CASE STUDY PRESENTED BY PREMIER RESEARCH

Getting Every Detail Right – With No Time to Think About How

Our customer was racing to beat a competitor to registration. One critical part of the timeline: Last patient out to database lock in two weeks. In sister studies that involved 800 patients at 90 sites. And several primary investigators who were heading off on vacation just when we needed their sign-offs on the data.

We also had to coordinate the efforts of a central laboratory, PK data people, a data management company, investigators and site staff. That left us with ultimate responsibility but no direct control over the other participants.

First, we put together a Premier Research team that could work independently and fast, and that knew how to coordinate clinical operations and data verification without any fuss or discussion.

We established clear lines of communication with everyone involved, and laid out for them precisely what had to happen, and when. (To catch investigators before they went on vacation, we locked their sites' databases first.)

Occasionally, feelings were hurt

The project manager somewhat sheepishly explained how she kept things moving so fast. "One group was falling down at one point. We couldn't worry about their feelings being hurt. We just had to get them back on track. We had to keep moving forward."

And we did – without even hurting their feelings too much. The customer was thrilled. After the study was over, they admitted that they hadn't known for sure whether anyone could pull it off. And they sent wonderful thank-you gift baskets to every single member of the Premier Research team!

It all goes to show that sometimes you need more than recruiting, data management or therapeutic area expertise. Sometimes it's just a matter of having someone in charge who has that marvelous gift of motivating everyone to do the right thing at the right time.

DERMATOLOGY

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Sometimes it's Just a Matter of Having Someone in Charge Who Has That Marvelous Gift of Motivating Everyone

Study Description:
Phase III randomized, double-blind, parallel-group study assessing efficacy and safety of a new treatment for papulopustular rosacea.

Therapeutic Area:
Dermatology.

Indication:
Papulopustular rosacea.

Services Provided:
Project management, clinical monitoring, investigator grant negotiation and contracts, grant payments, interactive web response system (IWRS), data verification, cleaning, and database lock.

Sites:
90, 45 in each of two parallel studies.

Geographic Scope:
United States and Canada.

Patient Population:
800 screened, 681 enrolled, and 580 completed.

Duration:
Six months.

Outcome:
Study completed on schedule; database lock completed in two weeks after last patient out.

premier research
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