

It's About How the Social System Works, Not Just the Science

The assignment sounded simple enough: Recruit 24 patients for a Phase I proof-of-concept study of inflammatory bowel disease. The first CRO that received the assignment showed how difficult it really was: They were able to recruit only nine patients in a year and a half. At that point, the sponsor asked Premier Research to step in.

We recruited and randomized 15 patients in six weeks.

It's easy ... if you know how

It wasn't magic. The first CRO had tried to recruit patients in Germany, where there was no shortage of treatments available. But our Eastern European staff knew – without having to look it up – that the health systems in Romania and Bulgaria don't cover biologics for inflammatory bowel disease. And that no one could pay for them out of pocket, since they cost around US\$2,000 a month.

So patients there were eager to participate in the trial. After a short feasibility assessment, we identified six suitable sites. We set up a half-day of intensive investigator training in

each country. The result: Every site staff became a dream team, performing critical screening tests perfectly, and we had our 15 patients within six weeks.

Next problem: patient retention

The study required an overnight stay at the clinics, and follow-up over three months. Again, our knowledge of the social system helped. We knew that workers in Romania and Bulgaria get few paid holidays, so we helped with their expenses and made sure each site staff actively encouraged them to continue throughout the trial and follow-up period.

The speedy success of our recruitment and retention effort not only saved the sponsor time and money; it also revealed a patient response rate of over 80 percent. The sponsor is now negotiating financing to continue development, and we're in the running to continue it with them.



AUTOIMMUNE DISEASES

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Our Recruitment and Retention Effort Saved Our Sponsor Time and Money

Study Description:

Phase I, open label, proof-of-concept study of a treatment for inflammatory bowel disease

Therapeutic Area:

Autoimmune diseases

Indication:

Inflammatory bowel disease including Crohn's

Compound:

Small-molecule compound that suppresses the formation of pro-inflammatory autologous messenger substances and inhibits the growth of activated immune cells in human blood

Services Provided:

Patient recruitment, screening, and retention

Geographic Scope:

Romania and Bulgaria

Patient Population:

24 patients with inflammatory bowel disease, 15 recruited by Premier Research in six weeks after another CRO recruited only nine in 1.5 years

Outcome:

Sponsor is negotiating external financing or partnership agreements to support further development



IT'S WHAT WE DO. BEST.™