

## CASE STUDY

# Challenging Expectations

## Worldwide Innovation Speeds Recruitment, Data Collection

### Study Description

A multi-center, randomized, double-blind, parallel-group clinical trial

### Study Objective

To compare the efficacy and safety of 200ug/day of the dry powder formulation of the study drug with 400ug/day administered from a multi-dose powder-device discus

### Study Compound

Steroid

### Patient Population

Patients 4 to 11 years old with a six-month history of treatment for asthma

### Treatment Period

Sixteen weeks

### Primary Efficacy Parameter

Better control of the asthma at a lower daily dose

### Participating Countries

Poland, Russia, Croatia, Bulgaria, Hungary

### Study Specifics

- > Active sites: 39
- > Patients randomized: 529
- > Recruitment period: 6 months
- > Recruitment dates:  
January – May 2001

### Quintiles Services

Project Management, Clinical, Regulatory, Biostatistics and Data Management

### Overview

Quintiles' global coverage, experience, and the systems to do the job were key to the success of this challenging trial.

### Key Challenges

- > *The customer wanted to test the efficacy of the study drug at a lower dose as many doctors are averse to prescribing high doses of steroids to children. Thus the target population was very limited: children between 4 and 11 years old who had received treatment for asthma for six months but had not received any medications specified by the protocol.*
- > *The customer required a fast recruitment timeline of six months to randomize 450 patients.*
- > *The study required the completion of diaries and the measurement of the cortisol levels in the patients' urine every 12 hours.*
- > *Pediatricians in general are not respiratory specialists, so they required support in identifying and treating these patients.*
- > *The fast recruitment timeline required a data management system that would enable the customer to have the statistical data as soon as possible upon completion of the study.*

### How Were These Challenges Met?

- > *Quintiles conducted a feasibility study to locate areas with large pediatric patient populations where there were not many respiratory specialists. Eastern Europe was identified as an area having hospitals with large service areas, high patient populations, and very little access to the medications specified against by the protocol.*
- > *To support the pediatricians, Quintiles supplied Study Site Coordinators and trained them in asthma and in completion of CRFs. These Study Site Coordinators were able to use databases to identify qualified patients prior to the start of the study.*

Quintiles' global coverage, experience, and the systems to do the job were key to the success of this challenging trial.

Through careful selection of countries and by providing support for both doctors and patients, Quintiles randomized 450 patients in six months.

- > *The Study Site Coordinators developed relationships with the parents and children, which increased compliance with diary completion and urine collection.*
- > *Quintiles used its FaxCollect system to fax diaries directly to the Data Management team and enable speedy query resolutions.*

### Outcome

Through careful selection of countries and by providing support for both doctors and patients, Quintiles randomized 450 patients in six months.

Quintiles' systems enabled database lock within four weeks of the last patient's completion of treatment. As a result, Quintiles delivered the final statistical report to the customer within six weeks of database authorization.

#### Contact Us:

On the web: [www.quintiles.com](http://www.quintiles.com)

Email: [clinical@quintiles.com](mailto:clinical@quintiles.com)

