CASE STUDY

Phase III Primary Biliary Cholangitis Study Completes Enrollment Ahead of Schedule

PPD® Biotech

BACKGROUND

A rapidly growing company chose PPD Biotech as their CRO partner for a global Phase III clinical trial in primary biliary cholangitis (PBC). Through PPD Biotech's extensive network of liver disease sites and the establishment of a customized governance, we collaborated to overcome unexpected delays and the challenges of identifying and enrolling patients with a rare liver disease.

CHALLENGES

PPD Biotech and client teams aligned around key milestones and timelines to achieve a shared objective: rapid enrollment of 240 patients across 24 countries. The top operational challenges this study faced included:

- Limited patient pool
- Competitive patient landscape
- Protocol delays pushed site activation back 90 days

Furthermore, this client was new to PPD Biotech. Meeting enrollment milestones were critical in achieving this company's corporate goals. Establishing trust would also be essential to success.

STRATEGY

SITE ACCESS – STARTING WITH STRONG FUNDAMENTALS

While this was PPD Biotech's first PBC study, because of our extensive liver disease experience, we developed a well-thought-out site and country mix. This was also the client's first project with us, but we gained their trust with an informative feasibility, which proved to be effective throughout the course of the study.

THE IMPORTANCE OF FLEXIBILITY: PROACTIVE PIVOTS

The PPD Biotech team understood the creative pathways needed to keep this Phase III trial on track. To help recover time lost during the 90-day delay, our teams proactively worked to identify as many sites as possible that could activate quickly in the U.S. This resulted in **24 fast-track sites activated in 3 months.**

Startup

DELAYS OVERCOME

In a Study Involving

240 PATIENTS

with a rare liver disease

DEEP KNOWLEDGE OF LIVER SITES, EXPERIENCED TEAMS AND CLOSE COMMUNICATION DROVE SUCCESS

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In addition, study documents were prepared in advance, ready for quick finalization at availability of protocol. The team further mitigated the effects of delays by anticipating possible issues with document translation. We created a process that allowed us to quickly incorporate final changes once all documents were approved. This kept global outreach efforts and trial progress on track.

In parallel to the work on site submissions and activations, the global teams tailored enrollment strategies for each site to rapidly gain momentum once enrollment began. For example, our **clinical team managers worked proactively with investigators to pre-screen potential patients and ensure sites could start screening and enrolling as fast as possible** once activated.

GOVERNANCE AND COMMUNICATION STRATEGY

Not only was this client facing challenges associated with increased speed-to-market pressures, but they were also entering a period of rapid growth.

To make certain any potential challenges were identified early and this study stayed on track, we established an executive steering committee linking executive and operational teams across both organizations. The governance team was kept informed on study progress via monthly executive debriefs issued by project leadership. The executive steering committee met quarterly at the client's office. At these meetings, key decisions were made, and direction was provided by leadership.

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THE RESULTS

As a result of our liver disease experience, flexible approach and cohesive collaboration between our teams, this biotech met its study milestones and subsequently awarded PPD Biotech an additional long-term safety study.

Careful planning led to a boost in patient screening:

73

PATIENTS SCREENED DURING THE FIRST 10 DAYS

Achieved milestone of screening lock

five

WEEKS

ahead of schedule.

For more information, please contact us at
+1 877 643 8773, +1 919 456 5600 | ppdbiotech.com