Rapid Start-Up for Pivotal Trial in Non-Alcoholic Steatohepatitis

A Case Study in Global Site Activation and Clinical Trial Monitoring

A small pharmaceutical company approached Labcorp Drug Development to ask for help running a late-stage trial in non-alcoholic steatohepatitis (NASH). The company needed extremely rapid start-up for a large global trial.

Achieving Expedited Approval While Maintaining Quality

After the client provided a draft of the protocol, our experts suggested modifications such as statistical analysis changes to increase the chances of regulatory approval. The revised protocol was then quickly submitted to the first ethics and regulatory authorities. Despite the fact that this first country often presents site activation challenges, we broke an internal Labcorp record for fastest ethics and Investigator Package approval. Within three days of ethics approval, our team performed the site initiation visit. Two days later, the site was open and ready for enrollment.

Understanding the Challenge

- Reach First Patient In (FPI) milestone as quickly as possible
- Select and activate over 200 suitable sites around the world
- Overcome enrollment challenges associated with requiring multiple liver biopsies
- Retain patients in long-term study

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We drew on the clinical trial data in our comprehensive Xcellerate® database to identify an abundance of sites that had previously participated in trials in NASH or were specialists in areas such as hepatology or gastroenterology. After client review of the site list, our team conducted pre-study visits for each location and used a detailed e-survey to gather key candidate site information such as site facilities, adequate site staff resources and whether they were running competing trials. At activated sites, systems were deployed to capture and integrate data electronically into the clinical database, including patient questionnaires and vendor information.

Labcorp's extensive modeling capabilities allowed the client to view realistic projections of the trial's progress. Our Organizational Strategy & Planning group was able to analyze site activation time data and run algorithms to predict the necessary patient recruitment rate to meet required milestones. Presented with these modeling scenarios, the client could determine whether the project was on track and whether contingency plans needed to be developed.

Our team also established risk-based monitoring for the trial, enabling the client to flag potential safety and data integrity issues before they become critical problems. We have the capability to organize and manage an adjudication committee to independently assess endpoints, as well as a data safety monitoring board to determine whether the study needs to be changed or stopped due to safety concerns.

Value to Client

Labcorp's suggested trial modifications reduced the risk that regulatory authorities would reject the protocol, saving the client valuable time. Enrolling the first patient quickly also allowed the client to inform their investors that they had reached a crucial milestone. With Labcorp's sophisticated modeling tools, the client could accurately track their operational progress.

With this large late-stage trial, Labcorp continues to build its expertise in NASH and establish its role as a leader in the field.

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