

CASE STUDY

OBSERVATIONAL STUDY IN A METABOLIC DISEASE

Project Summary

One of the largest ever observational studies undertaken in this therapeutic area, encompassing approximately 5,000 sites and nearly 60,000 patients in multiple countries across the world

Challenges

- Understanding the challenges of executing research programs in a real world setting
- Identification and qualification of thousands of sites within a short time frame
- Timely submission of patient data and managing very high volume data throughput
- Maintaining data quality across the whole study
- Maintaining operational flexibility across a diverse population of sites while efficiently applying the program budget

PAREXEL Solutions

- Leveraged established global infrastructure and proprietary e-technologies, combining local site support with robust centralized management
- Our proprietary Peri/Post-Approval Technology Solution deployed for global outreach to sites and critical acceleration of start-up
- Intuitive guidance and practical support provided to sites through electronic system and helpdesk to expedite timely data entry into EDC
- Immediate feedback to sites on data discrepancies and missing information using online, real-time data validation to drive high quality data

Benefits to Sponsor

- Site activation period reduced to 24 hours
- Recruitment goal completed several months early
- Sponsor site management costs reduced by 150%
- Real-time tracking and metrics through the Peri/Post-Approval Technology Solution allowed the sponsor to monitor site and data status on a continuous basis throughout the study
- Demonstration of the safety profile of therapy across a very broad population within a short time period