

Planning and implementation of a worldwide Phase IV study feeding into a database with online global data access for physicians

Background

The customer wanted to strengthen his position in a therapeutic area by further demonstrating the clinical value of his product in the day to day clinical situation. The plan was to implement a large international phase IV study in up to 200 sites with over 20'000 patients to be enrolled.

Business objectives

Provide physicians with a tool for improved clinical decision making and the means to assess on-line, and on a real-time basis, long-term clinical outcomes generated when patients are prescribed a specific medication in the context of multiple combination treatments. Another key objective for the system was to generate in a timely manner credible and clinically meaningful data for publications and presentations.

Approach

With the intent to facilitate logistics, to minimize data management and monitoring activities, to keep operating costs at a minimum and to allow physicians on-line access to analyses with their own data the decision was taken to opt for an Electronic Data Capture (EDC) system using state of the arte Internet technology for data entry and cleaning.

Solution and key actions

- Implementation of a hybrid electronic data capturing (EDC) solution, allowing for off-line data entry and easy data access
- Compliance with regulatory guidelines, data confidentiality and data security aspects
- Implementation of special website for the posting of regular global and country analyses
- Programming of user-friendly tool to allow physicians the analysis of their own data

Business benefits

- Two years after pilot started, close to 20'000 patients in over 180 sites in 35 countries enrolled
- First abstracts submitted one year after start of project
- Additional publications generated in half-yearly rhythm
- Privileged access of customer to participating sites
- Image of innovative company using state of the art technology