



Case Study:

Pharmaceutical company focused on non-alcoholic steatohepatitis (NASH) treatment

nRollmed recruits more than double the industry standard for 'silent' disease.

nRollmed
Faster patient recruitment for your clinical trial



The Challenge:

A pharmaceutical company was engaged in a Phase 3 trial with a promising compound to treat non-alcoholic steatohepatitis (NASH). NASH, a serious, inflammatory form of fatty liver disease, is often found in Type 2 diabetics and patients suffering from obesity. Finding patients with NASH is challenging as they are often undiagnosed and unaware of disease implications, including liver failure and liver cancer.

After unsuccessfully screening many patients, with a rapidly approaching deadline, the client hired nRollmed for a two-month period to boost recruitment. A total of 100 patients were needed for screening.

Currently, no drug has been approved for the treatment of NASH. The first line of treatment is a change in lifestyle. Therefore, any patient who had not yet tried lifestyle changes with professional guidance, was not referred to the sites.

Biopsy is the only definitive method of diagnosis. This was a sensitive issue when engaging with patients – it was important to be straightforward, but to also not scare away potential participants.



Customized and Collaborative Approach

To overcome the challenge of finding people with a disease that goes so frequently undetected, nRollmed employed a multi-layered strategy, targeting only those with common, relevant risk factors. A scoring system was developed to assess a candidate's likelihood of suffering from NASH.

nRollmed's team put together a strategy for discussing the need to have a biopsy with patients. A focus was placed on education about the disease and what the study would entail. The patients' approval for potentially undergoing a biopsy was verified before they were referred to the sites, ensuring that the sites' valuable time was not wasted.

As this process was refined, information was collected on the specific steps taken by successful sites, which nRollmed then shared with other sites so that they could replicate the process.

nRollmed's contribution to the recruitment process:



nRollmed provided 122 leads for screening



33 patients signed consent and **21 underwent biopsies**



nRollmed's recruitment rate was 0.4 randomizations per site per month, **more than double the industry average of 0.15**



nRollmed's Method



Awareness
campaign



Pre-
screening



Site
support



Sponsor
insights



Optimization



Results

In just over 2 months at 5 clinical sites in the U.S., nRollmed referred 122 patients, out of which 33 signed consent, 21 underwent biopsies, and 4 were randomized.

As a so-called 'silent disease', NASH poses a significant challenge to trial recruitment. The NASH clinical trial industry standard is 0.15 randomizations/month/site. nRollmed's ratio was 0.4, more than double the NASH clinical trial industry's statistic.