

# Data-Driven Market Success

## Scalability Optimizes Largest Observational Diabetes Study

### Challenge

The customer needed an experienced post-marketing ally who could plan for the unknown and design an observational study to eventually include several affiliates, thousands of sites and more than 55,000 patients — with start-ups staggered over time.

### Solution

Through its agile approach and established global network, Quintiles developed a streamlined, reliable program to generate multiple releases of valid data, efficiently and effectively, even as the study grew in size and complexity.

### Results

Quintiles met aggressive publication timelines, delivering quality, real-world evidence that helped the customer differentiate the product and drive market success.

Our foresight allowed our customer to publish compelling, evidence-based findings for abstracts and conference presentations throughout the study.

### Gaining Efficiencies in a Complex Operation

How do you successfully conduct what becomes the largest observational diabetes study ever? When our customer set out to differentiate their product in a crowded marketplace, they didn't know how successful or large the study would be. To guard against unnecessary investment risk, the customer planned to start the study small and scale up as the data indicated market potential. The catch: The customer needed an ally who could plan for the unknown and design a study that could eventually include several affiliates and thousands of sites, with start-ups staggered over time.

Combining post-marketing experience and operational ingenuity, Quintiles helped design a study that could grow quickly and efficiently despite its logistical complexity. Through strategic planning and flawless execution, we delivered quality data, balanced costs and helped our customer achieve their marketing objectives.

### Beginning with the End in Mind

Before the study began, Quintiles helped the customer develop the optimal operational designs, emphasizing streamlined processes and timely data validation. Knowing the interim analyses were vital to proving the product's market potential, we brought in our biostatisticians with expertise in methods to produce valid data from post-marketing studies.

Also, to manage the logistics of preparing data from different sites — each at a different stage of the study — we projected how many case report forms we would need, then planned how we would acquire that number before the scheduled analyses.

Our foresight allowed our customer to publish compelling, evidence-based findings for abstracts and conference presentations throughout the study, maximizing the study's value.

Through strategic planning and flawless execution, we delivered quality data, balanced costs and helped our customer achieve their marketing objectives.

By putting the right resources in place across our global network, we were able to scale up the study when results warranted expansion. With proactive process checks and local communication channels, we maintained data quality while achieving cost effectiveness, even as we added countries mid-study.

Our customer's affiliates also had their own local marketing goals and objectives, which we supported by providing country-specific data for their marketing activities, including expert panel meetings and symposia. The keys to working with the affiliates: excellent communication on a local level, streamlined processes and an understanding of their specific needs.

#### Quick Study Facts

- > **Objective:** *Generate data to demonstrate the safety and effectiveness of a marketed product*
- > **Product:** *A biphasic insulin aspart*
- > **Indication:** *Type 2 diabetes*
- > **Design:** *Phase IV, multi-center observational study*
- > **Sites:** *5,486 in Canada, China, Greece, India, Italy, Japan, Poland and Russia*
- > **Patients:** *55,514*
- > **Recruitment Timeline:** *6 months*

#### Differentiating Through Real-World Evidence

By successfully steering the largest post-marketing diabetes study ever conducted, we demonstrated our agility and precision to efficiently carry out an evolving global observational study and meet our customer's needs.

With proactive planning, we were able to coordinate milestones to meet the deadlines for each interim analysis. Implementing efficiency and outcomes-focused strategies from the start allowed us to stay flexible and successfully scale up to an eight-country study with more than 55,000 patients, even with the operational challenges of multiple affiliates and staggered database locks. As a result, our customer was able to provide real-world evidence that differentiated the product for payers and prescribers — and enhanced the product's commercial success.

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