

A Study That Wasn't Working. Until Premier Research Stepped In

A customer called on us to rescue a study that just wasn't going well. (It happens a lot.) The challenge was to deliver data the company needed to make a go-/no-go decision at a major internal meeting that couldn't be rescheduled.

The problems stemmed, in part, from a failure to communicate between a large, somewhat impersonal CRO and a small sponsor that was used to close personal relationships and more or less constant interaction with the team managing its studies.

We picked up the project precisely where the other CRO left off. We couldn't start over from scratch, so we had to live with their mistakes and somehow make up the time they had lost. It wasn't what you'd call an ideal situation.

The challenge: Clean up 250 patients' worth of data. Quickly.

The main issue was fixing a badly mangled database. The customer hired a new database host, using different software. We worked closely with them to determine what needed to be fixed and what output needed to be delivered by the deadline.

We picked up the project in March 2013 and completed data lock by the end of September. Our statistical team also delivered almost three times as many (16 instead of six) tables of "Topline Results" ahead of the original deadline.

One reason for our success was how we did things. Our statisticians were at the top of their form, and they had extensive experience with rescue operations. The study also demonstrated an old truism: a handful of dedicated professionals can often accomplish more – and do it faster – than an army whose main strength is in its numbers.

Actually, the customer summed it up better than we could. "You ... are the best partner we could have had. Your efforts to rescue this study have made all of us a success." How can we help you (and your next study) be successful?

GASTROENTEROLOGY



A Handful of Dedicated Professionals Can Often Accomplish More – With Less

Study Description:

Rescue of a Phase II, double-blind, placebo-controlled study to evaluate the safety and efficacy of Ipamorelin for the recovery of gastrointestinal function in patients following small or large bowel resection with primary anastomosis

Therapeutic Area:

Gastroenterology

Indication:

Post-operative recovery from small or large bowel resection with primary anastomosis

Compound:

Ipamorelin

Services Provided:

Completion of patient data collection, statistical analysis, and data lock

Sites:

50

Geographic Scope:

United States

Patient Population:

+/- 250 patients hospitalized for non-emergency, open partial small and/or large bowel resection

Outcome:

Complete database restructured, cleaned, and results delivered in six months



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