

Phase III PTSD Trial

Study Basics

Disease: Post Traumatic Stress Disorder

Phase: 3

Target geography: United States

Total number of sites: 44

Background

The sponsor was experiencing significant delays in trial timelines for two sister PTSD studies in the United States. With difficulties identifying sites with the right patient access and a high screen failure rate holding back their progress, they decided to partner with Inato to push the study over the finish line.



The Problem

When the sponsor first met with Inato, they had enrolled just ten of the intended 300 patients over the course of two and a half years. Their efforts were focused on partnering with veteran hospitals, however the slow processes to open this type of site, coupled with delays brought on by COVID, yielded a stagnant timeline. Additionally, for sites that were activated and enrolling, the higher than anticipated screen failure rate left few patients qualifying for the study.

Another key issue came about in the mismatch in finding sites with the right patients. The targeted demographic was proving difficult to enroll; with the eligibility criteria requiring patients to have experienced a traumatic event within the past nine years, all veterans of Iraq were deemed ineligible. Additionally, the study required the traumatic event occur after the patient was 16, eliminating anyone who had experienced childhood trauma. A solution was unclear. PTSD is an under-diagnosed disease that can affect any type of person; identifying which research sites were capable of recruiting this abstract and limited patient population proved incredibly complex.

Looking to overcome these barriers and find the right sites for this trial with a proven ability to access these patients, the sponsor chose to partner with Inato.



INATO SITES ENROLLED

180%

OF THE TOTAL INATO VERIFIED COMMITMENT.



Despite a condensed timeline, Inato sites enrolled at a rate

1.6x higher than other sites in the trial.

The Solution

The sponsor selected Inato sites across Florida, California, South Carolina, and Texas. Branching out from their previously established demographic, none of Inato's sites worked strictly with veteran populations. Instead, these sites unlocked access to an intimate network of patients within their communities who didn't fall into a single, easily identifiable demographic. With Inato's platform, sites that knew they could recruit PTSD patients were able to find and apply for the trial, flipping the traditional model of sponsors finding and inviting familiar sites. The new approach eliminated the sponsor's challenge in struggling to identify the right-fit sites. Many of the selected sites were led by psychiatrists with trusting patient connections, allowing them to boost retention rates and position them for successful enrollment.

SITE SPOTLIGHT

One Florida site significantly exceeded the sponsor's expectations with impressive screenings, achieving 500% of their Inato Verified Commitment (IVC).

These existing patient physician relationships also fostered the opportunity for Inato sites to combat the unexpectedly high screen failure rate. Thanks to each PIs' trusted relationships with their patients, Inato sites were able to screen well above the anticipated number and find patients that met the trial criteria, ultimately enrolling 180% of the total Inato Verified Commitment. In fact, had all 44 of the sites in the trial had the community access and enrollment success that Inato sites had, the sponsor would have been able to run the study with just 29 sites.