

CASE STUDY PRESENTED BY PREMIER RESEARCH

It Helps to Know What's Going to Happen Next

No guesswork here. It's a combination of experience and that often-overlooked scientific discipline called common sense.

We were conducting a Phase IIb trial of a new treatment for nonalcoholic steatohepatitis, or NASH. And we knew three things:

We knew that hepatologists would jump at the chance to enroll their patients, because the only existing treatment for NASH is the well-known lose weight – eat healthy – exercise more regime. This was the first simple, oral, once-daily treatment ever developed for the disease.

We knew that screening failures would be abnormally high, because NASH mimics a number of other liver diseases, and the only sure diagnosis is through a liver biopsy.

And we knew that many patients would drop out, despite the initial enthusiasm, because NASH is usually a silent, asymptomatic disease in its early phases. Many patients just wouldn't think the inconveniences of participating in the trial were worth the trouble.

Enrollment completed in 24 hours

Because we were prepared for both a surge of applicants and a high rate of screening failures, we were able to complete enrollment in 24 hours.

Once patients were accepted to the study, we faced another challenge: an unusually high degree of self-medication. Because their doctors could do no more than recommend a change in lifestyle, many patients were taking a variety of supplements and herbal remedies. To eliminate the noise this could cause in the data, we required patients to hold their self-medication constant for three months before the study.

The better you know what lies ahead, the more successful you'll be at getting beyond it. With all the elements firmly in place, the study is now proceeding smoothly.

HEPATOLOGY



premier
research

The Better You Know What Lies Ahead, the More Successful You'll Be at Getting Beyond it

Study Description:

One-year, liver biopsy-based, Phase IIb trial of the first compound ever developed to treat nonalcoholic steatohepatitis (NASH)

Therapeutic Area:

Hepatology

Indication:

Nonalcoholic steatohepatitis (NASH)

Services Provided:

Full service

Geographic Scope:

56 centers of clinical excellence in the United States and Europe (France, Belgium, Netherlands, Italy, United Kingdom, Germany, Spain, and Romania)

Patient Population:

139 diabetic and non-diabetic patients with a histological diagnosis of NASH by liver biopsy



IT'S WHAT WE DO. BEST.™