Case Study: Asthma Project C1MAR02

Introduction

This 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, tasked with screening 2404 subjects with controlled asthma to recruit 1682 randomised subjects in a period of just 9 months.

The Challenge

In addition to the logistical challenges present in a large study, CROMSOURCE recognised challenges within the nature of the protocol which required focus in order to successfully achieve the client goals. These including accurately capturing exacerbation data (on which the primary endpoint was based), and ensuring subjects remained compliant with the home based PEF monitoring schedule required by the protocol.

Operational Plan

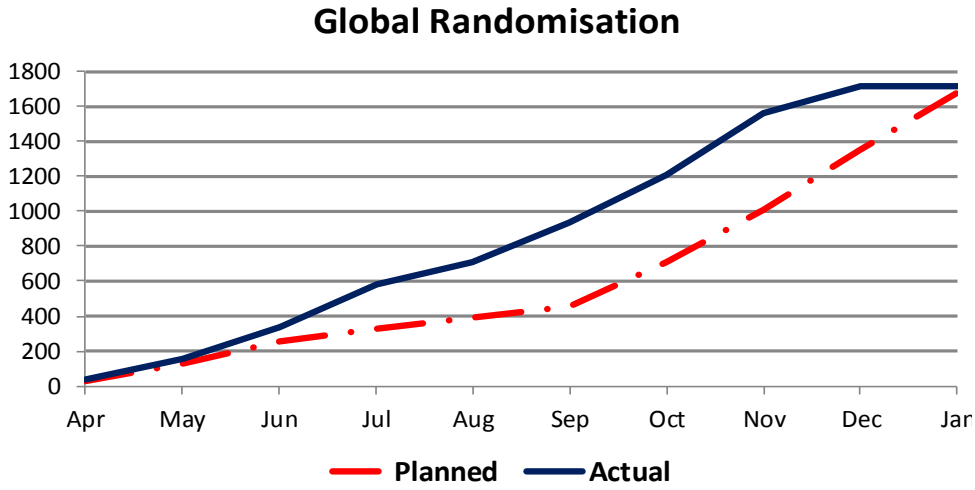
CROMSOURCE conducted a full Feasibility Plus analysis and identified sites with the highest recruitment potential and the highest proven quality. On the basis of protocol review CROMSOURCE implemented a plan to deeply train and engage sites and subjects in reporting exacerbations and in completing daily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

Result

Recruitment closed more than one month earlier than planned…

…screen failure rate was decreased 50%…

Number of evaluable subjects 12% higher than planned…



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 (17 vs 30%) that planned and the number of evaluable subjects was 12% higher than predicted.