

CASE STUDY

A Lock on Consistency

Quintiles Navigates Delays, Locks Database on Target

Study Description

A double-blind, randomized, placebo-controlled trial evaluating the safety and efficacy of the study drug

Study Objective

Phase III pivotal registration trial

Study Compound

Selective aldosterone receptor antagonist

Patient Population

Patients with heart failure within 14 days of acute myocardial infarction

Treatment Period

Maximum 31 months, minimum 7 months

Primary Efficacy Parameter

Co-primary endpoints

Participating Countries

28 – Australia, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Israel, Italy, The Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Russia, Slovakia, South Africa, South Korea, Spain, Sweden, United Kingdom, Switzerland, Taiwan, Ukraine

Study Specifics

- > Active sites: 673
- > Patients randomized: 6,642
- > Recruitment period: 24 months

Quintiles Services

Project Management, Clinical Monitoring, Clinical Trial Supplies

Overview

Quintiles has the experience and the resources to respond when study results are threatened. In this trial, we added sites when recruitment levels slowed and increased staff to handle the collection and processing of an exceptionally high level of data.

Key Challenges

The customer asked Quintiles to perform a full-service project with Quintiles managing the monitoring of the trial. However, half of the sites were monitored by the customer's own CRAs, and recruiting was competitive.

Motivating the customer management and monitoring teams was challenging because the customer was subject to acquisition by another company. Eventually, the customer was acquired by another pharmaceutical company, which then replaced the monitoring teams.

Recruitment was difficult in North America due to competing myocardial infarction trials and treatment protocols. After the required number of endpoints had been reached, over 5,500 patients completed the study simultaneously. This placed a sudden strain on data collection and processing.

How Were These Challenges Met?

After the customer was acquired by another company, Quintiles worked with the new customer to assure consistent standards and continuity. While the European Quintiles team remained relatively unchanged, Quintiles provided monitoring management in some customer-monitored countries during the transition period.

Strategic Recruitment

Since recruitment was slower than average in North America, Quintiles quickly added Russia and Ukraine and opened additional sites in other countries. Quintiles selected central Eastern Europe because there are fewer competing studies and the patients remain in the hospital for longer periods.

To manage the anticipated rise in data retrieval at the end of the project, Quintiles temporarily more than doubled the size of the Data Management team by using staff from other locations, hiring temporary staff, and offering incentives.

How Were These Challenges Met? (cont'd)

Doubling Data Management

To manage the anticipated rise in data retrieval at the end of the project, Quintiles temporarily more than doubled the size of the Data Management team by using staff from other locations, hiring temporary staff, and offering incentives.

Outcome

Although the project's difficulties delayed reaching the targeted 6,000 patients, the customer requested that Quintiles continue recruitment to achieve sample sizes in substudies. Because Quintiles had modeled the data retrieval workload and staffed accordingly, database lock occurred on target.

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