HEP B CASE STUDY

Navigating a dynamic study design in hepatitis B research

Overcoming enrollment challenges in a complex platform trial

A major pharmaceutical company partnered with Fortrea for a Phase II platform study. The trial's dynamic study design allowed for the addition and removal of study drugs in various treatment arms and combinations. This flexibility was driven by emerging data from multiple interim analyses at specific timepoints throughout the study.

Many of the target sites for this Phase II trial had previously participated in the Phase I trials of the study drugs under investigation. Using this strategic approach, Fortrea aimed to leverage existing relationships and expertise to navigate the intricacies of the study design.

Navigating enrollment challenges

During the initial phase of trial management, the study team encountered several challenges:

- Identifying and maintaining motivated principal investigators (PIs) and site teams willing to participate in this difficult and complex trial
- Encouraging PIs and site teams to motivate patients to enroll, given the trial's complexity
- Managing the unique nature of a platform study, including periods of no enrollment while data are being cleaned and reviewed and necessary "downtime" during protocol amendment approvals
- Maintaining PI and site motivation, momentum and patient identification activities during enrollment pauses, ensuring readiness when new treatment arms open

Early engagement with a collaborative approach

To address the challenges, Fortrea implemented a strategy centered on a one-team approach with the sponsor and sites. Early and transparent communication from the sponsor enabled Fortrea to clearly understand and convey the study strategy to the wider team and ultimately to the sites. This approach went beyond normal communication processes, including regional calls with PIs to share information about the sponsor's hepatitis B pipeline.

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Face-to-face engagement with PIs and site staff was prioritized whenever possible. This included study-level sponsor presence at conferences, with scheduled meetups with PIs. The sponsor engaged with key opinion leaders (KOLs) and PIs for publications and materials, and Fortrea followed up and encouraged PIs to meet with the sponsor team at these conferences. The approach also included country/regional Fortrea-sponsor visits to sites in Taiwan, Hong Kong, China, U.K., France and Spain.

To maintain motivation, Fortrea visited sites and sent email blasts at relevant intervals with short, precise messaging. Support from the sponsor's local affiliates further enhanced these efforts. Internally, Fortrea held quarterly meetings with country heads to keep them updated on the study status, discuss recent changes at a country level, request support with PI relationships and brainstorm solutions when challenges arose. This comprehensive approach ensured consistent engagement and support throughout the study's initial phases.

Study results

The collaborative approach and clear communication strategy yielded positive outcomes throughout the study. The Fortrea team felt supported at all levels—from project lead and director to country and portfolio levels. This open, transparent and respectful communication between the sponsor and Fortrea was replicated between Fortrea and sites, and ultimately between sites and their patients, fostering a collaborative study culture.

As a result of the open and transparent communication, PIs became invested in the sponsor's pipeline and felt valued as part of the drug development journey. This led to increased motivation to fulfill their commitments for patient enrollment and retention, resulting in:

- On-time enrollment
- Timely progress to subsequent treatment arms/cohorts
- High-quality data collection
- Lower patient dropout rates
- Complete datasets for efficient decision-making

Key metrics and achievements

Overall dropout rate equaled
8.5%
compared to an assumed 10%

8 interim analyses performed on time
aiding quick decisions for the dynamic nature of this platform study and the future hepatitis B portfolio

7 protocol amendments successfully implemented
9 treatment arms explored
476 patients screened
281 patients enrolled
249 patients completed

Additional enrollment challenges

Despite the initial success, the study team encountered an additional challenge after this first round of enrollment. Some countries and sites were unable to enroll patients due to a combination of timeline constraints. Enrollment in open sites for the treatment arms was completed before these other countries/sites received approval and were ready to enroll patients.

Solutions for impacted sites

To address challenges for these sites, the team implemented several strategies:

- Continued application of previously successful approaches
- Early risk assessment and communication with impacted PIs and sites
- Empowering PIs/sites to make informed decisions about continuing site activation, including Fortrea and the sponsor engagement with PIs about future study pathways and the overall hepatitis B pipeline
- Fortrea's local teams worked diligently to maintain relationships for future collaborations
- Compensation was provided to sites for early startup work

Further outcomes

These additional efforts yielded positive results. Two U.S. sites that couldn't participate in the platform study were invited and activated for the next hepatitis B study in the sponsor's portfolio. This demonstrated that PIs remained fully engaged with Fortrea and the sponsor, despite initial setbacks.

Lessons learned for platform studies

This complex platform study provided valuable insights for future research:

- Early and continuous engagement with PIs is crucial for maintaining motivation and study momentum
- A one-team approach, fostering open communication between sponsor, CRO and sites, creates a collaborative culture that drives success
- Flexibility in site management strategies, including face-to-face engagement and tailored communication, helps overcome the challenges of dynamic study designs
- Proactive risk assessment and transparent communication about potential enrollment challenges allow sites to make informed decisions about participation

Conclusion

The successful execution of this platform study in hepatitis B research demonstrates the power of collaboration, expertise and adaptability in advancing complex clinical trials. At Fortrea, we are committed to supporting innovative research designs. By fostering strong relationships with sponsors and sites, embracing transparency and continuously refining our approaches, we aim to contribute to the efficient development of treatments that can make a significant difference in patients' lives.

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