Case Study: Asthma Project C1NEX02

Recruitment closed more than one month earlier than planned…

…screen failure rate was below that planned…

Primary endpoint was met…

Introduction

This study was managed by CROMSOURCE on behalf of a mid-sized European pharmaceutical client.

The study involved 110 sites across all regions of Europe, tasked with recruiting 666 patients with controlled asthma in a period of four and a half months.

The Challenge

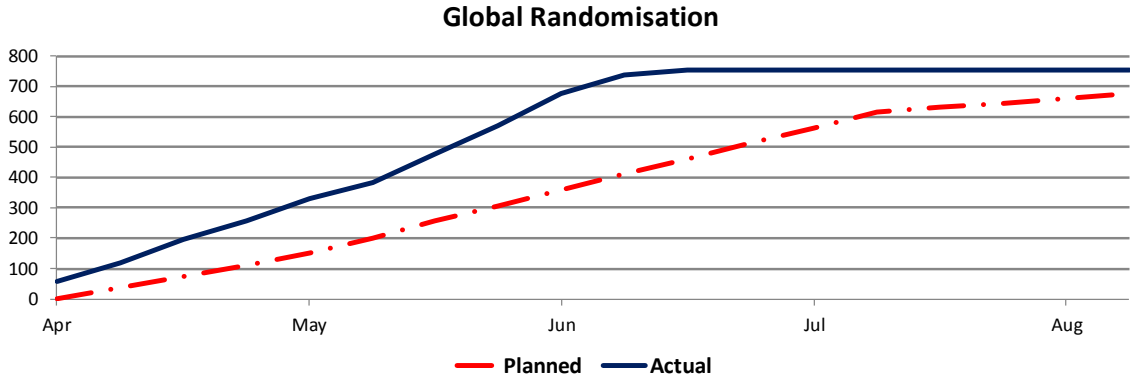
In addition to the critical nature of the timelines, CROMSOURCE recognised challenges within the nature of the protocol which required focus in order to successfully achieve the client goals. These including the presence of Peak Expiratory Flow as the primary endpoint, which CROMSOURCE recognized would require intense oversight to ensure subjects remained compliant with the PEF 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 PEF Compliance Team to focus strongly on this crucial variable.

Result

Recruitment began and remained ahead of schedule.



Recruitment closed more than one month earlier than planned, and all subsequent activities remained ahead of schedule. Due to the quality of sites selected and the CROMSOURCE operational excellence, screen failure rate was below that planned. Positive trial results were confirmed in the ITT and PP population, and the client was delighted with the result.