

Study Description

A randomized, open-label phase III study comparing Drug X with i.v. bolus 5-fluorouracil in combination with low-dose leucovorin as adjuvant chemotherapy in colon cancer patients with Dukes C tumors

Study Objective

To demonstrate that the study drug is at least equivalent to 5-FU in combination with low-dose leucovorin in terms of disease-free survival in patients that underwent surgery for colon carcinoma

Study Compound

Oral Formulation 5-FU Pro drug

Patient Population

Patients without prior chemo regimens that underwent surgery for colon carcinoma

Treatment Period

6 months

Primary Efficacy Parameter

Disease-free survival

Participating Countries

24

Study Specifics

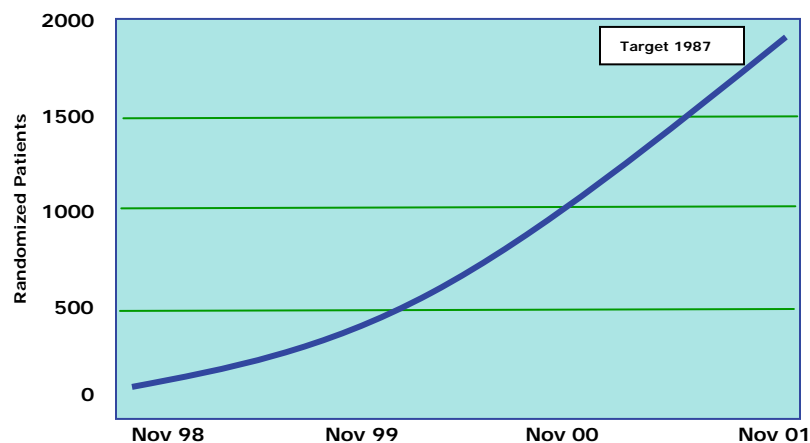
- Total number of active sites: 164
- Patients randomized: 1,987
- Recruitment period: 36 months
- Recruitment dates: November 1998 to November 2001

Quintiles Services

Project Management, Clinical Monitoring, Data Management

Key Challenges

- In this global study the customer required randomization of 1,987 patients to meet the clinical endpoint of 694 events (relapse of colon cancer or death).
- In January 2000, after over 600 patients had been enrolled, the customer discontinued the services of the clinical research organizations that had been responsible for project management and data management.
- Quintiles took over data management and coordination of the international monitoring team, which consisted of more than 40 CRAs in 24 countries and who were responsible for 164 sites.
- In addition Quintiles assumed responsibility for monitoring activities in 30 sites in 7 countries. The CRA affiliation was 50% customer, 25% Quintiles and 25% other clinical research organizations.



Key Challenges (cont'd)

- To enable presentation of efficacy data at ASCO 2004 in early June, the customer required Quintiles to provide a database snapshot for primary efficacy analysis within 10 days of the clinical cut-off date.
- Because the study continued long after the initial 6-month treatment period, the sites had to be continually motivated and the patients monitored to assess the primary and secondary objectives of the study.

How Were These Challenges Met?

- To meet the customer's critical timeline, Quintiles ensured that all in-house data was as complete and clean as possible before the cut-off. This resulted in the need to do a tight turnaround only on the relatively small amount of data collected just before the cut-off date.
- Quintiles achieved this goal by carefully planning the steps required to enter the data into the database and ensure that it was clean, in addition to making sure that all monitors knew what was expected of them.
- To maintain motivation throughout the study the Quintiles team contacted the sites frequently and sent out newsletters that kept the investigators up to date with the study and the recruitment status at each of the sites.

Outcome

Through exceptional project management Quintiles directed 3 different teams of CRAs and successfully coordinated all of the information in time to meet the customer's need for a 10-working-day database closure.