaled quickly and easily if the study requirements change.