Case Study
Asthma Study
Rapid Enrolment

Description

A 48-week, multicentre, multinational, randomised, double-blind, 2-arm parallel group study, comparing the efficacy of study drug versus comparator drug in asthmatics ≥18 years of age.

Primary Endpoint: Time to first severe asthma exacerbation.

Services: Full service (including vendor management - central lab, ECG, centralised spirometry, and clinical trial supply management).

Study Phase: IIIb

Indication: Patients aged ≥ 18 years with asthma.

Study Duration
16 months (including 9 months recruitment)

Clinical Sites
212

Patients
2,404 screened / 1,682 randomised

Treatment Period
2-week run-in period followed by a 48-week randomised treatment period

Regions
14 European countries

- Bulgaria
- Czech Republic
- Croatia
- France
- Germany
- Italy
- Poland
- Romania
- Russia
- Serbia
- Spain
- Turkey
- United Kingdom
- Ukraine

Introduction

The study was managed by CROMSOURCE on behalf of a mid-sized European pharmaceutical client. The trial involved 212 sites in 14 countries across all regions of Europe. CROMSOURCE was tasked with screening 2,404 subjects with controlled asthma to recruit 1,682 randomised subjects in a period of 9 months.

The primary efficacy endpoint of the study was the time to first severe asthma exacerbation. Centralised blood exams, ECG, and spirometry were performed using different vendors.

Study drug management (packaging, labelling, storage, distribution, and central randomisation) was supported by a specialised vendor, considering the critical need to maintain tight temperature control during shipment.

The Challenge

CROMSOURCE recognised that one of the most important challenges for meeting the enrolment requirements for this study was the need to accurately capture the exacerbation data (upon which the primary endpoint was based) and ensuring subjects remained compliant with the home-based PEF monitoring schedule required by the protocol.

Operational Plan

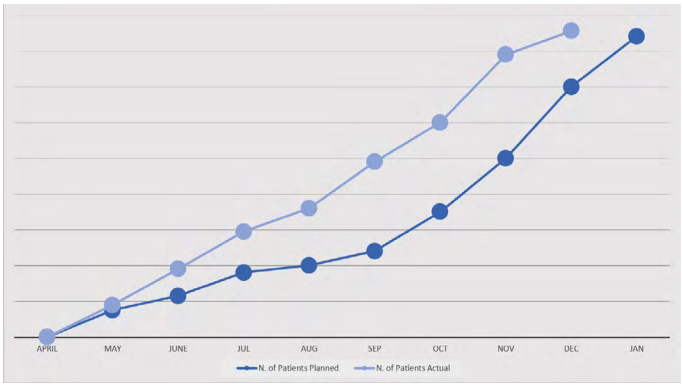
CROMSOURCE conducted a full Feasibility Plus™ analysis and identified sites with the highest recruitment potential and the highest proven quality. On the basis of protocol review CROMSOURCE implemented a plan to train and engage sites and subjects in reporting exacerbations and in completing daily PEF monitoring.

Result

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

- The recruitment closed more than one month earlier than planned
- The screen failure rate was far lower than planned (17% vs. 30%)
- The number of evaluable patients was 12% higher than predicted by the client

Global Randomisation



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, over 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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