

## CASE STUDY

# Strategic Response

## Global Flexibility, Expertise and Network Avert Delays

### Study Description

Open, randomized, controlled, multi-center phase III study in non-small cell lung cancer (NSCLC)

### Study Objective

To compare the efficacy of standard of care chemotherapy with the same chemotherapy plus antibody

### Study Compound

Cetuximab, cisplatin and vinorelbine

### Patient Population

Late-stage NSCLC patients

### Treatment Period

Average 4-6 cycles (12-18 weeks)

### Efficacy Parameters

Overall survival time defined as the time from randomization to death

### Participating Countries

29 - Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Chile, Czech Republic, France, Germany, Hong Kong, Hungary, Republic of Ireland, Italy, South Korea, Mexico, Netherlands, Poland, Portugal, Russia, Singapore, Slovakia, Spain, Sweden, Switzerland, Taiwan, Turkey, Ukraine and United Kingdom

### Study Specifics

- > Number of active sites: 148
- > Patients recruited: 1,126
- > Target enrollment period: 13 months

### Quintiles Services

Project Management, Clinical Monitoring, Medical Monitoring, Data Management, Pharmacovigilance

### Targeting a Global Disease

Lung cancer is the most frequently diagnosed major cancer and, according to the World Health Organization, the leading cause of cancer-related mortality in both men and women worldwide. A sharp increase in lung cancer deaths in developing countries has been seen in the last decade as smoking — the single most important risk factor for lung cancer — becomes more prevalent. Between 80 and 90 percent of all lung cancers are the non-small cell type.

### Wide-Ranging Challenges Rapidly Resolved

Quintiles conducted the trial in 21 countries and monitored results in 8 others. As might be expected with a study conducted in multiple countries across five continents, site selection proved logistically challenging and time consuming. In turn, this led to a protracted study start-up. Recruitment was also an issue due to a 30 percent screen failure rate (double what had been anticipated) and competitive recruitment with sponsor-monitored sites.

The trial met with two more unexpected challenges. One was an unanticipated Data Safety Monitoring Board (DSMB) review halfway through the study. The other was insufficient tissue sample collection due to problems securing samples in some countries.

### Enlisting Global Network

Because Quintiles has a substantial worldwide presence, as well as significant experience with lung cancer studies, the challenges were readily overcome.

Quintiles resolved stalled contractual negotiations regarding site selection and worked with additional sites to make up the three-month start-up delay. Additionally, Quintiles took on the monitoring role for the sponsor-managed sites, including deploying Quintiles contract research associates to assist sponsor sites.

According to the customer, Quintiles was selected for geographical presence, previous experience in oncology, and a study team comprised primarily of professionals who had recently completed a trial on lung cancer.

### Extensive Expertise Required

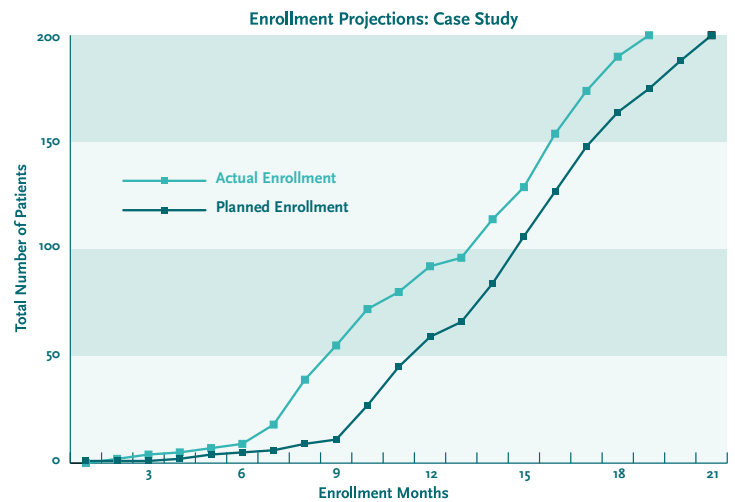
With feet on the ground across the globe, Quintiles had crucial knowledge of local suppliers and regional regulations to quickly and proactively remedy potential logistical problems — such as finding alternative providers of courier services and import / export experts.

Because the strong relationship and close communication with the sponsor fostered a flexible approach, a rapid compromise on data collection was reached in response to the DSMB review.

And, finally, Quintiles was able to step in and obtain the necessary tissue samples for the sponsor.

### Comprehensive Solutions for Overall Success

Despite challenges during start-up, owing to a proactive and rapid response in expanding site numbers, Quintiles met all recruitment goals — on time, within quality parameters and below the tolerated budget variation. The customer expressed definite satisfaction with Quintiles' performance, responsiveness and development of an amicable customer relationship with a transparent exchange of information at all times.



Contact Us:

On the web: [www.quintiles.com](http://www.quintiles.com)

Email: [clinical@quintiles.com](mailto:clinical@quintiles.com)

