



M3 GLOBAL RESEARCH CASE STUDY

NASH Patient Journey

THERAPEUTIC AREA

Liver Disease

METHODOLOGY

WATIs

STAKEHOLDERS RECRUITED

Non-Alcoholic
SteatoHepatitis (NASH)
Patients

COUNTRY

United States

About NASH

Non-Alcoholic SteatoHepatitis (NASH) is the most severe form of non-alcoholic fatty liver disease (NAFLD). NASH is characterized by the presence of an abnormal accumulation of fat in the liver which in some individuals can progress to liver cell injury (hepatocellular ballooning) and inflammation, sometimes called necroinflammation. These are commonly considered

to be the drivers of disease progression, or as the underlying causes of the disease. As NASH evolves over time, it can result in excessive scarring in the liver (fibrosis), a natural response to injury which can lead to liver cirrhosis or liver cancer.

Source: The NASH Education Program

Business Objective

M3 Global Research's client was seeking NASH patients that had fibrosis stage F3/F4 to complete a 60-minute interview with an additional pre-work assignment that

involved a one-week diary online. The fibrosis stages range from F0 (no fibrosis) to F4 (cirrhosis).

Challenges

Despite the healthy M3 Global Research panel and best efforts of the recruiting team, there is not a large population of 'identified' NASH patients. This is because many patients are not aware of what NASH stands for, and are only aware of their symptoms, which is typically

referred to as 'fatty liver' rather than its proper term of NASH. This made it challenging for M3 to achieve the bid incidence rate (IR).

An additional challenge on this project involved the

screening criteria that the client had put together due to the need to recruit a very specific type of NASH patient. In the initial project description, the client had not specified that only stages F3 and F4 patients should be recruited. This led to a large decline of IR feasibility from what was originally estimated.

The client required the use of a mobile diary, an app-based program that the respondent had to log into via

a tablet or smartphone. Many respondents are not yet familiar with this method, which provided an additional barrier to overcome, on top of the challenge to identify qualified respondents. For some respondents, a technical barrier such as this can increase the termination rate and thereby drive the IR down.

The M3 Global Research Solution

M3 began its recruitment within its own panel to identify potential NASH patients. The next step was to seek the help of the M3 panel team for non-matched sample, social media outreach, and for the patient solutions team to identify potential additional recruits. The team followed up with referrals from healthcare professionals (HCPs), members from a client list as well as our proprietary panel, and peer-to-peer referrals. M3 leveraged other resources within its internal and external networks including panel, patient solutions, phone team, and partners.

After pushing recruitment and leveraging further resources, M3 reviewed and presented the terms to the client and did additional follow up where needed with potential terms for acceptance based on additional feedback. M3 also looped in a partner in an aim to further assist in recruitment.

Results for Success

Patient studies can be challenging when looking to recruit from a small population – studied disease or condition. M3 decided to take on the project despite its difficult nature and with the mutual understanding that the client's specific criteria could hinder overall feasibility given the targets and strict subquotas.

The M3 team set clear client expectations about what was realistic and in the end was able to recruit 10 NASH patients through internal efforts from panel team and a partner support group.