

Irritable Bowel Syndrome



Study Description

A double-blind, placebo-controlled, randomized, multinational study to investigate the safety and efficacy of two doses of Drug X against a comparator compound over 26 weeks in patients with diarrhea-predominant irritable bowel syndrome

Study Objective

Pivotal global phase III study

Study Compound

5HT3 Antagonist

Patient Population

Patients with diarrhea-predominant IBS

Treatment Period

6 months

Primary Efficacy Parameter

Adequate relief of symptoms

Participating Countries

Australia, Belgium, Canada, Bulgaria, Denmark, France, Germany, India, Netherlands, Poland, Israel, Romania, Russia, Spain, South Africa, New Zealand, Ukraine

Study Specifics

- Total number of active sites: 148
- Patients randomized: 800
- Recruitment period: 10 months
- Recruitment dates: March 2002 to December 2002

Quintiles Services

Project Management, Clinical, Packaging, Regulatory, IVRS, Laboratories, Data Management, Clinical Events Validation, Adjudication, Study Site Coordinators, Pharmacovigilance, Project Medical Officer

Key Challenges

- The customer wanted 750 patients randomized in 10 months. Based on an almost identical parallel US study for the same customer, Quintiles estimated that recruitment would take about 13 months. Quintiles' challenge was to find ways to shorten the recruitment time to 10 months.
- The study protocol limited the IBS population to patients with documented IBS symptoms for at least six months prior to entering the study – a criterion that eliminated all new patients.

How Were These Challenges Met?

- Using Quintiles' IVRS system, the Project Team quickly ascertained which types of patients were failing the screening. Armed with this information, investigators could more accurately target appropriate patients and administer the screening questions more effectively.
- To maximize patient recruitment, Quintiles selected only highly motivated, experienced investigators. In Germany, Belgium, Israel, Denmark, Netherlands and Poland, SSCs assisted investigators by helping to identify suitable patients and conducting patient interviews. The SSCs minimized patient drop out by maintaining regular contact with the patients, which motivated them to keep their scheduled clinic visits.
- Other strategies included
 - a highly successful newspaper advertising campaign in Germany that made it a top recruiting location;
 - a reward system for investigators based on the number of patients randomized; and
 - a patient retention plan in Eastern Europe in which patients were given mobile phones that they were allowed to keep at the end of the study.

Outcome

Using the IVRS system, Quintiles successfully randomized 800 patients out of 1300 screenings. This number was a significant improvement over the parallel US study and represented a reduction in failure rate from 50% to 35%. The drop-out rate also showed a sharp decline to only 20%.

In addition, Quintiles locked the database just one month after the last patient finished the study and sent top-line results to the customer the following week.

Through exceptional project management, Quintiles accomplished the customer's ambitious goal in only nine months -- one month short of deadline.

Patient Recruitment

