CASE STUDY PRESENTED BY PREMIER RESEARCH

Merging Science and Nuance to Treat Post-Traumatic Stress Disorder

Patient enrollment is a key challenge in most clinical trials, and studies of drugs to treat post-traumatic stress disorder require an especially nuanced approach to recruiting. The target population of military service members is inherently circumspect, and the conditions that afflict these men and women add greatly to the challenge.

Such was our experience in a recent Phase II study of a proposed treatment for PTSD. Not surprisingly, recruiting for this double-blind placebo evaluation advanced slowly at first. Casting a large net doesn't work when your target is a highly specific patient group composed of military personnel. What's more, there had been no military-specific PTSD studies in several years when we began recruiting, so the industry apparatus was a bit rusty.

Drawing on our long-established site relationships, we evaluated more than 90 U.S. sites before selecting the 25 used in the trial. We looked at every factor, including the intangibles: What did the site look like? How were patients greeted on arrival? And we looked at their relationships with veterans groups, recognizing that sites known to local veteran advocates are generally more successful at building trusting relationships with this population.

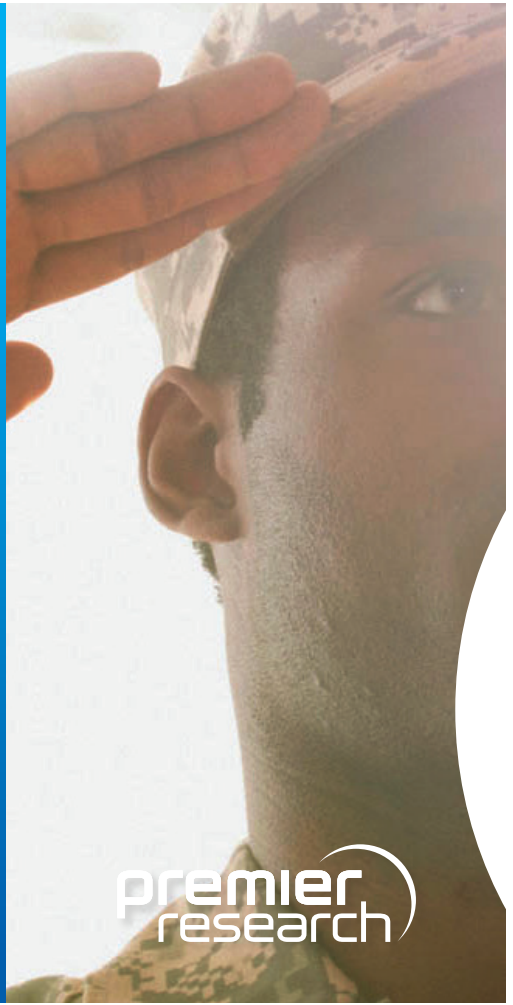
Making close connections

After a slow first few months, enrollment accelerated rapidly as we more closely engaged the sites and launched a central advertising campaign that included social media outreach. Our size was a distinct advantage: Being a smaller CRO, we're better able to forge and maintain close connections with sites than large organizations that relate on a less personal level.

Our success speaks for itself: We randomized 246 patients ahead of schedule, concluding enrollment in December 2015.

The study evaluated two dosages of the drug to give PTSD patients more restful and restorative sleep with fewer flashbacks and other interruptions. The Phase II trial found the larger dose effective, paving the way for a Phase III trial that also was awarded to Premier Research.

NEUROSCIENCE



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Every Variable Counts, Even the Intangibles — So We Weighed Every Factor

Study Description:
Phase II study of a drug proposed for treatment of post-traumatic stress disorder

Therapeutic Area:
Neuroscience – Psychiatry

Geographic Scope:
25 sites in the United States

Patient Population:
246 military personnel randomized

Length of Enrollment Period:
13 months

Outcome:
Phase II trial completed successfully; planning for Phase III trial now underway

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