



Case Study

Medical device company testing novel treatment for Major Depressive Disorder

nRollmed triples enrollment rate; trial sped up by 15 months.

nRollmed
Faster patient recruitment for your clinical trial



The Challenge

A medical device company launched a multi-site US study to confirm the efficacy of its novel non-invasive device for treating Major Depressive Disorder (MDD). The goal was to see if the novel device was equal or superior to the earlier FDA-cleared version of the device.

The sponsor's goal was to recruit 116 participants overall. After 16 months, the study only managed to recruit 21 patients. nRollmed was hired to help several of the struggling sites to recruit.

The major challenge was the stringent criteria in the protocol. Patients needed to be experiencing an active depressive episode. They also needed to have no cardiac or neurological issues. In addition, migraines were not allowed, which eliminated many interested patients. Additionally, the patients needed to be resistant to at least one depression treatment, but also needed to be stable on their current treatment for at least 2 months.

Another major challenge was that common comorbidities such as anxiety disorder, bipolar, OCD, PTSD, an eating disorder or a personality disorder, were not allowed. Finally, patients were asked to attend visits 5 days a week which was a difficult time commitment.

The nRollmed Process Drives Recruitment Results



40 nRollmed patients were randomized, **accounting for 51% of patients recruited** during the time that nRollmed was active, or 34% of total randomizations.



Study's enrollment rate **triples from 1.3 randomizations/month to 4** with nRollmed's help.



15 months of recruitment time saved



A Customized and Collaborative Approach

- nRollmed's recruitment strategy was to increase awareness of the study in an online campaign. People could choose to learn more on a custom website built by nRollmed. Patients were interviewed by a dedicated pre-screening team to make sure they met the initial criteria for joining; only then were they referred to the nearest site for a screening visit.
- Each site was provided with a management platform to make it easy to manage the patient referrals. The platform also allowed the sponsor to understand each individual site's progress.
- Site support was an equally important aspect for successful recruitment. 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. nRollmed's team was then able to tailor the service to each site's needs. nRollmed conducted regular calls with the sites, which helped iron out issues and kept the study top-of-mind for the sites. nRollmed also helped reduce the sites' workload by helping them reach patients for scheduling and sending out appointment reminders for the site.



nRollmed's Method



**Awareness
campaign**



**Pre-
screening**



**Site
support**



**Sponsor
insights**



Optimization



Results

Over the 12 months working on the study, 40 patients from nRollmed were randomized. This accounted for 51% of the patients recruited in the time nRollmed was active. Overall, nRollmed's patients made up 34% of the study's total randomizations. With nRollmed's help, the study completed recruitment 15 months early.