

## CASE STUDY

# Precision Planning

## Simplifying Data Management in a Complex Study

### Study Description

Phase IV multi-center, open-label, observational, non-randomized study

### Study Objective

To evaluate the safety and effectiveness of a biphasic insulin aspart for the treatment of type 2 diabetes

### Study Compound

Biphasic insulin aspart

### Patient Population

Patients with type 2 diabetes, including those who have never received insulin or an insulin analogue

### Treatment Period

6 months

### Primary Efficacy Parameter

Incidence of major hypoglycemic events reported as serious adverse events during 26 weeks of the drug therapy

### Participating Countries

8 – Canada, China, Greece, India, Italy, Japan, Poland and Russia

### Study Specifics

- > Active sites: 5,486
- > Patients recruited: 55,514

### Quintiles Services

Data Management, Biostatistics, Project Management

### Moving Parts. Multiple Players.

Without rigorous data management, the quality and credibility of a clinical trial suffer. One customer's recent post-marketing study — in eight countries with more than 55,000 patients — put this principle to the test.

For this global trial, our customer worked with multiple players, including affiliates and an external CRO. With data coming from isolated teams across numerous language barriers, the coordination, documentation and data management presented huge challenges. Also, site start-ups were staggered throughout the trial, creating different deadlines for database lock. To meet their objectives, the customer needed a CRO capable of steering a large-scale, multi-country study from start to finish. With our expertise in complex data management, we were the right ally for the job.

### Connect the Dots.

By making data management part of the discussion from the beginning, we set the stage for success. Even before the trial began, Quintiles helped the client develop the operational design for the study. The study started in only three countries, but we implemented a flexible data management system to accommodate the sites in additional countries that would be added as the trial progressed. We also streamlined the management process by pre-printing forms with corresponding serial numbers.

Because Quintiles had little to no direct interaction with the sites, we designated a single clinical research associate (CRA) or clinical team lead (CTL) for each country to serve as the link between the local and global study managers. Using a proactive approach, we identified scenarios we could face in each country and discussed contingency plans. We also made sure each affiliate site knew what we expected of them.

During the trial, we maintained frequent communication with countries for status updates and query retrieval to avoid bottlenecks. Because many of the sites and investigators communicated in their native languages, this added complexity to controlling data quality. To ensure data wasn't jeopardized or misinterpreted, our multi-lingual team members translated all of the paper forms into the appropriate language for the CRAs to distribute to the sites. Once the forms were filled out, our team translated them back to English for data entry.

By implementing detail-oriented strategies from the start, we were prepared to handle the logistics of data management for an eight-country trial with tens of thousands of patients.

Our customer also needed interim data analyses for abstracts and conference presentations that took place during the course of the study. To manage the logistics of preparing data from different sites — each at a different stage of the trial — we projected how many case report forms we would need, then planned how we would acquire that number before the scheduled analysis.

### Clean, High-Quality Data. On Time.

By implementing detail-oriented strategies from the start, we were prepared to handle the logistics of data management for an eight-country trial with tens of thousands of patients. Even with the added challenges of language barriers and staggered timelines, our aggressive planning ensured clear communication and efficient data transfer.

We not only achieved database lock for every site on time to a quality standard, we also delivered interim statistical analyses throughout the trial, giving the customer valuable results they could use to meet several marketing objectives.

Country	No. of Patients	Database Lock	Error Rate
Canada	1,630	June 16, 2008	0%
China	22,053	March 31, 2008	0.002%
Greece	1,068	Dec. 19, 2008	0.015%
India	18,124	June 26, 2008	0.006%
Italy	1,371	April 1, 2008	0.009%
Japan	2,126	Sept. 28, 2007	0.02%
Poland	4,122	March 20, 2008	0.01%
Russia	4,870	Dec. 1, 2008	0.014%

Despite the multi-country trial with 5,486 sites and more than 55,000 patients, Quintiles maintained all data records and achieved database lock to a quality standard.