

CASE STUDY

# *Multinational Coordination*

## Streamlined Recruitment 5 Weeks Early

### Study Description

Phase II, multicenter, open-label study of a thalidomide analogue

### Study Objective

To evaluate the efficacy and tolerability of a thalidomide analogue in relapsed/refractory non-Hodgkin's lymphoma

### Study Compound

An immunomodulatory thalidomide analogue

### Patient Population

Patients with biopsy-confirmed, aggressive non-Hodgkin's lymphoma who had relapsed or were refractory to previous lymphoma therapy

### Treatment Period

Study medication was administered on days 1-21 every 28 days until disease progression or the occurrence of unacceptable adverse events.

### Primary Efficacy Parameter

Response rate evaluated using International Workshop Lymphoma Response Criteria

### Participating Countries

6 – Canada, France, Germany, Italy, Spain, United Kingdom

### Study Specifics

- > Number of active sites: 33
- > Patients recruited: 107
- > Recruitment period: 11 months
- > Recruitment dates: April 2007 to March 2008

### Quintiles Services

Project Management, Clinical Monitoring, Medical Monitoring, Data Management, Regulatory, Site Contracts

### Key Challenges

Quintiles' customer was a large biotechnology company with offices in both North America (NA) and the European Union (EU). The NA and EU offices had no experience with working together to conduct a clinical trial before the study in non-Hodgkin's lymphoma was initiated. In addition, the company did not have established communication channels, standard processes or infrastructure for the efficient conduct of a multinational study. Study conduct was also threatened by challenges relating to review and final approval of site contracts.

### How Were These Challenges Met?

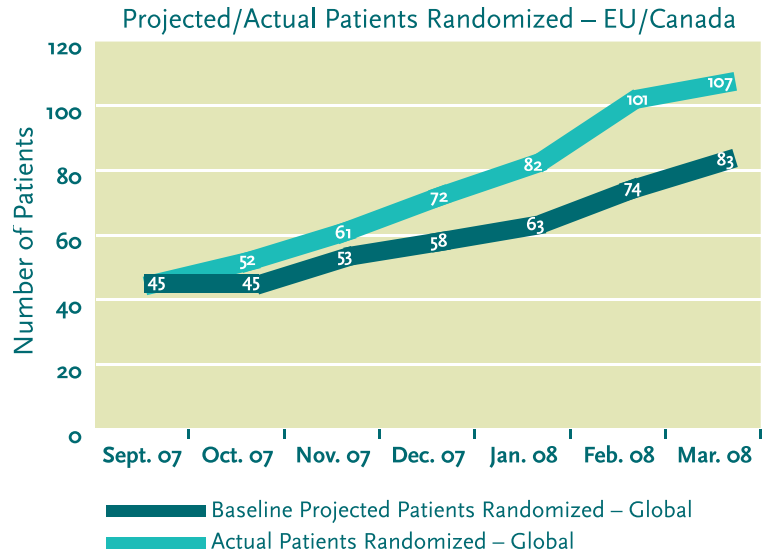
Quintiles project leaders served the customer as mentors and coaches in multiple aspects of the planning and conduct of a multinational clinical trial. Additionally, they worked with the NA and EU offices to establish communication channels and processes that increased the efficiency and effectiveness of working together. Project managers also assisted the customer with streamlining the process for review and approval of site contracts and were proactive in initiating and submitting such contracts. The team worked diligently to meet an aggressive schedule of site initiation and site maintenance visits. Finally, Quintiles maintained the same core personnel on the project team for the duration of the study in order to ensure continuity.

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### Outcome

The enrollment target was achieved more than 5 weeks ahead of schedule, and the target enrollment rate of 0.3 patients/site/month was exceeded in both NA and EU (Figure). Data management was also efficiently completed with four clean data sweeps delivered to the customer according to schedule.

The customer was extremely pleased with Quintile’s work, and the study team was awarded a subsequent study with the same compound as well as several additional projects. High marks were given with respect to communication, responsiveness, teamwork, site initiation, and project management on the customer satisfaction survey. Furthermore, the successful enrollment, CRF collection and query resolution contributed to the study being presented at the American Society of Hematology conference by the customer.



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