

CASE STUDY

Therapeutic Focus

Diabetes Depth Circumvents High Study Dropout Rate

Study Description

A dose-ranging clinical study to evaluate the safety, efficacy, and tolerability of five doses of the study drug compared with placebo

Study Objective

To measure HbA_{1c} after 12 weeks of treatment and to compare the change from baseline with placebo for each dose

Study Compound

Insulin sensitizer

Patient Population

Type II diabetes patients with no prior exposure to anti-diabetic medication

Treatment Period

Three months

Primary Efficacy Parameter

HbA_{1c} after 12 weeks of treatment. For each dose, the change from baseline was compared with placebo

Participating Countries

4 – Czech Republic, Hungary, Lithuania, Poland, United Kingdom

Study Specifics

- > *Active sites: 68*
- > *Patients randomized: 420*
- > *Recruitment period: 9 months*

Quintiles Services

Clinical Monitoring, Project Management, Study Site Coordinators, Regulatory Affairs, Central Laboratory

Overview

The Quintiles team had the experience to know that this trial would require aggressive recruiting. They were able to identify sites in promising locations and provided those sites with the tools and resources needed to identify and screen the required number of participants.

Key Challenges

Based on previous experience, Quintiles predicted a failure rate of 44% with this patient population. In order to achieve the customer's target of 420 patients, Quintiles would need to locate a large number of sites and screen at least 750 patients.

The customer presented a challenging timeline of nine months to complete recruitment of this limited population.

How Were These Challenges Met?

Global Reach

Through extensive geographical presence and experience with diabetes, Quintiles selected quality sites predominantly in Central and Eastern Europe where there is less competition for patients.

Precision Identification

Quintiles encouraged sites to complete an "identification log." This activity began as soon as a site was confirmed as participating in the study. Each site identified suitable patients when they attended routine clinic visits. Some sites used the Quintiles Study Site Coordinators to facilitate the identification process and to help with the work flow. All sites initially used the clinical database to identify patients suitable for inclusion in the study.

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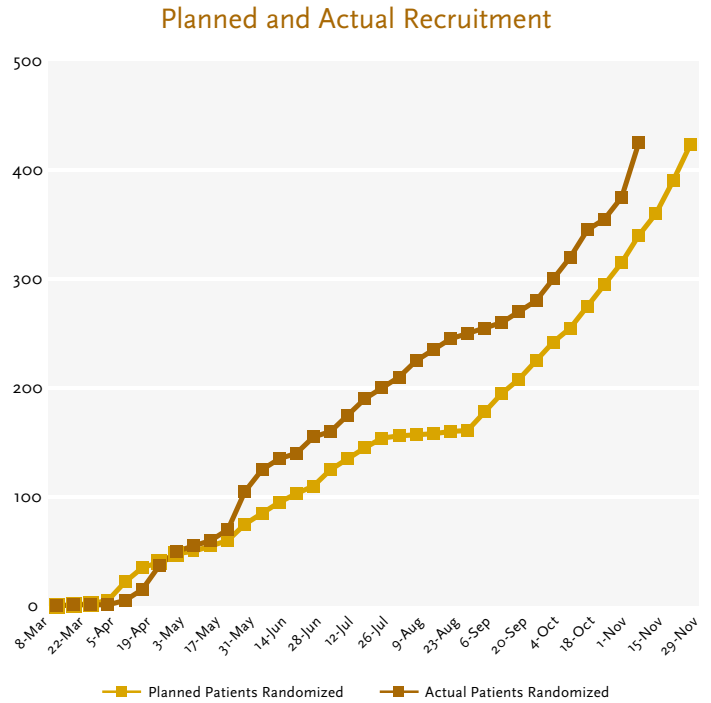
How Were These Challenges Met? (cont'd)

Continuous Contact

After the study began, the Quintiles team continued to contact more primary care physicians to make them aware of the study and to request that they refer patients to the study rather than initiating treatment.

Outcome

Due to its global reach and extensive experience with diabetes studies, Quintiles overcame a dropout rate of 42% to successfully recruit 420 patients a full month ahead of schedule.



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