

Case Study:

Medical device company testing PTSD treatment

nRollmed recruits 50% of study's patients in 30% of the time





The Challenge:

A medical device company launched a multi-site study in the US to confirm the efficacy of its device for treating PTSD.

The study's enrollment goal was 100 patients. Three years later, only 30 patients had been recruited. The sites struggled to find patients since many suffered from disqualifying comorbidities. Many of the sites quickly exhausted their existing patient pool and had no way of expanding it.

Since PTSD is a disorder involving intense suffering, and interferes with daily life, education about the disorder was not difficult. Nor was it a challenge to achieve interest in the study. However, finding patients with the proper diagnosis was challenging; prospective patients were often found to either have been misdiagnosed, have outdated diagnoses, or were not diagnosed by a medical professional.

Further complicating recruitment efforts was the requirement to screen out those diagnosed with cPTSD, a newly recognized form of PTSD associated with a history of multiple traumatic events occurring over a longer period of time.

nRollmed's Contribution to the Recruitment Process



nRollmed recruited 49 patients



nRollmed was responsible for the successful recruitment of 66% of patients during the time that they were active



nRollmed was responsible for 50% of the total randomized subjects. By working with nRollmed, 24 months of recruitment time was saved



Customized and Collaborative Approach

The nRollmed team built strong relationships with the staff at each site, listened to their specific challenges, and learned their preferences, availability, and capacity for receiving patient referrals. Based on the information garnered, nRollmed's team was able to tailor the service to each site's needs.

Additionally, nRollmed consulted with each site to determine their level of comfort regarding patient referrals with an unclear diagnosis. Some sites were willing to perform a professional assessment. Other sites preferred prospective patients to see their own doctor for diagnosis before on-site screening.

nRollmed's team worked closely with the sites and sponsor to articulate a broad and carefully worded question that would be IRB-approved to screen out cPTSD patients. The pre-screening script was then updated to include this question, enabling the team to further optimize the screening funnel. The addition of this component saved sites valuable time.



nRollmed's Method





Results

Recruitment for the PTSD trial was successfully completed with nRollmed's participation. nRollmed was active for only 30% of the total recruitment period and in that time brought in an additional 49 randomized subjects.

nRollmed's active participation resulted in the recruitment of 50% of the study's total patients.

When comparing the enrollment that took place without nRollmed's participation, working with nRollmed enabled the sponsor to complete the trial 24 months earlier.

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"From our first collaboration with nRollmed, we were very impressed with their ability to recruit patients for a particularly challenging indication (obsessive-compulsive disorder). As a result, we partnered with nRollmed for our next two studies (PTSD and MDD), spanning several sites in the US and Israel. nRollmed's professional and experienced team was consistently able to assess the needs of each site and adapt their methods according. We received excellent results and support throughout all three of the trials. We will definitely be turning to nRollmed for future studies."

Vice President and Site Manager and Sponsor Company

