



case study:

A COMMUNITY-BASED PHASE IV ENDOCRINE STUDY

Challenge: Maintaining quality on a huge study for which on-site monitoring was not possible.

This two-year, phase IV study of Type II Diabetes involved 419 community-based sites, of which a majority required no on-site monitoring, while sites enrolling 20 or more patients received one routine monitoring visit and one close-out visit.

Solution: Implement a program of in-house monitoring. In lieu of regular monitoring visits, we carefully communicated with sites by phone, fax, email, and express mail to answer questions, resolve issues, control quality, and expedite the flow of CRFs and other documents between the sites and i3 Statprobe. To facilitate smooth operations, we implemented a clinical database to track the flow of documents and materials to and from the sites; any sites experiencing problems were visited as necessary until their problems were resolved.

Weekly reports were run from the database to assist i3Statprobe and the sponsor in identifying and resolving issues and maintaining project progress. Over the course of the trial, i3 Statprobe continually adjusted resource levels to ensure that sufficient personnel were always available to monitor incoming data, resolve queries, and keep up regular communication with the sites.

Result: Expedited collecting and processing at considerable cost savings. The in-house monitoring program resulted in considerable cost savings for the sponsor and expedited the process of collecting and processing the study data. Our data management, programming, biostatistics, and writing groups all met project deadlines under challenging circumstances, garnering kudos from the client.