Liver Disease Researchers Struggle to Find Patients for Clinical Trials

As pharmaceutical companies race to develop treatments for NASH, they find one thing is missing: willing test subjects.

January 4, 2018 By Casey Halter

As the rate of liver disease continues to rise along with the rate of obesity, more than a dozen pharmaceuticals are racing to develop treatments for non-alcoholic steatohepatitis (NASH), a liver condition caused by fat accumulation and characterized by inflammation or damage to the liver. However, according to a recent report in Bloomberg, these drugmakers face a major hurdle: a dearth of patients willing to volunteer for clinical trials to test the new treatments.

The article notes that the treatment market for NASH is currently predicted to reach as much as $40 billion by 2025. Intercept Pharmaceuticals, Genfit and more than a dozen other drug companies are currently locked in a race to develop first-generation drugs to treat the illness. However, executives and physicians overseeing clinical trials of these medications say it's been difficult to fill patient rosters.

For instance, Intercept managed to fully enroll just one key trial this year, and that was only after it made changes that enabled it to almost halve the number of participants in the study. Earlier this year, a late-stage study at Genfit was delayed by months, prompting the French company to work with medical centers and doctors to persuade more patients to join.

Currently, NASH affects an estimated 3 to 12 percent of Americans. However, the progressive liver disease is still little known due to the fact that it is virtually asymptomatic for years. What's more potential patients for trials often live in rural areas and lack access to medical trials. Doctors also note that enrolling in late-stage trials for NASH treatments often requires painful and invasive liver biopsies, which, without the guarantee of effective treatment, many NASH patients are reluctant to undergo.

However, pharmaceutical companies warn that these obstacles could delay plans to seek regulatory approvals as well as any NASH treatment rollouts.
