Strive to Be More Than a Partner with Small Biotechs

Case Study: NASH Phase IIb Clinical Trial Management & Consulting

A biotechnology start-up had initially developed a diabetes drug and wanted to switch to a non-alcoholic steatohepatitis (NASH) indication. After seeing a Labcorp Drug Development webinar about the disease, the company approached us for help. The client needed a partner with deep NASH expertise that could provide scientific and medical consulting for a Phase IIb clinical trial and manage all aspects of the study.

Providing Rapid Site Selection and Comprehensive Project Management

Labcorp helped the client revise their protocol to maximize the amount of information and data quality while maintaining a reasonable price. For instance, our experts streamlined the activities performed at some patient visits and refined parameters such as inclusion and exclusion criteria. We also suggested which lab assays and imaging tools would provide the most cost-efficient and accurate methods to measure the severity of NASH and signs of improvement.

Understanding the Challenge

- Refine the protocol to gather critical information while adhering to a limited budget
- Select 37 sites in the United States and recruit 200 subjects
- Complete the trial within two years of signing the contract

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The client initially did not have sufficient funds for a full contract but still wanted to move forward with the project. Labcorp was able to offer flexibility and signed a short-term start-up agreement with a fixed scope of work. To make as much progress as possible during that time, our team sent questionnaires to over 100 sites, drawing on an extensive network of NASH investigators, and began performing pre-study visits to ensure that candidate sites had the appropriate infrastructure to perform the study successfully. We also started customizing the electronic data capture (EDC) system for the client's protocol and setting up the Interactive Web Response System (IWRS), a tool to help with tasks such as determining randomization and tracking patient screening and enrollment.

Once the client's funds were available and the full contract was signed, Labcorp proceeded to officially select sites, negotiate contracts, complete regulatory paperwork and recruit patients. Within about two months, the first patient had been screened, the IWRS went live shortly afterward and EDC go-live is proceeding as expected. As the trial progresses, Labcorp will provide project management and monitoring services, including verifying that data has been captured correctly in electronic systems, regulatory documents are up-to-date and the drug is being properly stored and dispensed.

Value to Client

By partnering with Labcorp, the client gained access to highly knowledgeable subject matter experts who guided the protocol's development. Our existing relationships with NASH physicians allowed the company to select sites with a history of strong performance. We also offered the client central laboratory testing and expertise in relevant fields such as genomics.

Labcorp is quickly emerging as the leading CRO in NASH development. Our team partners with you throughout the process, from preclinical studies to market access research to regulatory consulting. In addition to working with large pharmaceutical companies, we are committed to providing services to small biotechnology companies seeking to bring their NASH treatments to market.

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