Fifty-Five Percent Reduction in Enrollment Time. 100% Satisfaction: Hepatic Case Study

A virtual biotech company selected us to conduct a hepatic impairment study that was part of the critical path for development of a dyslipidemia treatment.

Understanding the Challenge

- Complex Phase II study design
- Strict protocol requirements
- Accelerated enrollment and tight timelines due to a delayed study start

Exceeding Expectations

Faced with several challenges from the outset of the study, Covance called upon its dedicated hepatic impairment team to build robust and rigorous processes that would set our client up for success. First, within two weeks, our experts developed a study protocol that met FDA requirements. Next, we reached out to our network of sites prior to contract and briefed them on the study parameters to ensure rapid start up once approvals were given. Furthermore, we teamed site PIs, project managers and medical monitors to develop custom inclusion/exclusion criteria that delivered quickly – while significantly reducing the risk of enrolling ineligible patients. Finally, we inspired sites to exceed their original quoted enrollment timelines by instituting an aggressive, competitive recruitment plan and by offering sites the incentive to enroll the healthy match for each patient as well.

Our relentless focus on results did not stop at recruitment. We maximized timely delivery of the IRB documents by centrally controlling the submissions and by populating investigator documents on behalf of the sites. We also tracked patient screening and enrollment in real time to help facilitate trial operations and mitigate risk. Lastly, due to our client's need for accelerated enrollment, we adjusted our resources to manage the increased amount of data being generated in a compressed amount of time.

Because of our extensive experience in hepatic trials, our team surpassed originally proposed timelines by 55% and our client was able to file their NDA well ahead of schedule. By proactively revealing opportunities to help expedite the trial, we managed against potential study delays and seamlessly adapted resources to rapidly changing timelines.

Advancing a drug quickly is a goal of every drug company. Let us help you obtain as much information – as fast as possible – to make the right go/no-go decision.

Learn more about our drug development solutions at www.covance.com

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