

## CASE STUDY

# Supercharging Possibilities

## Global Presence Doubles Enrollment, Extends Recruitment

### Study Description

A randomized, controlled, open-label study of Drug X in combination with Drug Y compared with Y alone as first- and second-line treatment for HER2 positive, hormone receptor positive metastatic breast cancer in postmenopausal women

### Study Objective

To evaluate the efficacy and safety of Drug X in combination with the oral aromatase inhibitor Y compared with Y alone as first- and second-line treatment for postmenopausal, hormone-receptor positive (ER+ve and/or PR+ve) patients with HER2 over expressing metastatic breast cancer

### Study Compound

Monoclonal Antibody

### Patient Population

Patients with ER and/or PR+ve and HER2+ve metastatic breast cancer

### Treatment Period

Up to 24 months

### Primary Efficacy Parameter

- > The progression-free survival (PFS), defined as the time interval from randomization to progression of disease or death
- > Determine and compare the overall survival, duration of response and two-year survival in each treatment arm

### Participating Countries

8 - Poland, Israel, Hungary, India, Lithuania, Ukraine, Turkey, Bulgaria

### Study Specifics

- > Number of active sites: 40
- > Patients randomized: 202 (80 for Quintiles; 122 for sponsor)
- > Recruitment period: 20 months (target)
- > Recruitment dates: August 2002 to May 2004

### Quintiles Services

Project Management, Clinical Monitoring, Clinical Supplies Management

### Key Challenges

The sponsor had set a target of 202 patients in 60 sites worldwide. But because a very small number (5%) of cancer patients qualified for the study, the sponsor was able to recruit only 29 patients in a 16-month period. Recognizing the need to expand beyond its typical geographic range and monitoring experience, the sponsor turned to Quintiles for assistance in recruiting patients for the study.

### How Were These Challenges Met?

After conducting a feasibility assessment, Quintiles qualified 40 new sites in eight countries: Bulgaria, Hungary, Ukraine, Turkey, Israel, Lithuania, Poland and India. These areas were especially promising because of the availability of patient populations and the presence of established Quintiles offices in each country.

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### Outcome

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At that time, the sponsor asked Quintiles to continue recruitment. When recruitment ended in May 2004, Quintiles had randomized 80 patients, thereby enabling the sponsor to reach its own stretch target of 202 patients.

Quintiles patient recruitment by country

