

CASE STUDY

Responsive Recruitment

Nimble Strategies for Changing Protocol

Study Description

Randomized, controlled, multicenter Phase III study in stage 3 colon cancer

Study Objective

Compare combination chemotherapy against combination chemotherapy with cetuximab

Study Compound

EGFR inhibitor

Patient Population

Adults 18 to 70 with fully resected stage 3 colon cancer and KRAS wild-type tumor status

Treatment Period

6 months

Efficacy Parameters

Disease recurrence as primary endpoint and survival as secondary end point

Participating Countries

Austria, Belgium, Denmark, France, Germany, Italy, Portugal, Spain, UK

Study Specifics

- > Number of active sites: 331
- > Patients recruited: 2,562
- > Target enrollment period: 48 months

Quintiles Services

Clinical, Data Management, Pharmacovigilance, Project Management, Regulatory

Sustaining Crucial Efforts

Colon cancer is the third most common cancer worldwide, with the highest rates in industrialized nations, and a major cause of cancer-related morbidity and mortality.¹ In early stages, colon cancer is highly treatable and curable, but the five-year survival rates for stage 3 colon cancer are as low as 44 percent.

Recruitment Stymied by Significant Amendments

Initially, this study proceeded smoothly, with patient recruitment five-and-a-half months ahead of schedule. As the trial evolved, the sponsor changed the scope to only include patients with KRAS wild-type tumors, which reduced the available patient population by 48 percent. In order to obtain approval of this protocol amendment, the trial had to be stopped for four months.

Three protocol amendments followed after the trial was resumed. A fourth and final late-stage protocol amendment to reduce the age limit for eligible patients further narrowed the patient population by an additional 12 percent and increased screen failure rate by 6.5 percent.

Speedy Results Despite Shifting Needs

Quintiles was able to absorb the four-month delay and develop a new strategy to keep the sites motivated and deliver on time. Though the final protocol amendment rendered the original timeline obsolete and included the recruitment of an additional 450 patients, Quintiles worked against increasing odds to generate high-speed patient recruitment in 83 percent of active sites.

Quintiles demonstrated the ability to quickly adapt to changing circumstances and to scale appropriate resources at short notice in order to meet shifting needs.

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