

CASE STUDY

Maximizing Retention

Precision Data Management Sustainable for Long-Term

Study Description

Phase IIIB, randomized, multicenter, open-label, study of a thiazolidinedione

Study Objective

To compare cardiovascular outcomes in patients treated with an add-on thiazolidinedione with those in patients treated with metformin plus sulfonylurea

Study Compound

A thiazolidinedione

Patient Population

Patients with Type 2 diabetes who had inadequate glycemic control while receiving metformin or sulfonylurea

Treatment Period

Median of 6 years

Primary Efficacy Parameter

Time to the combined cardiovascular endpoint

Participating Countries

25 – Australia, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Netherlands, New Zealand, Poland, Romania, Russia, Slovakia, Spain, Sweden, Ukraine, United Kingdom

Study Specifics

- > Number of active sites: 338
- > Patients recruited: 4458
- > Recruitment period: 24 months
- > Recruitment dates: April 2001 to April 2003

Quintiles Services

Clinical Monitoring, Data Management, Endpoint Management, Biostatistics, Project Management, Regulatory

Key Challenges

This study involved cardiovascular outcomes assessed over 6 years. The complex nature of the outcomes, which needed to be documented in detail for clinical endpoint adjudication by the Clinical Event Committee, made data collection and evaluation challenging. In addition, the long duration of the study threatened to compromise patient retention.

These challenges were intensified because approximately half of the investigators were general practitioners and endocrinologists who were not accustomed to preparing dossiers for clinical endpoint adjudication or to retaining patients over the long term in clinical trials.

How Were These Challenges Met?

To address the challenge of data collection and evaluation, Quintiles' CEVA group provided expert, integrated oversight group management for the Clinical Event Committee. In addition, Quintiles assigned a dedicated, medically qualified Clinical Trial Leader to advise and coach the study sites in preparing dossiers for clinical endpoint adjudication and to liaise among CRAs, data management, CEVA, and the customer regarding clinical endpoints.

To address the challenge of patient retention, Quintiles worked with the sponsor to develop a retention plan that resulted in a protocol amendment. The amendment added a sub-study designed to re-enroll previously withdrawn patients and modified some elements of the study protocol such that patients could be more easily followed through the study's end. In addition, the Quintiles clinical team worked to educate sites about the importance of patient retention. Finally, a patient database was developed to identify active patients at risk for becoming lost to follow-up. Quintiles project leaders coached sites on ways to retain at-risk patients on a patient-by-patient basis

Outcome

At the beginning of the study, the target timelines of 3 months for endpoint dossier completion and 3 months for endpoint adjudication were set. By employing the interventions described above, these timelines were reduced as the study progressed.

The customer gave Quintiles particularly high marks with respect to project and data management and expertise in managing the data-collection and adjudication processes for complex clinical endpoints.

By the end of the study, stretch timelines of 1 month for endpoint dossier completion and 1 month for endpoint adjudication were consistently met—a very strong performance considering the complexity of the dossiers. At database lock, there was no backlog of non-adjudicated endpoints.

With Quintiles' intervention to improve patient retention, the dropout rate was reduced to less than 2.8% compared with a rate of 13.5% before the retention protocol amendment was instituted (Figure).

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