CASE STUDY
Pediatric Respiratory Infections

Study description
A phase IV, European, multicentre, randomised, placebo-controlled, double-blind, parallel-group stud to evaluate the efficacy and safety of x compared to placebo in children suffering from recurrent upper respiratory tract infections.

Study objective
The objective of this study was to confirm the efficacy and safety of X compared to placebo in children suffering from recurrent upper respiratory tract infections.

Patient population
420 patients (including the drop-outs)
Children of both sex, aged between 2 and 6 years (or in 7th year), with a history of recurrent upper respiratory tract infections (minimum 4 documented episodes during the previous year)
It was planned to include a total of 336 patients (168 per treatment group) in approximately 100 study centres.

Study duration
Study period/patient: 7 months

Primary Efficacy parameter
Mean rate of URTIs up to the end of the treatment period.
Secondary: to assess the proportion of patients with at least one additional URTI up to the end of the study period, to evaluate the severity and the duration of URTI symptoms.

Participating countries
Austria, Belgium, Czech Republic, Hungary, Italy, Romania, Slovakia, and Switzerland.

Study details
Total number of patients: 420
Recruitment period: one season - from September 2007 to February 2008.
First patient in: November 11 2007
Last patient out: February 20 2008

Sintesi Research Services
Project Management, Regulatory, sites coordination, investigators and CRA meetings, communication/project updating services.

Key challenges
The sponsor wanted to perform study involving paediatricians who are not respiratory specialists therefore they required a support and a preliminary training on study procedures.

To maximize the recruitment the Sponsor implemented a pre screening phase giving Sintesi Research two months to collect pre-screening sheets coming from the 100 European sites.

Upon collection the Sponsor together with Sintesi evaluated the data and chose the most performing sites.

The Sponsor also wanted to perform two blood sampling one at the beginning of the study and the other one at the end of the treatment.

The study also required: the completion of a validated children questionnaire to asses quality of life and the performance of intermediary phone calls with appropriate forms to remind the parents or the legal guardian the next scheduled visit.

Keys of project success

During the start up phase in selecting countries we have considered the existence of completive trails.

To optimize recruitment a detailed pre-assessment of the patients clinical records (considering above all concomitant therapies).

Sintesi Research has performed a strict and precise monitoring activities to control regularity activities.

To maximize and accelerate patients recruitment Sintesi Research performed a very exact country and sites evaluation and selected highly motivated investigators.

Sintesi Research staff closely worked with the sites keeping regular contacts also by performing weekly teleconferences for a quick update on the study.

To keep all the sites informed and to push them to recruitment a fortnight newsletter showing the enrolment site by site was send to each investigator and to his staff.

A free drug supply for all the sites that reached the target was promised.

Sintesi Research

To discover Sintesi Research services contact us.

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