That Was Easy ...

This case is a story with no drama. No sudden crisis. No last-minute rescues. It's about a clinical trial that ran perfectly from start to finish. And that in itself is a story worth telling.

The sponsor needed to test a new nonsteroidal anti-inflammatory drug (NSAID). They had worked with Premier Research before, and knew our track record in analgesia studies: More than 870 pain trials treating over 110,000 patients, including trials for all of the NSAID analgesics on the market today.

Our experience enabled us to quickly line up what we knew were the 40 best sites in the country for this type of analgesia study. The sites hadn't done any similar studies recently, so we knew they had lots of patients geared up and ready to go.

We also knew exactly what tools and training the sites would need, so we had clinical and lab supplies and training materials lined up ahead of time. We held the investigator meeting on a Friday, and started enrolling patients on Monday.

An all-time record for rapid recruitment

The sites recruited 300 patients in eight weeks – a Premier Research record for rapid recruitment. Then came the only little bump in the road: We were moving so fast that the sponsor ran out of the study drug. They quickly shipped more.

The final result: We filed the regulatory submission earlier than expected – a whole year earlier.

It wasn't good luck – or even our extensive experience. We also had a wonderful, well-organized sponsor, who kept communications open throughout, made quick decisions, and worked hand-in-hand with us every step of the way. In fact, our relationship was so effective that the sponsor awarded us three more studies in short order.

Which just goes to show that it doesn't take an exciting story to deliver exceptional results.

ANALGESIA

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Study Description:
A Phase III, multicenter, randomized, double-blind, placebo-controlled, fixed-dose, parallel group, efficacy and safety study of a new NSAID analgesia compound

Therapeutic Area:
Analgesia

Indication:
Osteoarthritis (OA) of the knee or hip

Services Provided:
Full-service Phase III study

Geographic Scope:
United States

Sites:
40

Patient Population:
Approximately 300 subjects (100 subjects in each of three treatment groups)

Duration:
Approximately 15 weeks for each individual subject

Outcome:
Regulatory submission filed a full year ahead of schedule

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