Case Study

Paediatric Asthma Study – Rapid enrolment and high level of protocol compliance

Description

A 12-week, multicentre, multinational, randomised, double-blind, double-dummy, 3-arm parallel group study, to test the efficacy of the study drug versus a comparator drug in partly controlled asthmatic children.

Primary Endpoint: Change from the baseline to the end of the treatment in pre-dose morning FEV1.

Services: Full service (including vendor management - central lab, ECG, centralised spirometry, and clinical trial supply management). Organisation and management of a Data Safety Monitoring Board (DSMB) for the monitoring of patient safety.

Study Phase: III

Indication: Partly controlled symptomatic asthmatic children aged ≥ 5 and < 12 years.

Study Duration
15 months (including 8 months of recruitment)

Clinical Sites
The study was conducted in 88 sites in 11 European Countries

Patients
1,000 screened / 699 randomised

Treatment Period
2-week run-in period followed by a 12-week randomised treatment period

Regions
11 European countries

- Bulgaria
- France
- Germany
- Hungary
- Italy
- Poland
- Romania
- Russian Federation
- Slovakia
- Spain
- Ukraine

Introduction

The study was managed by CROMSOURCE on behalf of a mid-sized European pharmaceutical client. It was one of the critical trials for the paediatric Investigation Plan (PIP).

The study involved 88 sites across all regions of Europe. CROMSOURCE was tasked with recruiting a total of about 1,000 paediatric patients with partly controlled asthma in a period of 8 months.

The primary efficacy of the study was the change from baseline to the end of treatment in pre-dose morning FEV1.

The Challenge

In addition to the challenges inherent to paediatric projects (that should be tailored to the need of children and their families), CROMSOURCE recognised that the presence of centralised spirometry and daily centralised home-PEF monitoring in subjects aged 5-11 years old would be a challenge for the logistics and data quality but also for patient retention.

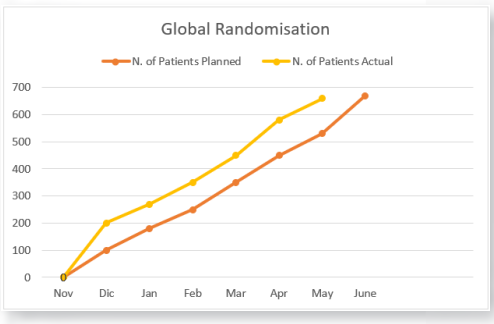
Operational Plan

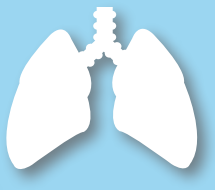
CROMSOURCE conducted a full Feasibility Plus™ analysis and identified sites with the highest recruitment potential experience in studies including children. CROMSOURCE ensured sites were very well-trained with respect to the central spirometry aspect and that they understood the importance of the home-PEF assessments. In addition, a patient retention strategy was planned and implemented, including provision to the sites of small gifts (pencils, Legos etc.) to give participants during the course of the study. This strategy was approved by the applicable Ethics Committees.

Result

Due to the quality of sites selected and CROMSOURCE's operational excellence:

- Recruitment began and remained ahead of schedule, closing 1.5 months earlier than planned.
- The screen failure rate was 30% lower than predicted.
- The drop-out rate was extremely low (<3.0%) ensuring a higher number of evaluable patients.
- The high level of protocol compliance was evident with only 9 subjects from the ITT population being excluded from the Per Protocol Population.





RESPIRATORY EXPERTISE

For over 25 years, CROMSOURCE has conducted trials focused on respiratory disease. We are able to advise clients on the design and implementation of the entire respiratory development plan.

CROMSOURCE's respiratory experience includes hundreds of studies in thousands of patients, both in adult and paediatric populations, Phase I through Registry, in a wide range of indications including, but not limited to, asthma, COPD, cystic fibrosis, lower respiratory tract infections, lung cancer, smoking cessation, upper respiratory tract infections, rhino sinusitis, and chronic bronchitis.

About CROMSOURCE

CROMSOURCE is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialising in clinical development and staffing solutions. CROMSOURCE was founded in 1997, more than 25 years ago. Its successful growth has been built on stability, integrity, and high levels of customer satisfaction, all of which contribute to a high rate of repeat and referral business. We have grown steadily, but responsibly, to become an organisation of over 350 organised and well-trained experts.

CROMSOURCE Quality
ISO 9001:2015 multi-site certified quality management system
ISO 14155:2020 conformity confirmed

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