

case study:

i3 RID MEETS THE CHALLENGE OF AMBITIOUS COPD STUDY

Challenge: COPD study with aggressive timeline, tight budget, strict enrollment guidelines.

A Phase II study of a treatment for COPD had an aggressive timeline and tight budget, which prevented an extension of the enrollment period and allowed only a limited number of sites. An additional challenge included the fact the study was a seven-arm, crossover design and only subjects who completed the full sequence were eligible for analysis.

Solution: Know the sites, know the patient population. With deep experience in the respiratory arena and access to an extensive network of investigative sites, i3 was able to conduct a thorough site selection process to recruit sites that could meet the aggressive timeline — and target the proper patient population. i3 implemented a strong site training program to maximize the number of qualified subjects and minimize patient attrition. Because of their understanding of the clinical setting and focus on respiratory illnesses, the i3 project managers could better support the sites. The sites, in turn, were more fully engaged and better equipped to meet project expectations.

Result: Meet aggressive project goals, maintain tight budget. As a result of respiratory experience and close ties with study sites, i3 was able to retain all sites and subjects (all patients completed all seven treatment arms). Study enrollment was closed as scheduled and the study was managed within budget.